

Standing Committee on the Law of Patents

Twenty-Sixth Session
Geneva, July 3 to 6, 2017

DRAFT REPORT

prepared by the Secretariat

INTRODUCTION

1. The Standing Committee on the Law of Patents (“the Committee” or “the SCP”) held its twenty-sixth session in Geneva from July 3 to 6, 2017.
2. The following States members of WIPO and/or the Paris Union were represented: Albania, Algeria, Angola, Argentina, Australia, Austria, Bahamas, Brazil, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Côte d’Ivoire, Cyprus, Czech Republic, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Holy See, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Kenya, Kuwait, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mauritania, Mauritius, Mexico, Monaco, Morocco, Myanmar, Nepal, Nigeria, Norway, Pakistan, Panama, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Serbia, Seychelles, Singapore, Slovakia, South Africa, Spain, Sudan, Sweden, Switzerland, Thailand, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Viet Nam, and Zambia (87).
3. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Intellectual Property Organization (OAPI), African Regional Intellectual Property Organization (ARIPO), African Union (AU), Eurasian Patent Organization (EAPO), European Patent Organization (EPO), European Union (EU), Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office), South Centre (SC), United Nations (UN), and World Trade Organization (WTO) (10).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), Cámara Industrial de Laboratorios Farmacéuticos Argentinos (CILFA), Chartered Institute of Patent Attorneys (CIPA), Civil Society Coalition (CSC), CropLife International (CROPLIFE), European Law Students' Association (ELSA International), Fridtjof Nansen Institute (FNI), Innovation Insights, Institute of Professional Representatives Before the European Patent Office (EPI), International Association for the Protection of Intellectual Property (AIPPI), International Bar Association (IBA), International Chamber of Commerce (ICC), International Federation of Intellectual Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Latin American Association of Pharmaceutical Industries (ALIFAR), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP) and Third World Network Berhad (TWN) (21).
5. A list of participants is contained in the Annex to this report.
6. The following documents prepared by the Secretariat had been submitted to the SCP prior to the session: "Draft Report" (SCP/25/6 Prov.3.); "Draft Agenda" (SCP/26/1 Prov.2); "Report on the International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/26/2); "Responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination (Parts 1 and 2)" (SCP/26/3 and SCP/26/4, respectively); "Constraints Faced by Developing Countries and Least Developed Countries (LDCs) in Making Full Use of Patent Flexibilities and Their Impacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries" (SCP/26/5); and "Proposal by the Delegation of Canada" (SCP/26/6).
7. In addition, the following documents prepared by the Secretariat were also considered by the Committee: "Proposal from Brazil" (SCP/14/7); "Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group" (SCP/16/7); "Corrigendum: Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group" (SCP/16/7 Corr.); "Proposal by the Delegation of Denmark" (SCP/17/7); "Revised Proposal from the Delegations of Canada and the United Kingdom" (SCP/17/8); "Proposal by the Delegation of the United States of America" (SCP/17/10); "Patents and Health: Proposal by the Delegation of the United States of America" (SCP/17/11); "Questionnaire on Quality of Patents: Proposal by the Delegations of Canada and the United Kingdom" (SCP/18/9); "Proposal by the Delegation of the United States of America regarding Efficiencies of the Patent System" (SCP/19/4); "Proposal by the Delegation of Brazil regarding Exceptions and Limitations to Patent Rights" (SCP/19/6); "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.); "Proposal by the Group of Latin American and Caribbean Countries (GRULAC)" (SCP/22/5); "Proposal by the Delegation of the United States of America on the Study of Worksharing" (SCP/23/4); "Proposal by the Delegation of Spain" (SCP/24/3); and "Proposal by the African Group for a WIPO Work Program on Patents and Health" (SCP/24/4).
8. The Secretariat noted the interventions made and recorded them on tape. This report summarizes the discussions reflecting all the observations made.

GENERAL DISCUSSION

AGENDA ITEM 1: OPENING OF THE SESSION

9. The twenty-sixth session of the Standing Committee on the Law of Patents (SCP) was opened by the Director General, Mr. Francis Gurry, who welcomed the participants. The session was chaired by Ms. Bucura Ionescu (Romania). Mr. Marco Aleman (WIPO) acted as Secretary.

AGENDA ITEM 2: ADOPTION OF THE AGENDA

10. The SCP adopted the draft agenda (document SCP/26/1 Prov.2).

AGENDA ITEM 3: ADOPTION OF THE DRAFT REPORT OF THE TWENTY-FIFTH SESSION

11. The Committee adopted the draft report of its twenty-fifth session (document SCP/25/6 Prov.3) as proposed.

GENERAL DECLARATIONS

12. The Delegation of Senegal, speaking on behalf of the African Group, observed that divergent responses had been provided to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. The Delegation noted that those differences underscored different perception of those issues by countries. The Delegation stated that the agenda of the SCP included other issues which covered essential areas for developing countries in general, and particularly, for the African region. Specifically, the Delegation looked forward to the discussions on the role of patents in social, economic and technological development of the Member States. The Delegation continued that the mechanism within the global intellectual property (IP) system clearly identified legal obstacles that should be removed so that the system could serve both economic and social growth and development. The Delegation further stated that the SCP should agree on a work program which would take into account the global environment and the pressing needs of developing countries in current circumstances. Furthermore, the Delegation was of the view that the work program of the Committee should be structured around the Development Agenda which was the general reference point for WIPO in terms of development issues. The Delegation was also of the view that discussions within the SCP should more contribute to dissemination and transfer of technology. The Delegation continued to attach considerable importance to the issue of exceptions and limitations to patent rights and the use of flexibilities, which were the balancing elements in the international IP system. However, the Delegation wished to stress that the issue of patents and health remained the priority of the African Group. That was because the problem was related to the accessibility to drugs and treatments, which were essential for meeting public health challenges in African countries. The Delegation also continued to support the proposal by GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5.

13. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, expressed its confidence in the experience and leadership skills of the Chair and also expressed its appreciation for the hard work done by the Secretariat towards the preparation for the meeting. The Delegation further stated that, even if the Paris Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) had set minimum international standards of patent protection, the patent laws remained essentially territorial and governments had flexibilities to formulate their domestic patent laws. Noting that those flexibilities were

critical for policy makers in drafting and amending domestic patent laws, in accordance with national development priorities and socio-economic realities, the Delegation stated that the TRIPS flexibilities took into consideration those differences, and allowed governments, especially those with limited resources, the necessary policy space to meet their health needs, and, at the same time, to foster innovation. The Delegation continued by saying that the work of the Committee was very important in creating a balance between the rights of patent owners and the larger public interests, particularly in the areas of public health, technology transfer and patent-related flexibilities. The Delegation stated that its Group would constructively participate and contribute towards a productive discussion on those important developmental issues. The Delegation expressed its hope that the exchange of Member States' experiences, and case studies on the effectiveness of exceptions and limitations, during the current session of the SCP, would provide guidance for improving and further enhancing the efficiency of the patent system in a manner sensitive to the diverse needs of members of the Committee. More specifically, the Delegation expressed its hope that the SCP would provide valuable information about the reasons of why exceptions and limitations had not been utilized to their fullest extent, despite their presence in the statutes in most developing countries and LDCs, and the constraints that prevented their optimal use. The Delegation was of the view that the submissions in document SCP/25/3 clearly indicated the need to ensure that WIPO's technical assistance in designing national patent laws, or national IP strategies, would take those constraints into consideration, and WIPO would provide assistance to developing countries on how to overcome them and make full use of the available flexibilities. The Delegation wished to take the opportunity to draw the attention of the Committee to the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (UNHLP Report). The Delegation noted that the Report had specifically explored the policy incoherence between intellectual property, trade and human rights, and made a number of recommendations in that regard. The Delegation continued that some of those recommendations were specifically addressed to WIPO and were directly relevant to the subject of the sharing session on patents and health. The Delegation stated, therefore, the Asia and the Pacific Group wished to request the SCP to initiate those exploratory discussions based on that important report. Further, the Delegation noted that the Committee should ensure that the study on the constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact to affordable and especially essential medicines in those countries, should involve the United Nations Development Program (UNDP) which had facilitated the preparation of the UNHLP Report. The Delegation stated that its Group was also interested in continuing discussing on the proposals made by some delegations with regard to the agenda item "patents and health". The Delegation further emphasized that the Committee should give equal prominence to that issue in the work of the SCP as it did to the issue of quality of patents. In particular, the Delegation was of the view that there should be a work program on opposition systems that would comprise a questionnaire or a survey on different kinds of opposition mechanisms available in various countries, the procedures and modalities for their use, constraints in their use, and how such systems could be strengthened and constraints could be removed. In relation to the topic of quality of patents, the Asia and Pacific Group was of the opinion that the SCP should agree on a common understanding of the term "quality of patents". Specifically, the Delegation questioned whether the term meant efficiency of patent offices in processing patent applications, or the quality of patents granted, ensuring that the offices did not grant patents of questionable validity. In that regard, the Delegation welcomed documents SCP/26/3 and SCP/26/4 which contained responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. The Delegation expressed its hope that those documents would be a good basis for Member States to clarify the meaning of that term. Further, the Delegation requested the Secretariat to provide regular information to the Member States on the outcome of patent applications in different jurisdictions and on the outcomes of opposition procedures. Referring further to Article 29.2 of the TRIPS Agreement, which stated that "Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grant",

the Delegation requested that the Secretariat conduct a study on the extent to which that provision had been implemented in different countries, and how its broader use might promote quality. The Delegation encouraged other Member States to make a joint effort and engage constructively in order to reach a consensus on a future work of the Committee based on the issues of particular relevance to common interest of its members.

14. The Delegation of Paraguay, speaking on behalf of GRULAC, thanked the Secretariat for the preparation of the session. The Delegation stated that for its Group, the discussions on the topic within the Committee deserved its attention and that it should make substantive contributions. The Delegation noted that, since the creation of the SCP in 1998, the Committee had been serving as a forum to discuss different issues relating to the international development of patent law, and that since its sixteenth session in 2011, the Committee had been addressing five topics, in addition to some other issues. The Delegation called upon GRULAC and all regional groups to hold an inclusive and constructive debate which, despite the existence of different visions and priorities, would enable the Member States to agree on future work that precisely reflected that reality, the balance of which would require flexibility on the part of all. In that context, the Delegation stressed the importance of the inclusive nature of any informal consultation process that would take place. Further, noting that exceptions and limitations to patent rights, patents and health, and the transfer of technology were matters of special importance for its Group, the Delegation expressed its hope that a consensus would be reached on those topics in order to move forward. With regard to agenda item on exceptions and limitations to patent rights, the Delegation stated that GRULAC had always supported its discussion. The Delegation was of the view that exchange of information was always useful to serve as a reference to Member States, and that it would enable them to learn about concrete cases and realities. Therefore, the Delegation stated that those types of exercises should be maintained, bearing in mind that the topic was an integral part of the intellectual property system. In that context, the Delegation expressed its support to the proposal by the Delegation of Brazil, contained in document SCP/14/7, and the development of a non-exhaustive manual on the subject. With regard to agenda item 7 on patents and health, the Delegation stated that many Member States were interested in discussing that important topic, bearing in mind the difficulties of countries in ensuring the availability of medicines in a sustainable manner. The Delegation continued that, hence, the debate on the relationship between patents and health was a key to promoting the delicate balance required for the patent system. The Delegation noted that a variety of documents and proposals on the table on that topic should serve as the basis for developing a work plan on the matter. With regard to agenda item 9 on transfer of technology, the Delegation expressed its appreciation of the sharing session on the relationship between patent systems and transfer of technology which took place at the previous session, where the issue of the sufficiency of disclosure had been shown to be crucial for the dissemination of knowledge in developing countries. Therefore, the Delegation was of the view that that agenda item should continue studying the examples and cases in which the disclosure enabled and facilitated the transfer of technology, as well as the way of making such information accessible to the public. With regard to its proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5, the Delegation stated that it had taken careful note of the various comments and reactions at the previous sessions of the SCP and expressed its appreciation for the support it had received from some Member States. Further, recognizing that there had been no consensus on the proposal, the Delegation highlighted that a special consideration for its Group was technical assistance and training, and that, in that context, GRULAC was considering alternative proposals. In conclusion, the Delegation noted that it was essential to continue the work of the Committee and that part of that commitment was reflected in the various proposals it had tabled. The Delegation stated that its Group was committed to make progress with the discussions during that session.

15. The Delegation of Georgia, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), stated that during the previous sessions, a tremendous amount of efforts and of time had been dedicated to the discussion on the future work program of the Committee. The Delegation expressed its hope that during the twenty-sixth session, the Member States would agree on the future work and reach consensus. The Delegation therefore welcomed the discussions on different proposals, and expressed its hope that the balance would be retained in the discussion of the work program for five topics. In its view, those five agenda items accommodated the interests of all Member States in a delicate balance. Noting that the interest of each individual Member State lied at least in one of those five topics, the Delegation encouraged the Member States to bear that in mind when engaging in discussions on the future work. Further, the Delegation stated that its Group favored the work on the agenda item on quality of patents, and that there was a need to continue work on improving the quality of patents. Therefore, the Delegation supported the proposal put forward on that topic by the Delegation of Canada, the United Kingdom, Denmark, the United States of America and Spain. On the question of confidentiality of communications between clients and their patent advisors, the Delegation supported a soft law approach. The Delegation further expressed its belief that the proposal of GRULAC to review the 1979 WIPO Model Law for Developing Countries on Inventions might shift the achieved balance on the agenda. Moreover, in its view, the proposal would not necessarily reflect the various needs of countries that were supposed to benefit from it, and its continued discussion could create an imbalance in the SCP discussions. Finally, the CEBS Group believed that the Member States should focus their efforts on a substantive discussion based on different proposals put forward during previous sessions, or any new proposals, and achieve an agreement on the future work of the Committee. Nevertheless, the Delegation reiterated that an excessive amount of time should not be dedicated to the discussions on the future work. In conclusion, the Delegation stated that its Group was ready to engage in those discussions in a constructive manner and highlighted the importance it attached to the work of the Committee.

16. The Delegation of Japan, speaking on behalf of Group B, expressed its appreciation to continuous commitment of the Chair to the work of the Committee as well as to the Secretariat for its efforts in preparation for the session. The Delegation stated that its Group supported the work of the SCP and attached a great importance to its mandate. The Delegation expressed its hope that the discussion on five agenda items would lead to a fruitful outcome taking into account the interests of all Member States. The Delegation further stated that Group B strongly believed that the SCP – a multilateral forum in the field of patents – had a responsibility to provide a venue for discussions on issues of substantive law in a manner responding to the evolving real world. The Delegation noted that quality of patents, including opposition systems, was an important aspect of the patent system and that the large number of responses to the questionnaire on the subject underscored that fact. The Delegation continued that, in that regard, as had been underlined by its Group, the international work sharing and substantive patentability requirements, such as inventive steps, were important issues. Recalling that the national experts from various countries and regions had shared their experiences on the evaluation of inventive step during previous sessions of the SCP, the Delegation noted that Member States from several regional Groups had shown great interest to the discussions on that topic and technical topics, in general. The Delegation continued that work sharing could provide a useful frame for experts to learn from each other and recalled that the proposals on work sharing had received wide support from the Member States. The Delegation noted that responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination showed that work sharing was effective in assisting offices with limited capacities in improving quality of their search and examination. The Delegation stated that the Committee should build on the importance many Member States placed on that subject and intensify its work on those technical topics in order to ensure and increase the quality of issued patents worldwide. With regard to the topic on “confidentiality of communications between clients and their patent advisors”, the Delegation stated that it was an

important area that showed great differences in the national laws. The Delegation recalled that the importance of protecting communications between patent advisors and their clients had been extensively discussed in the Committee, and that the users of the patent system had stressed the need to address the subject at the international level. The Delegation stated that Group B therefore believed that the Committee should take a step forward towards a regulative solution at the international level, for example in the form of a soft law. With respect to the proposal of GRULAC to review the 1979 WIPO Model Law for Developing Countries on Inventions, the Delegation noted that that topic was not part of five topics on the agenda and that its continued discussion would be unproductive and would adversely affect the balance of the work program. The Delegation concluded that it expected the Committee to agree on some concrete and substantive work within the five topics on its agenda for the future sessions.

17. The Delegation of Estonia, speaking on behalf of EU and its Member States, thanked the Secretariat for preparing the meeting. The Delegation stated that the EU and its Member States were pleased that the previous session of the SCP had held four interesting sharing sessions. The Delegation expressed its regret that, although considerable time on deliberations on the future work program had been spent, the SCP had not been able to reach a consensus. The Delegation expressed its hope that the consensus would be found at the twenty-sixth session of the SCP. The Delegation stated that the program for the coming days should provide opportunities for all Member States to make steps forward on important issues. Further, the Delegation highlighted the areas of its interest. In particular, the Delegation attached considerable importance to advancing work on the quality of patents along the lines proposed by the Delegations of Canada, the United Kingdom, Denmark, the United States of America and Spain, and, as endorsed by all other Member States of the EU, as it believed that work on that topic would be of interest to Member States across the spectrum of development. The Delegation was keen to continue discussions on the topic of confidentiality of communications between clients and their patent advisors, as convergence of differing provisions would be of benefit to users of the patent system, irrespective of the level of development of individual WIPO Member States. On patents and health, the Delegation expressed its belief that any further work in that area should reflect a balanced approach, taking into account the various factors of relevance to patents and health as, for example, proposed by the United States of America in document SCP/17/11. At the same time, the Delegation wished to recall that they could not go beyond the mandate of the SCP and WIPO, and that discussions about other factors of access to medicines than patent protection should be left to other more appropriate fora. With regard to discussions on the future work of the Committee, the Delegation stressed the importance of retaining the delicate balance in the current work program of the Committee. Further, the Delegation expressed its hope that during the twenty-sixth session, the Committee would manage to agree on a balanced work program based on the non-exhaustive list of issues which would also enable the Committee to work towards international harmonization of substantive patent law. Finally, the Delegation wished to highlight that the EU under its enhanced cooperation procedure had made significant advances on the European patents with unitary effect. In that context, the Delegation noted that significant advances had also been made on the creation of the Unified Patent Court. The Delegation stated that the Unitary Patent would help to attract and retain innovation, talent and investment.

18. The Delegation of Iran (Islamic Republic of) aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. The Delegation stated that the activities of the Committee were of high importance as it provided a multilateral forum for discussing patent-related issues and sharing of ideas and experiences in areas crucial to development. The Delegation noted that extensive and in-depth exchange of information on the issues in the agenda of the SCP would assist Member States to further deepen their understanding, to learn from one another, and to improve domestic legislation and practices. The Delegation stated that the Committee should focus on the role of the patent system in fostering innovation, taking into account the different levels of development as well as the

priorities and goals of each country. The Delegation further stated that deliberations of the Committee should also be conducted in accordance with the Development Agenda recommendations on the basis of a deep understanding of the impact of the patent system on development concerns and the use and adequacy of existing flexibilities of the patent system to address those concerns. The Delegation was of the view that the discussions on the topics of exceptions and limitations to patent rights, patents and health, and technology transfer were significant to balance the interests of patent holders with the public interest of making effective use of flexibilities for a better realization of the social value of the patent system. The Delegation continued that the deliberation on those topics would help the Committee to better understand the challenges encountered by developing countries in their economic and social developments, and to explore ways to better adapt the patent system to meet the needs and priorities of the national development. The Delegation stated that, in that context, it continued to believe that the international harmonization of patent law, given the variations in levels of social, economic and technological developments, and significant differences between approaches and objectives among national patent law, would not benefit the Member States. The Delegation continued that the activities of the SCP should facilitate the dissemination and transfer of technology, and ensure that the patent system contributes to fostering innovation for broader human and social development. Therefore, the Committee was highly expected to discuss the issue of how patents could be a barrier to the transfer of technology. In conclusion, the Delegation expressed its hope that the Committee would make significant progress in advancing discussions on issues of particular relevance to the common interests of the Member States.

19. The Delegation of Nepal thanked the Director General of WIPO and the Secretariat for supporting the Government of Nepal in various areas of IP regime, including in the formulation of a new comprehensive National Intellectual Property Policy 2017. The Delegation informed the SCP that a new Constitution of Nepal had provisioned the intellectual property right as the right to property and fundamental rights. In addition, the Government of Nepal had formulated the National Intellectual Property Policy, which included policies on copyright, patent, industrial design, trademark, geographical indication and policy for plant variety protection. The Delegation continued that, likewise, policies on trade secrets, layout designs of integrated circuits, traditional and indigenous knowledge, traditional cultural expression and intangible culture protection, were also provisioned in the National Intellectual Property Policy. To implement that Policy, the Government of Nepal hoped that WIPO would provide technical and financial support. The Delegation also stated that, in that regard, they needed to know experiences and the best practices from the international community. The Delegation further informed the SCP that Nepal held Foreign Investment Summit on March 2 and 3, 2017. The Delegation stated that the world community was keen to look at Nepal as a new potential investment destination. The Delegation further stressed that for any country to attract foreign direct investments, IP rights become a prime concern. The Government of Nepal was in the process of formulating new Intellectual Property Act in line with the Policy covering various IP rights. As regards the issue of transfer of technology, the Delegation stated that the transfer of technology to the developing countries like Nepal was complex and lengthy process. In that regard, the Delegation sought support from WIPO. The Delegation further underlined the importance of the issue of exceptions and limitations to patent rights to developing countries. In addition, the Delegation stressed the need for a clear-cut guideline to administer the quality of patents among the Member States.

20. The Delegation of South Africa aligned itself with the statement of the Delegation of Senegal on behalf of the African Group. The Delegation stated that the work of the Committee had the potential to play a meaningful role for the attainment of the socio-development imperatives of Member States, particularly developing countries. The Delegation wished to remind the delegates that the Committee was mandated to “serve as a forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international

development of patent law [...] and to provide Member States with an effective mechanism for setting priorities and allocating resources". The Delegation further stated that the debate on IP rights and industrialization revealed that IP protection could either enhance or impede economic development, depending on the structure of the IP protection system and the particular circumstances of each country. The Delegation noted that there was an increasing consensus that certain elements of the current structure of the international patent system placed impediments on the socio-economic development endeavors of developing countries. The Delegation continued that, those included the system's potential to limit the diffusion of innovative technology more widely and to impose high prices for patent-protected goods, particularly, with regard to such important social goods as medical technologies, thus denying millions of people lifesaving medicines or plunging them into poverty because they were forced to pay unaffordable fees for their health care. The Delegation stressed that it was the duty of WIPO, particularly the SCP, to continue discussing those problems, including exploring how best patent regimes could be designed to expand the opportunities for access and diffusion of technology and the attainment of affordable healthcare. The Delegation stated that failure to discuss those issues and to find agreement might have the potential to threaten the integrity and legitimacy of the system of patent rights and related duties. In conclusion, the Delegation expressed its hope that a work program on how WIPO could contribute to the resolutions of those issues would be agreed in the twenty-sixth session of the SCP.

21. The Delegation of Brazil supported the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation stated that since its creation in 1998, the SCP had been an important forum for discussions, exchange of ideas and coordination on different aspects of the current international patent system between the international community. The Delegation stated that Member States in the SCP, with the valuable support from the Secretariat, had set priorities and allocated resources to try to fulfill the main objective of the patent system: the promotion of economic, social and cultural progress for all countries through technological innovation. The Delegation was of the view that, notwithstanding the SCP's pivotal role, the Committee's effective contribution to the improvement of the current patent system had fallen short of its potential. Specifically, the Delegation noted that, at the previous session, minimum progress had been made on a range of important issues. The Delegation continued that the repeated failure of reaching consensus on relevant topics could lead to increasing distrust and loss of legitimacy of the current patent system and of the SCP. The Delegation stressed that Member States had a responsibility to prevent that from happening. In that sense, the Delegation urged all delegations to engage in the discussions in a constructive and positive manner. The Delegation was of the view that it was possible to make progress on many topics on the agenda. The Delegation also considered that the SCP's agenda would allow Member States to attain the objective of building a more inclusive, balanced and effective patent system, a desire shared by all. Noting that the issues of patent and health, exceptions and limitations to patent right and transfer of technology remained of utmost importance to Brazil, the Delegation stressed that those topics were also in the interest of every country and that the SCP was the right forum to discuss them. Further, the Delegation stated that there was no doubt that market-driven R&D had produced a number of important health technologies that had improved health outcomes significantly worldwide. The Delegation continued that, however, it should be recognized that significant gaps in health, innovation and access persisted. The Delegation stated that the SCP was the most appropriate forum for Member States of the United Nations to discuss and try to address the asymmetry between profit-driven innovation models and public health priorities. The Delegation wished to reiterate its belief that the market-driven R&D and profit-driven innovation were effective mechanisms for progress. However, the Delegation stated that important gaps between profit-driven innovation models and public health priorities remained. In its opinion, those gaps could be addressed without jeopardizing what had been working. Further, the Delegation supported the proposal of the African Group on patents and health, contained in document SCP/24/4. The Delegation was of the view that the proposal contained a balanced set of activities divided into three elements with clear linkage with relevant

Development Agenda recommendations. The Delegation was particularly interested in the issue of the establishment of publicly accessible databases on patents information status and data on medicines and vaccines. The Delegation expressed its hope that the exchange of views during the twenty-sixth session would facilitate further discussions on that important topic. The Delegation thanked the Delegation of Canada for its proposal, and stated that the proposal contained elements which could contribute to the discussion. As regards the exceptions and limitations to patent rights, the Delegation stated that at the previous sessions, it had provided important elements for the consideration by the Member States, shedding light on the tools necessary for adapting patent systems to the demands of contemporary society. The Delegation stated that Brazil was committed to working with other members to reach an agreement on the third phase of its proposal (documents SCP/14/7 and SCP/19/6): producing a non-exhaustive manual on exceptions and limitations to patent rights. The Delegation was convinced that progress on the subject would benefit all countries, without exception. On technology transfer, the Delegation was of the opinion that additional efforts should be made in the Committee to develop a work program that would contribute to the improvement of current patent system in order to increase the transfer and dissemination of technology in a manner conducive to social and economic welfare, in line with the Development Agenda. The Delegation stated that such a work program would also benefit all countries, without exception. In that regard, the Delegation supported the continuation of discussion on GRULAC's proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation further continued that, the focus on their priorities would not preclude them from engaging, in good faith, in discussions on the issue of quality of patents. The Delegation was aware of the importance of that topic and remained willing to engage in knowledge-sharing activities so as to enhance the mutual understanding of patent laws and procedures. In conclusion, the Delegation expressed its hope to have fruitful discussions in order to agree on a balanced and effective work program for the SCP.

22. The Delegation of India aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. The Delegation wished to reaffirm its position that patent monopoly rights were granted to applicants under the principle of *quid pro quo* for the disclosure of their inventions to the public in order to foster innovation, industrial development and to boost the national economy. The Delegation stated that the fundamental objective of the patent office should be rightful grants and improvement of the quality of the patent system as a whole, which would infuse protection of public interest by filtering out frivolous patents. The Delegation was of the view that harmonizing patent laws across countries having vast differences in economy, industrial and scientific development would only create concentration of IP assets with certain regions which would not help developing countries and LDCs. The Delegation firmly believed that the objective of Member States was to ensure that the global intellectual property regimes encourage the use of the TRIPS flexibilities. On the issue of quality of patents, including opposition systems, the Delegation's position was that the work sharing did not have a direct linkage with the quality of patents and that quality of examination needed to be improved substantially in conformity with the national policy objective of a country, so that high social cost of granting patents to insignificant improvements would be eliminated to a greater extent. Further, the Delegation informed the Committee that the Indian Patent Office has recently joined WIPO CASE which allowed the access to search and examination reports of various countries. However, the Delegation was of the view that, it should not be made mandatory and should be left to the individual Member States to take decision according to their national objectives. On the issue of patents and health, the Delegation reaffirmed its view contained in document SCP/21/9 concerning the feasibility study on the disclosure of INN in patent applications and/or patents, as well as its view on the proposed study on overbroad Markush claims under the agenda items "patents and health" and "quality of patents, including opposition systems". Further, the Delegation stated that the UNHLP had specifically explored the policy incoherence between IP, trade and human rights and had made a number of recommendations in that regard. The Delegation noted that some

of those recommendations were specifically addressed to WIPO and were directly relevant to the subject discussed during the sharing session on patents and health. The Delegation stated that it wished to see that the SCP initiate discussions based on that report. Further, the Delegation emphasized that ever-greening policies for patenting incremental innovations without substantial improvement would have adverse impact on delivery of healthcare services. The Delegation expressed its hope that the sharing session on the use of health-related patent flexibilities enhanced Member States understanding of those issues, particularly of developing countries and LDCs. On the issue of confidentiality of communications between clients and their patent advisors, the Delegation reiterated its view that the issue was of substantive nature and could be governed by national laws, and expressed its concern over the manner in which the matter had been progressing towards a soft law approach for the harmonization. On the issue of transfer of technology, the Delegation stated that there should be a balance of rights and obligations, and that the protection of rights should be based on the technological content disclosed in patent applications. Furthermore, the Delegation stated that any revision of the 1979 WIPO Model Law for Developing Countries on Inventions should present the needs of developing countries and LDCs to fully utilize the TRIPS flexibilities. Finally, the Delegation expressed its hope that the Committee would be able to achieve fruitful, productive and meaningful outcome.

23. The Delegation of China stated that it had always attached great importance to the work of the SCP. Noting that it was an important platform for the patent system, the Delegation expressed its hope that Member States would make common efforts to make the patent system beneficial to the social and economic development. The Delegation observed that during the previous sessions of the SCP, Member States had made great efforts to advance discussions on various items on the agenda. The Delegation wished to continue to constructively participate in the discussions, especially on the issue of exceptions and limitations to patent rights, patents and health, and transfer of technology. The Delegation believed that those issues would assist in balancing the interest of patent holders and public interest. The Delegation was of the view that the SCP should carry out extensive information and knowledge sharing among Member States on those issues. The Delegation believed that such an exercise would be beneficial to all countries. As regards the quality of patents, in the view of the Delegation, various measures should be taken to assist countries, such as capacity building and the information sharing. Noting that the situation and interest of countries might be different from one to another, the Delegation stated that efforts should be made to take into account, to the extent possible, the interests of all countries to make a progress in the SCP.

24. The Delegation of Côte d'Ivoire aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation urged the Committee to give priority to finding the needed balance in international IP system taking into account the needs of Member States to further their development. The Delegation also urged delegations to show a greater desire for compromise and constructive attitude to achieve a mutually beneficial outcome of the Committee.

25. The Delegation of Belarus underlined the importance of the SCP for discussion of patent-related issues. The Delegation expressed its hope that such discussions would enable Member States to make a considerable contribution to further development of the international patent system so as to further economic and social growth in countries.

26. The Delegation of the Republic of Korea emphasized the importance of the SCP as the only global forum in the field of patents. Noting that over the past few years the SCP had provided Member States with an opportunity to share their experiences and insights on such important issues as exceptions and limitations to patent rights, quality of patents, patents and health and transfer of technology, the Delegation expressed its belief that the Committee should play a greater role by providing substantive and technical discussions to improve the patent

system. The Delegation also expressed its strong belief that enhancing quality of patents should be one of the core topics of the SCP, since it was very important for the improvement of the patent system. The Delegation stressed that high quality of patents was essential to avoid unnecessary social-economic cost and to achieve the goal of the patent system, i.e., innovation and economic development. Therefore, the Delegation wished to reiterate that the Committee should study and exchange their views on work sharing, since it was one of the most effective solutions to achieve tangible output in enhancing the quality of patents. Noting that documents SCP/26/3 and SCP/26/4, responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination, were good starting points for the Member States to reach a common understanding on those issues, the Delegation expressed its hope that some progress would be achieved in the discussion of those topics during the current session. The Delegation also expressed its hope that Member States would also make a step forward in other issues such as, confidentiality of communications between clients and their patent advisors, patents and health and transfer of technology.

27. The Delegation of the Russian Federation noted that despite the fact that Member States had not managed to build consensus on the future work of the Committee at the previous session, in the course of preparing for the twenty-sixth session, considerable work had been made. Specifically, the Delegation noted that the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination had been finalized by the Secretariat and the responses received from the Member States had been presented in documents SCP/26/3 and SCP/26/4. In addition, the Delegation noted that the Secretariat had also prepared document SCP/26/5 on constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impacts on access to affordable especially essential medicines for public health purposes in those countries. The Delegation stated that the information presented in those documents would be very good basis to further discussions on those topics. Noting that work had also been carried out on other issues on the agenda, the Delegation underlined that that showed the value of the work of the Committee as the main international forum dedicated to issues of international patent law. The Delegation noted that the Russian Federation was particularly interested in continuing the development of the work of the Committee, and therefore, requested delegations to look for compromised solutions to advance the work of the Committee to achieve practical results. As regards the topic of exceptions and limitations to patent rights, the Delegation supported the proposal to work towards the development of a non-exhaustive manual in order to systemize all existing information on the issue.

28. The Representative of the South Center stated that the twenty-sixth session of the SCP marked the ninth year since the SCP had reconvened in June 2008 with a focus on developing a balanced work program on issues relating to the law of patents to address development and public policy questions that arose in the context of the patent system. The Representative continued that, in that process, the SCP had limited its focus to a selected number of issues drawn from the list of non-exhaustive issues that had been identified by the SCP in 2008. The Representative noted that the list included critical issues such as, exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, and transfer of technology. He further stated that while a number of studies, fact-finding surveys, sharing sessions had informed the discussions on those issues in the SCP, it was imperative that the SCP would move forward to develop meaningful action oriented solutions to address various challenges. The Representative stressed that it would be critical for the SCP to advance its work on exceptions and limitations to develop a non-exhaustive manual on exceptions and limitations, as a reference for WIPO Member States. On the issue of quality of patents, he stated that the SCP should also address the importance of opposition systems for ensuring the grant of high quality patents through a robust search and examination process. The Representative continued that, on the issue of patents and health, it would be critical for the SCP to move beyond experience sharing, fact-finding studies or literature reviews to develop an

action oriented work program to address the challenges related to access to medicines in the context of the patents system. He noted that, in that regard, it would be important for the SCP to substantially engage on the proposal by the African Group and the Development Agenda Group on patents and health. The Representative further noted that many elements of that proposal were reflected in the recommendations of the UNHLP Report which had been adopted by consensus among all members of the UNHLP after extensive consultations with a diversity of stakeholders all over the world. In conclusion, the Representative also expressed his support to the proposal by GRULAC for a revision of the 1979 WIPO Model Law for Developing Countries on Inventions.

AGENDA ITEM 4: REPORT ON THE INTERNATIONAL PATENT SYSTEM: CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS

29. Discussions were based on document SCP/26/2.

30. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing the document SCP/26/2, and stated that such information would contribute to a better understanding of the international patent system.

31. The Delegation of Ecuador aligned itself with the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation stated that the strategic use of intellectual property constitutes a fundamental tool in order to promote and strengthen innovation and research. The Delegation expressed its wish to share with the Committee the work undertaken on the said subject at the national level. The Delegation explained that on December 2016, "The Organic Law of Social Economy on knowledge Creativity and Innovation" had entered into force, regulating the national system of science, technology, traditional knowledge and their links with the educational and cultural system. The Delegation remarked that one of the basic principles of that law was to consider intellectual property rights as a tool for the proper management of knowledge, assuring the balance between the right holders and the users. The Delegation further stated that the use of exceptions and limitations, compulsory licenses, and new criteria for patentability had also been included, allowing the State to adopt the necessary means to assure education, health, technological/scientific development, innovation, and technology transfer. Within that legal framework, the Delegation believed that there was a direct link between the management of knowledge, a responsible research, and a social innovation. The Delegation stated that financial, tax and administrative incentives had been contemplated within the law, encouraging activities related to technology, science and innovation, also linked with the patent system. In the view of the Delegation, the law was a legal instrument which supplemented the public policies which had been implemented over the years in Ecuador, encouraging innovation and research, and allowing the growth in the number of patent applications filed and patents granted in the recent years. The Delegation believed in knowledge as the main source of innovation and development, where intellectual property and the patent system played a critical role. The Delegation expressed its wish to make available to the international community the model that had been implemented in its country, as a result of the issuance of that law, as well as the experiences resulting from its implementation. The Delegation noted that the said model had been debated at international and national levels by the industry, the academy and the civil society. The Delegation stated that Ecuador's goal was to encourage an innovation system under goal No. 9 of the 2030 Sustainable Development Goals (SDG), which sought to increase scientific research and improve the technological capabilities of the industry by encouraging innovation, increasing the number of people working in the area of research, and investing greater resources in the public and the private sectors. In

that regard, the Delegation expressed its support to the development of adequate legal framework to encourage the development of national technologies. The Delegation finally expressed its wish to keep the Secretariat informed about any further development on that subject, as well as to share with the members any additional information.

32. The Delegation of Argentina supported the statement made by Paraguay on behalf of GRULAC. The Delegation stated that a deep and comprehensive exchange of information on various issues would help Member States to enrich their knowledge and improve their national practices and legislation. The Delegation further shared with the Committee the latest developments in its country. Specifically, the Delegation stated that the patents office of its country had made important efforts to reduce the processing time for patent applications without affecting the quality of examinations. In that regard, the following was highlighted by the Delegation: (i) hiring new thoroughly trained examiners; (ii) the signing of the Patent Prosecution Highway (PPH) pilot agreements with the Offices of PROSUR member countries (Brazil, Chile, Colombia, Ecuador, Paraguay Peru and Uruguay), PPH with the United States Patent and Trademark Office (USPTO), and the negotiations to sign a PPH with the European Patent Office (EPO) and the Japan Patent Office (JPO) were at an advanced stage; (iii) taking into account the public policies for the promotion and development of industrial property, in September 2016, Resolution P-56 had been issued with the purpose of optimizing the efficiency of the patent office by empowering it to use the search and examinations reports carried out by other offices in respect of the same invention, provided that such offices necessarily carry out substantive examinations and have the same standards of application of the patentability requirements applied by its office. The Delegation stated that the aforementioned resolution was optional and did not exempt examiners from carrying out the substantive examination of the patent application in question in the light of the national legislation. Furthermore, the Delegation had created a new web page that provided information, among other things, on the status of applications and the payment of patent annuities, as well as an online filing system for patent and utility model applications.

33. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/26/2 and for the update of the website on national/regional laws. The Delegation was of the view that such activities facilitated better understanding of regional and national patent systems and served as a reference and good basis for future discussions.

34. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for the preparation of document SCP/26/2, and the update of the website on national/regional laws. The African Group was delighted to see that the number of African regional and national patent offices reported their laws and contributed to the update of the website.

35. The Delegation of Turkey stated that, on January 10, 2017, a new IP law of Turkey had entered into force. The new IP law aimed at modernizing the national IP system and harmonizing it with the legislation of the EU. The Delegation wished to inform the Committee about some of the highlights from the patent law perspective. In particular, the Delegation stated that: (i) the name of the Turkish Patent Institute had been changed to "Turkish Patent and Trademark Office"; (ii) under the new law, it would be possible to recruit 50 more patent examiners to enhance the institutional capacity of the office; (iii) the patent granting period had been shortened and streamlined by a simplified procedure; (iv) post grant opposition had been introduced by the new law to make the patent system more reliable; (v) the preparation of search reports for utility models had been made mandatory under the new law; (vi) the concept of "reinstatement of rights" had been introduced; (vii) under the new law, the ownership of inventions originating from universities had been given to the universities themselves rather than the academicians; (viii) under the new law, public institutions had a right to use the state-

funded inventions to meet their own needs without paying any royalties; and (ix) disclosure of origin of genetic resources on which inventions were based had been introduced. The Delegation informed the Committee that it had shared the detailed information on relevant changes in its IP law with the Secretariat, and that those changes were available on the SCP Electronic Forum website.

36. The Delegation of the United States of America referred to the website on the opposition and administrative revocation mechanisms and stated that while its country's post-grant review process technically fell within the definition of opposition systems, it was not an opposition system but rather a post-grant review of an issued patent. Noting that such review process was available only within the specific time period after the grant of a patent, the Delegation stated that the *inter partes* review procedure would become available after that time period. The Delegation noted that the *inter partes* review was in many ways similar to the post-grant review proceeding. In addition, the Delegation stated that it would provide information to the Secretariat on other procedures available in its country, such as the supplemental examination and the post-grant validity review relating to Covered Business Method (CBM) patents.

37. The Delegation of Estonia, speaking on behalf of the EU and its Member States, stated that the SCP Electronic Forum website, where the information had been updated based on the input received from Member States, served as a useful reference in furthering discussions and a good basis for better understanding certain aspects of national and regional patent laws. The Delegation expressed its appreciation to countries which had submitted such updated information.

38. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, expressed its appreciation to Member States which provided the Secretariat with the updated information on various aspects of their national laws.

39. The Delegation of Spain thanked the Chair for giving it the opportunity to provide information to the Committee on the important updates with regard to patent legislation in Spain. The Delegation stated that the new patent law had entered into force on April 1, 2017. The Delegation noted that in order to understand the changes brought to the new patent law, it was necessary to inform the Committee about the situation before the amendment. In particular, the Delegation stated that, previously, the applicant could decide whether he wanted a patent granted after a substantive examination or a patent granted without such examination. In practice, only 10% of applicants had opted for substantive examination. That would mean, the Delegation stated, that a number of patents with questionable validity were created, and that their validity had to be determined by courts. Under the new patent law, all patent applications had become subject to a substantive examination. Further, regarding the new procedure for granting patents, the Delegation stated that the Patent Law Treaty had been incorporated into the new law. That would mean, the Delegation explained, in order to obtain a filing date, it was not necessary to file a whole set of claims, and that such claims would be required to be furnished at a later stage of patent prosecution. The Delegation further stated that the new granting procedure had become similar to the one regulated in the PCT and the EPC. The main goal was that the applicant could obtain the search report as soon as possible, always before 12 months from the filing date. The Delegation further explained that post-grant opposition was introduced under the new patent law. Under that procedure, any person might oppose the granting of a patent within six months following its publication in the Official Bulletin of Industrial Property for any of the following reasons: (a) the claimed invention does not fulfil one or some of the patentability requirements; (b) its description is not sufficiently clear and complete for a person skilled in the art to carry it out.; (c) the content of the patent exceeds the content of the patent application as filed. Further, the Delegation informed the Committee that limitation and revocation of rights by right holders had been introduced, which was a novelty in the legislative history of patents in Spain. The patent or supplementary protection certificate (SPC) owner

might request that the patent or the SPC be limited by amending the claims, or revoked, throughout its life. The Delegation stated that the effect of limitation or revocation was retroactive to the filing date. The Delegation further stated that, according to the new patent law, the prior art included the contents of Spanish patent or utility model applications, of European patent applications that designate Spain and of PCT international patent applications that had entered the national phase in Spain, as originally filed, if they were filed earlier than the filing date of the application under examination and were published in Spanish after such filing date. Further, under the new law, disclosures made by the applicant due to a non-commercial test were no longer regarded as non-prejudicial. In addition, the Delegation stated that conditions under which compulsory licenses could be obtained had also been changed. Specifically, two new grounds for the grant of compulsory licenses had been introduced: (i) in order to put an end to practices contrary to legislation on protection of competition; (ii) the manufacture of pharmaceutical products for export to countries that have public health problems, according to Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006. Another new feature of the law was that all legal procedures related to patents would take place in specialized commercial courts located in three Spanish cities: Barcelona, Madrid and Valencia. Another amendment brought by the law was that industrial property agents were required to keep the confidentiality on the issues they were involved and that they had the right to refuse disclosure of communications with customers or third parties relating to proceedings before the Spanish Patent and Trademark Office.

40. The Representative of ARIPO informed the SCP about the new amendment of the Harare Protocol which had taken effect on January 1, 2017. Specifically, the Representative stated that the following amendments had been introduced: (i) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body were no longer considered patentable (Section 10(j)(iii) of the Harare Protocol); (ii) re-establishment of right had been introduced (Section 5*bis* of the Harare Protocol); (iii) a possibility to request for limitation (post grant amendment) had been introduced (Section 5*ter* of the Harare Protocol); (iv) substantive examination had been made subject to request by the applicant (Section 3(3) of the Harare Protocol).

AGENDA ITEM 5: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

41. Discussions were based on documents SCP/14/7 and SCP/19/6.

42. The Secretariat informed the Committee that the website containing the questionnaire on exceptions and limitations had been updated, based on the information received from the Member States.

43. The Delegation of Senegal, speaking on behalf of the African Group, stated that the topic on exceptions and limitations was of paramount importance, as it contributed effectively to creating the essential balance between private rights and general interests. The Delegation referred to the important progress made since the fourteenth session of the SCP, and stated that developing countries and LDCs had difficulties with the implementation of exceptions and limitations. Therefore, the Delegation emphasized that there should be a more accessible system to favor and encourage access to technology and knowledge. The Delegation pointed out that in order to implement effective exceptions and limitations, a legal framework and technical support would be necessary. The Delegation concluded its statement by referring to the SDGs, and expressed its hope that economic development would be achieved by all Member States.

44. The Delegation of Georgia, speaking on behalf of the CEBS Group, stated that the exceptions and limitations to patent rights represented the balance between the rights of the patent owners and those of the larger public. Therefore, the exceptions and limitations should be discussed at the same time as the criteria used in order to determine whether an invention was patentable or not. The Delegation pointed out that the discussions on novelty, inventive step and industrial applicability were necessary for a holistic approach. The Delegation declared that the members of the CEBS Group were prepared to share national experiences on the exceptions and limitations implementation and could consider it as a part of the future work.

45. The Delegation of Paraguay, speaking on behalf of GRULAC, affirmed that it supported the proposal made by the Delegation of Brazil, contained in document SCP/14/7, and considered an exhaustive consideration of that topic useful.

46. The Delegation of Japan, speaking on behalf of Group B, recognized that the use of exceptions and limitations was appropriate in specific circumstances and that innovation was fostered by an effective patent system in which the delicate balance between the interests of the rights holders and the general public was maintained. The Delegation highlighted that enormous work had been carried out by WIPO, including in the SCP, and referred to the great number of valuable references which could be used by any country when considering its national law. The Delegation was of the opinion that the discussion on that topic had provided sufficient information for reflection. The Delegation affirmed that any future work in regard to that topic should be conducted in a balanced manner, taking into account the interests of the rights holders and the general public, and should be based on the extensive documentation elaborated by WIPO. In addition, the Delegation noted that any discussion should be based on facts and should not be prejudiced. In its view, however, the creation of any manual, handbook or prototype would prejudice the outcome and represented a one-size-fits-all approach. The Delegation stressed that the creation of such manual, handbook or prototype was not acceptable and that the use of exceptions and limitations should be judged on a case-by-case basis.

47. The Delegation of Estonia, speaking on behalf of the EU and its Member States, thanked the Secretariat for the work carried out since twenty-fifth session of the SCP. The Delegation wished to highlight that it found the sharing session during the twenty-fifth session of the SCP on case studies including court cases on exceptions and limitations very useful, as it had proven effective to address development issues and/or economic strengthening. The Delegation believed that such sharing sessions and case studies had proven to be a useful source of knowledge for understanding that topic, and emphasized the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on the legal standards used to determine whether an invention was patentable, such as novelty, inventive step and industrial applicability. The Delegation stated that those topics were closely interlinked and concluded that a holistic approach should be taken in order to find appropriate balance between the interests of right holders and the general public. The Delegation affirmed its readiness to continue discussions on exceptions and limitations to patent rights.

48. The Delegation of Brazil aligned itself with the statement made by the Delegation of Paraguay on behalf of GRULAC, and stated that an effective IP system by definition required a delicate balancing act. Each and every Member State needed some policy space to develop and adapt the most adequate set of IP regulations within the boundaries of internationally agreed objectives, principles and standards to assure predictability and confidence. The Delegation further stated that one of the tools to reach that result was to accept exceptions and limitations as an intrinsic element of the law of every single Member State. In its opinion, those served a number of purposes by conferring the necessary flexibility to guarantee national security and to shape public policies to meet *inter alia* the goals of economic growth, competition, and health surveillance. The Delegation noted that the discussions on exceptions

and limitations at the SCP had provided many important documents for the consideration of members which shed light on the tools necessary for adapting patent systems to the demands of contemporary society. The Delegation looked forward to making progress on the third phase of its proposal, laid down in documents SCP/14/4 and SCP/19/6, which dealt with the elaboration of a non-exhaustive manual on exceptions and limitations to patent rights. The Delegation explained that such manual would be for the benefit of all countries, as it would provide important information regarding the designing of exceptions and limitations as well as the challenges that were encountered by countries, when implementing or trying to implement them, and could serve as a valuable tool for the promotion of awareness to be used by WIPO and other organizations. The Delegation further explained that the manual should contain a description of the exceptions and limitations, the purpose of such exceptions and limitations and the options that countries had used to implement them as well as the obstacles that members reported to have faced and the result following such implementation. The Delegation continued that many sources of information could be used for the elaboration of the manual such as document SCP/15/3 including the annexes, the five studies produced by the Secretariat for the twentieth session of the SCP, the seminars held during the twentieth and twenty-first sessions of the SCP, the Member States' Experiences and Case Studies contained in documents SCP/23/3 and SCP/25/3, and the discussions which took place during the sharing sessions. The Delegation noted that that was of course a non-exhaustive list, and that the Secretariat could also take documents on exceptions and limitations, which were prepared by other international organizations such as the World Trade Organization (WTO), the World Health Organization (WHO) or the United Nations Conference on Trade and Development (UNCTAD), into account. The Delegation affirmed that it did not prejudge the final content of the manual and endorsed all members to engage in the preparation of such manual, as with more countries participating in the drafting process, the stronger and more useful such manual would be.

49. The Delegation of Argentina stated that innovation was a fundamental aspect of any country's competitive advantage. It pointed out that a one-size-fits-all approach for intellectual property was inappropriate and that each country had to have its own policy, taking into account the level of its development. The Delegation noted that the impact of the patent system was always asymmetric, depending on the level of development of a country. The Delegation further stated that exceptions and limitations to patent rights were essential to ensure that countries could have the necessary room for maneuver in terms of legislation to promote their national goals and national development plans. The Delegation continued that countries needed to consider a balance between the rights of the public and the right holders, and that exceptions and limitations together with flexibilities made it possible for governments to develop policies aimed at achieving their development goals: their goals in terms of competitiveness, etc. The Delegation aligned itself with the statement made by the Delegation of Paraguay, on behalf of GRULAC.

50. The Delegation of Chile thanked the Chair for her work and the Secretariat for preparing the documents for that meeting. It aligned itself with the statement of the Delegation of Paraguay, made on behalf of GRULAC. The Delegation stressed that it had given constant support to the SCP, especially on the work on exceptions and limitations, and highlighted that the SCP had made considerable progress in regard to that topic. The SCP had produced a lot of reference documents, which are of use to all Member States. The Delegation hoped that the SCP could continue to be a forum for the exchange of experiences of the Member States in regard to challenges and their solutions on the implementation of exceptions and limitations, and the best practices when making full use of exceptions and limitations. The Delegation believed that a tool, which would facilitate the implementation and use of the TRIPS flexibilities in a way that was in line with the need of Member States, would be a non-exhaustive manual as outlined in the proposal made by the Delegation of Brazil. The Delegation continued that having such manual would be an important step forward in what the Delegation believed to be the correct direction.

51. The Delegation of Indonesia aligned itself with the proposal made by the Delegation of Brazil, contained in document SCP/19/6. The Delegation stated that it attached great importance on the issue of exceptions and limitations and thanked the Secretariat for compiling information on exceptions and limitations to patent rights. The Delegation continued that the discussion on that issue had been going on since the fourteenth session of the SCP and produced much valuable information. However, in its opinion, there had been only limited analysis in regard to exceptions and limitations. The Delegation stated that studies on exceptions and limitations should not be limited only to information sharing, but needed to be extended to cover evaluations of the effectiveness and challenges faced in the implementation of exceptions and limitations. The Delegation therefore believed that it would be important for the SCP to consider undertaking the third phase of the work program as described in the proposal by the Delegation of Brazil, as well as further analyzing on how various exceptions and limitations were utilized by different countries in addressing various public policy objectives. The Delegation pointed out that taking a step forward on that issue would contribute to ensuring the ultimate goal of promoting social economic development in the broader context of the 2030 agenda for sustainable development, and ensuring that the global IP regimes and application of flexibilities were consistent with and contributed to the achievement of the SDGs.

52. The Delegation of Iran (the Islamic Republic of) stated that, as any rights, patent rights could not be absolute, since they had to benefit the public at large and rights and obligations had to be in balance with each other. The Delegation believed that exceptions and limitations to patent rights played an important role in establishing an appropriate patent system, and that a flexible policy space was necessary to allow Member States to adopt the sets of exceptions and limitations more adequately, according to their level of development. Recognizing the studies on exceptions and limitations based on the input received from the Member States and the other activities by the SCP, the Delegation noted that after all that work, it was time for the Secretariat to prepare an analysis of the exceptions and limitations that had proven to be effective to address the concern of developing countries. The Delegation continued that all materials produced during the past years needed to be taken into account in such study. The Delegation pointed out that the submissions regarding the practical experiences and challenges on exceptions and limitations, contained in document SCP/25/3, had clarified that while such exceptions and limitations had been available in domestic law, their scope had been often unclear. Accordingly, in its opinion, there were several structural constraints which prevented many Member States from using exceptions and limitations. The Delegation therefore observed that it was essential to ensure that any technical assistance by WIPO in regard to national patent law or national IP strategies should take those constraints into account and provide assistance on how developing countries could overcome such constraints and make full use of the available flexibilities. Concerning future work, the Delegation supported the implementation of the third phase of the proposal made by the Delegation of Brazil, which was the deliberation on a manual on exceptions and limitations in a non-exhaustive manner. It considered that such a manual could serve as a reference for Member States. In addition, the Delegation supported undertaking further analysis on how various exceptions and limitations were utilized by different countries in addressing various public policy objectives, as such information was vital for countries to improve their patent legislation and the institutional implementation.

53. The Delegation of Ukraine congratulated the Chair on her reelection and thanked the Secretariat for its work. The Delegation noted the considerable importance of exceptions and limitations to patent rights and supported the preparation of further documents. The Delegation stated that any efforts, which would be made by the Chair, the Secretariat or any delegations, would be very helpful. The Delegation welcomed the work that had already been carried out during the previous years and had promoted the continuing exchange of experience on that question. The Delegation affirmed its interest in questions that related to the practical implementation and enforcement of Member State laws on exceptions and limitations, and stated its willingness to learn more about the procedures involved in compulsory licensing.

54. The Delegation of Tunisia stated that the SCP was the right setting for exchange of opinions and discussion on the various issues, including exceptions and limitations. The Delegation pointed out that the SCP needed to try to guarantee a balance between the interests of rights holders and the interests of the public. The Delegation aligned itself with the proposal made by the Delegation of Brazil and supported starting the third phase of that proposal on the preparation of a non-exhaustive manual on exceptions and limitations to patent rights. The Delegation further aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group.

55. The Delegation of China was of the view that exceptions and limitations to patent rights were essential in most national patent laws, as they helped to strike a balance between the rights holders and society, which was an important part of a well-formed patent system. The Delegation stated that the SCP had made good progress on that subject: delegations and NGOs had shared their experiences and challenges with respect to exceptions and limitations, and compiled information on exceptions and limitations in various countries. In its view, such compilation was very important and vital for countries to improve their patent laws. The Delegation supported continuing the discussions on that subject so that the SCP could continue compiling experiences made by Member States, which could contribute to the implementation and improvement of all patent systems.

56. The Delegation of Ecuador stated that limitations and exceptions contributed to a balance in the patent system, which had been highlighted in the previous statements. The Delegation pointed out that Ecuador used its national legislation to support flexibility in order to boost its national industrial development, and to get access to protected technology, especially cutting edge technology, which was necessary for economic development. The Delegation noted that it was important to tackle the issue of exceptions and limitations in line with the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation aligned itself with the proposal made by the Delegation of Brazil, which would lead to the elaboration of a non-exhaustive manual on the use of exceptions and limitations.

57. The Representative of KEI aligned himself with the proposal made by the Delegation of Brazil to develop a non-exhaustive manual on limitations and exceptions to patent rights. The Representative requested the Secretariat to examine, how certain countries implemented limitations and exceptions to remedies associated with the exclusive rights of patents, with a focus on the flexibilities found in Article 44 of the TRIPS Agreement, including cases where non-voluntary authorization to use patents replaced injunctions to enforce exclusive rights.

58. The Delegation of Brazil expressed its appreciation for all Member States that had shown support for its proposal. The Delegation clarified that it tried very hard to make it clear from the start that that was an exercise in dialogue, and that it was open to dialogue and all views. The Delegation wished to encourage all Member States of all Regional Groups to engage in such dialog. Every view and every opinion would be taken into full consideration. The Delegation affirmed that the final result of that would become better if more Member States participated in it.

59. The Chair requested the Delegation of Brazil to clarify who should be users of the manual on exceptions and limitations.

60. The Delegation of Brazil replied that its proposal was addressed to a wide range of readers, including right holders and national governments. The purpose of the manual was to be a reference for policymakers as well as academics when conducting research. The Delegation stated that there was a lot of material available and that it had full confidence in the Secretariat's expertise and technical knowledge of that very complex matter. The Delegation pointed out that such reference would be a great contribution from WIPO to the discussions on the issue at the national and international levels. The Delegation believed that such manual

would be useful to every country, as every country of every level of development had been making use of exceptions and limitations regularly. The Delegation noted that it did not want to frame that issue as of interest only to a group of countries.

61. The Delegation of Japan, speaking on behalf of Group B, stated that any outcome under that agenda item should be fact-based and not prejudged. In its opinion, however, the creation of any manual, handbook or the like would prejudice the outcome. The Delegation reiterated that the establishment a manual was not acceptable to it.

62. The Chair requested the Delegation of Japan to explain why it thought that such manual would prejudice the outcome.

63. The Delegation of Japan, speaking on behalf of Group B, replied that the word “manual” might prejudice the outcome and content of such document.

64. The Delegation of Brazil clarified that if more members engaged in such an exercise, it would be better and more useful and welcomed the participation of every regional group and every country. The Delegation noted that it was trying to understand how the word “manual” would be prejudging the results, as every country including countries with different viewpoints on that issue would be invited to contribute. It further noted that the Delegation was ready to call the document differently. The Delegation pointed out that it did not understand how a factual document, which meant to report which countries had been using exceptions and limitations, how they had been interpreted in their patent systems and the challenges faced by them, would be prejudging the result. The Delegation hoped that every country would take part in it.

65. The Delegation of South Africa aligned itself with the proposal made by the Delegation of Brazil. The Delegation stated that South Africa was in a stage where it would like to introduce substantive examination and that it was also in the process of drafting policies around the issues of balancing the rights of inventors and protecting the public. The Delegation noted that it regarded the document, or whatever it should be called, as a reference manual and as an important tool, which could be used to guide it. The Delegation continued that information was available, but not in a consolidated manner, and therefore, such document or manual could be very useful, especially for developing countries as a reference to look at.

66. The Delegation of Senegal, speaking on behalf of the African Group, aligned itself with the statement made by the Delegation of Brazil. The Delegation stated that it did not see how a manual could detract from the discussions, as it would be a compilation of different suggestions and items of information that could be put together in one tool. The Delegation affirmed its support to the proposal put forward by the Delegation of Brazil.

67. The Delegation of Zambia thanked the Chair for her leadership and aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation believed that exceptions and limitations were very critical in every national law, as they helped fostering development and also provided a basis for national security, as well as the policies that a country might undertake. The Delegation stated that its country was doing the mid-term review of the national IP policies in regard to flexibilities, including exceptions and limitations, and that Zambia had recently held a national IP symposium to which it had invited stakeholders to express their views on the review of the IP policies. The symposium had made it very clear that those flexibilities were very critical and would help to shape the national policy to be used as a tool for national development. The Delegation therefore supported the proposal made by the Delegation of Brazil. It observed that the fact that the manual would be non-exhaustive showed that there was room for other issues. The Delegation stated that it was in support of any development of ideas that would help that matter to be moved forward.

68. The Delegation of India aligned itself with the statement made the Delegation of Brazil and stated that the proposed manual on exceptions and limitations would be a welcome addition to the contribution made by the SCP and would be a useful tool for all Member States.

AGENDA ITEM 6: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

69. Discussions were based on documents SCP/17/7, 8 and 10, SCP/18/9, SCP19/4, SCP/20/11 Rev., SCP23/4, SCP/24/3, SCP/26/3 and 4.

70. The Secretariat made a presentation on documents SCP/26/3 and 4. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_26/scp_26_questionnaire_wipo.pdf.

71. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for the presentation and preparing document SCP/26/3 and the Member States who had responded to the Questionnaire. The Delegation invited other Member States to respond to the Questionnaire. The Delegation stated that based on the responses, the majority stated that a high quality patent should meet the legal requirements prescribed in the applicable law. According to those responses, a patent that met the legal requirements had a high presumption of validity, and would most likely not be revoked if it was challenged. The Delegation noted that many responses further elaborated on how they understood the high quality patent granting process. Many offices considered that in the search and examination process, it should be comprehensive to comply with the applicable law and established standards. The Delegation further noted that some offices, which had shown a strong interest in defining what "quality" meant, had not provided answers to that Questionnaire. The Delegation remained very interested to learn, how those offices defined the term and their measures to improve the quality of patent examinations in their offices. The Delegation pointed out that timeliness of office actions and decisions was also mentioned by many countries along with the importance of well trained staff having sufficient skills to carry out their duties. In addition to the above, some offices noted the aspect of a transparent process of any communication between the office and the stakeholders. The Delegation thanked the Secretariat for preparing document SCP/26/4 and pointed out that the responses showed that extensive coordination had been carried out between IP offices at the bilateral, international, and regional levels, e.g., between the offices of developed countries, between the offices of developed and developing countries or between developing countries. The Delegation continued that a wide range of cooperation had been observed, e.g., sharing patent information and tools to conduct searches, assisting in training and capacity building of staff of other offices, sharing examination work and collaborating in prior art search and examination. The Delegation noted that in regard to cooperation in the area of search and examination with other offices, many responses indicated that there was a positive impact on the validity of granted patents, and that prior art found by other offices, particularly those documents in a foreign language, complemented the search work of examiners. Furthermore, examiners, when conducting their own patentability evaluation, might consult opinions on patentability by other offices since they provided the rationale of the decisions taken by examiners in other offices, or might consult commercial databases of other offices. The Delegation further noted that another issue was the reduction of the pendency period and improving the efficiency in patent examination through the utilization of search and examination work conducted by other offices. Some responses mentioned that the PPH program allowed peer office actions which reduced costs for applicants as well as for other offices. The Delegation declared that it was clear from the responses of the different offices that work sharing was effective in assisting offices with more limited capacities in improving quality. The Delegation stressed that it would like to see work to proceed on all the proposals on work sharing, contained in document SCP/23/4, and further noted that some responses addressed certain challenges relating to cooperation in search and examination. It was noted that on one hand, such cooperation might require additional human and financial resources, while on the

other hand, a successful cooperation might result in saving the resources. The Delegation stated that it was glad to see that there was continuing interest in the topic of inventive step, and that a large number of responses to the questionnaire highlighted the importance of patentability requirements in order to obtain high quality patents. The Delegation, therefore, was of the view that the Committee should further work on that substantive issue, such as a further study by the Secretariat on the assessment of the inventive step based on the proposal by the Delegation of Spain, contained in document SCP/24/3. With respect to work sharing and collaboration, the Delegation believed that further discussion on that issue in the SCP would be valuable, given the importance to many Member States. The Delegation highlighted the proposal contained in document SCP/20/11 REV., proposing an annual work sharing event, which the Delegation regarded to be a productive forum for sharing experiences and best practices. Such event would allow participants to identify ways to increase the usefulness of work sharing and cooperation programs while noting that during the previous sessions some delegations had expressed concerns about the lack of definition of the term “quality of patents”, the Delegation regarded the Questionnaire as a positive step forward in finding a definition. The Delegation noted that the answers to the questions showed that seeking a definition of “quality of patents” was useful but not essential to continue working on that topic. According to the Delegation it was important not just to talk about the definition of “quality of patents” itself, but to consider the best possible ways to enhance the quality of patents from various points of view. The Delegation noted that further work in that area should therefore incorporate the questionnaire set out in the document SCP/18/9.

72. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation of the compilation of responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination of Patent Applications. The Delegation stated that the issue of “quality of patents” was at the core of the patent system and that high quality patents enabled Intellectual Property to fulfill its functions. The Delegation noticed that work sharing was one of the instruments for the patent offices to help them to avoid duplication of work and could contribute to a high quality examination process. The Delegation believed that that work would benefit all Member States and all patent offices, and welcomed the questionnaire-based study on the definition of the term “quality of patents” and cooperation of patent offices in patent applications. The Delegation thanked the Secretariat for preparing documents SCP/26/3 and 4, summarizing the tendencies and approaches on how each Member State understood that term. The Delegation noted that 57 Member States responded to the Questionnaire and accordingly showed various definitions on the term “quality of patents”. The Delegation further stated that the study showed that, although there were different opinions the factors that defined the “quality of patents”, there was a similar understanding on the main issues, and the study also illustrated the cooperation between the IP offices at different levels, which gave a positive impact on the efficiency of patent examination. The Delegation encouraged use of work sharing among patent offices of different sizes and different levels of development. It welcomed the work relating to the inventive step in the SCP and supported the proposal put forward by the Delegation of Spain (SCP/24/3). The Delegation believed that a better understanding of the assessment of the inventive step would increase the “quality of patents”. Furthermore, the Delegation favored discussing the proposals made by the Delegation of the United States of America, contained in documents SCP/19/4 and SCP/23/4, as well as earlier proposals concerning the “quality of patents” made by the Delegations of Canada and the United Kingdom (documents SCP/17/8 and SCP/18/9), the Delegation of Denmark (document SCP/17/7) and the Delegation of the United States of America (document SCP/17/10).

73. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for preparing documents SCP/26/3 and 4. The Delegation pointed out the relatively short amount of time given to Member States to provide their responses to the six questions dealing with those issues, as the relevant communication had been sent out only in January 2017. The Delegation assumed that that might be the reason why only 57 offices and two regional offices had responded to the questionnaire. The Delegation pointed out that it was clear from document SCP/26/3 that there were fairly deep differences in the concept and the approach with regard to “quality of patents”. The Delegation stated that some Member States referred to the procedure and management within offices, and other Member States looked at it from the point of view of search and examination. The Delegation noted that some offices emphasized the patentability criteria as a barometer to judge the quality of a patent, i.e., novelty, inventive step, industrial application and disclosure, while others believed that in addition to those criteria, there were other requirements that had to be met depending on the law in force. As a result, the Delegation observed that it was applicable in a given jurisdiction but could not necessarily transposed into other geographical areas as national flexibilities and the discretionary power, granted to domestic authorities under domestic legislation, had to be taken into account. The Delegation noted that the responses provided to the questionnaire strengthened its view that patentability criteria could be applied in different ways, depending on national legislation and that a solid opposition system was very important in guaranteeing patent quality. The Delegation emphasized in that regard the importance of defining the quality of a patent and the importance of transparency in that respect. The Delegation noted that cooperation on search and examination between patent offices did not always guarantee the quality of a patent, and that it was necessary to agree on a definition of “quality of patents”, which was acceptable to everyone.

74. The Delegation of Estonia, speaking on behalf of the EU and its Member States, reiterated its support and commitment for advancing work on the “quality of patents”. The Delegation remained convinced that international cooperation was an important tool for improving the “quality of patents” and efficiency of the patent granting process worldwide. In particular, the Delegation considered that work sharing, as it avoided any duplication of work, reduced backlogs and improved the overall efficiency of the search and examination process. The Delegation noted that studies on how work sharing could amplify efficiency of patent offices worldwide were a useful source of information, and therefore welcomed the questionnaire on the definition of the term “quality of patents” and implementation of cooperation and collaboration between patent offices in search and examination of patent applications. The Delegation thanked the Secretariat for preparing the documents SCP/26/3 and 4 and the presentation. The Delegation welcomed the focus in the questionnaire on how Member States understood the term “quality of patents”, and stated that the information gathered would be helpful, when continuing work in that area. The Delegation was pleased to see that 57 Member States and two regional patent offices responded to the questionnaire and encouraged the remaining Member States, who did not respond, to do so. The Delegation noted that the study showed that there were various approaches in defining the term “quality of patents”, and that the meaning of the term might be different for each stakeholder in different contexts but that nevertheless, two main concepts emerged from the responses. First, the term “quality of patents” related to the quality of a patent itself which was meeting the patentability requirements. And second, the term was related to the patent grant process within the IP offices. The Delegation noted that although there were different opinions on what factors define the “quality of patents”, there appeared to be a similar understanding on the main issues. Further, the Delegation stated that the study also showed the wide range of cooperation between IP offices and the growing use of different collaboration methods at bilateral, regional and international level which facilitated the work of IP offices. The Delegation continued that work sharing had also proven to have a positive impact on efficiency of patent examination and the validity of granted patents. Given the positive benefits of work sharing, the Delegation encouraged more widespread use of work sharing among patent offices of different sizes and from different levels

of development. The Delegation stated that it saw merit in a study by the Secretariat on how different laws and practices might limit the potential for work sharing and what voluntary measures could be put in place to address any problems at the international level. The Delegation thanked the Secretariat for its presentation during the twenty-fifth session of the SCP and providing a platform for sharing information among participating IP offices with regard to search and examination reports. The Delegation believed that a dedicated page on the WIPO website for various other work sharing activities would further improve access to existing initiatives and enable patent offices to collaborate more efficiently. The Delegation further welcomed the interesting discussions during the twenty-fifth session of the SCP regarding the Member States' experiences on international work sharing and collaboration, during which the Delegation saw examples from Member States on how the examination and administration of patent applications could be facilitated by work sharing programs. The Delegation supported the idea of conferences in the margins of sessions of the SCP on that topic, as hearing about such successful examples could help more Member States to learn about and to participate in work sharing programs. The Delegation thanked all Member States for the sharing sessions on examples and cases relating to assessment of inventive step held during the twenty-fifth session of the SCP, and welcomed the fact that that complex topic had continued to be discussed in the SCP, as proper evaluation of inventive step was key to guarantee a high quality patent system. In order to follow up and proceed from the study on inventive step, contained in document SCP/22/3, the Delegation emphasized the importance of further examining that concept as well as methods of assessing the inventive step used in the WIPO Member States. The Delegation referred to the proposal that had been made by the Delegation of Spain, contained in documents SCP/19/5/ Rev. and SCP/24/3, and had been endorsed by all other Member States of the EU. The Delegation reiterated its support for advancing work in the Committee pursuant to the proposals made by the Delegation of the United States of America, (documents SCP/19/4 and SCP/23/4), and by the Delegations of the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11), as well as earlier proposals concerning the "quality of patents" made by the Delegations of Canada and the United Kingdom (document SCP/17/8), by the Delegation of Denmark (document SCP/17/7), and by the Delegation of the United States of America (SCP/17/10). The Delegation expressed its commitment to advance work program on "quality of patents", which reflected key elements of those proposals and looked forward to constructive discussion on that agenda item.

75. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, stated that it continued to support the idea that the SCP should have discussions on opposition systems. The Delegation noted that there should be a work program on opposition systems that could comprise the questionnaire on the different mechanisms available in the country, the procedures and modalities for their use, constraints in using the opposition system effectively and how such opposition systems could be strengthened. The Delegation was of the view that the SCP should arrive at a common understanding, on what was meant by "quality of patents" and welcomed documents SCP/26/3 and 4 on the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. The Delegation thanked the Secretariat for its presentation and expressed its hope that those works would be a good basis for Member States to narrow gaps on the meaning of "quality of patents".

76. The Delegation of Brazil affirmed its readiness to engage constructively in discussions on the "quality of patents", and hoped that other delegations might follow. The Delegation declared that it was willing to discuss everything on "quality of patents", based on the common understanding that there had to be a balance between right holders and users of patents, and that the discussions had to be in compliance with Articles 1.1 and 27 of the TRIPS Agreement. The Delegation stated that it was not willing to accept any outcome related to harmonization but that that did not hinder the discussions. The Delegation noted that while it was willing to discuss any topic, it would like to focus on three main topics, the first being the access to tools and databases for IP offices. The Delegation believed that having adequate search tools and

databases could help all countries whether developed and developing. The Delegation continued that the second topic should be communication and transparency as it believed that a quality patent was based on a transparent process and efficient communication process between patent offices and stakeholders. The Delegation stated that the third topic should be staff training, as that clearly added value to IP offices.

77. The Delegation of Argentina thanked the Secretariat for preparing documents SCP/26/3 and 4. The Delegation stated that, like the majority of Member States, it agreed that weak patents undermined and destroyed the credibility of the patent system. The Delegation believed that work done so far did not lead to harmonization, and further stated that if an office completed the work done by another office, there was no doubt it would improve the quality of the patent at issue. The Delegation stressed that while every patent office would grant or refuse an application on the basis of its national legislation and/or applicable patentability criteria, work sharing could help them to ensure that the national patent system would grant only high quality patents. The Delegation reiterated that the reuse of work done by another office would not harmonize any patentability criteria, as each office would assess the patentability of the invention in the light of its own national legislation.

78. The Delegation of El Salvador thanked the Chair for her leadership and the Secretariat for preparing documents SCP/26/3 and 4. The Delegation noted that the responses to question one showed that patent offices attach great importance to patent granting process, not limiting themselves simply to search and examination, in order to grant a high quality patent. As indicated in paragraphs 9 and 10 of document SCP/26/3, some offices highlighted the importance of control mechanisms and the quality of the national legal framework within which they were operating. The Delegation noted that in order to exchange experiences and information on that issue, it would be good to know if patent offices made use of examination manuals and that such manuals could be presented to the SCP as a contribution to the further debate and also be used as a source of support or an instrument by other offices, particularly those which did not have tools of that kind. The Delegation stated that examination manuals would facilitate the work of the examiners, would make the legal framework stronger and could also be useful to applicants as they gave them greater certainty, on how the examiner would proceed in examining his or her patent application. The Delegation noted that that made it easy for them to be more specific about certain aspects, and encouraged them to include elements that they might leave out if they did not have access to such manuals. In regard to question six, contained in document SCP/26/4, the Delegation therefore suggested that at the subsequent session of the SCP, examination manuals or handbooks be submitted for consideration. The Delegation informed the Committee that its IP office used a manual which was also used by the countries of Central America and the Dominican Republic, which made it possible to standardize procedures in that region. The Delegation noted that it would submit that manual for consideration at the subsequent SCP session together with the Delegations of Costa Rica, the Dominican Republic and possibly other countries from the Central American region.

79. The Delegation of Iran (Islamic Republic of) took note of the information contained in documents SCP/26/3 and 4 and extended its appreciation to the Secretariat for their preparation and presentation. The Delegation observed that the responses to the questionnaire showed that the first and most important stage in considering and discussing the quality of patents was reaching to a common understanding on the meaning of the term "quality of patent". The Delegation believed that the lack of common understanding on the meaning of such concept would make it difficult to fully comprehend the proposal on the topic on quality of patents. The Delegation was of the opinion that quality of patents could not be enhanced by simply adopting the practice of other patent offices or by collaborating with other offices through work sharing activities. The Delegation considered that despite its importance, quality of patents should be left to the regulations at the national level and discussed and decided by national authorities, taking into account the national priorities of each specific country. In the Delegation's view,

work sharing was a matter of procedure which fell outside the mandate of the SCP as a substantive Committee. With regards to that agenda item, the Delegation reiterated its position that such topic should not be construed as a tool for harmonizing patent law or for norm setting in the future. The Delegation believed that harmonizing patent laws across countries could widen the differences in economic and scientific development among countries, and could create a concentration of intellectual property assets within certain regions which would not help developing and least developed countries. In the view of the Delegation, the quality of examination needed to be improved substantially in conformity with the national policy objectives of each country in order to avoid the high social cost of granting patents to insignificant improvements. Furthermore, the Delegation observed that experience sharing might improve the quality of patents and also skills and technical expertise of patent officers through bilateral and regional cooperation between patent offices, as the responses to the questionnaire had indicated. The Delegation noted that despite the fact that opposition systems continued to be maintained in the agenda along with the quality of patents, the focus of discussion under that agenda item had been exclusively on patent quality. The Delegation thus suggested giving equal prominence to the topic of opposition system in the future SCP work program. The Delegation recommended that such a work program comprise a questionnaire survey on the different types of opposition mechanism in national laws, procedures and modalities for their use, constraints in using the opposition systems effectively, and how opposition systems should be regulated and reviewed.

80. The Delegation of Japan thanked the Secretariat for its effort in preparing the meeting, especially in preparing the working documents SCP/26/3 and 4 relating to the topic of quality of patents. The Delegation found that document SCP/26/4 stressed how work sharing among patent offices could serve to supplement the initial search report with the search conducted by other patent offices and enable patent offices to understand the grounds of other countries' decisions before making their own decision. The Delegation believed that many countries shared a common understanding that patent rights acquired through such a process had high legal stability and that effective work sharing activities enhanced the quality of patents. Furthermore, the Delegation noted that according to document SCP/26/4, many countries responded that one of the important effects of work sharing was shortening examination pendency. The Delegation specified that, while at the first glance, it appeared that pendency itself had no relation to the quality of patents, many countries were aware that reducing backlogs and granting patents in a timely manner were important aspects of quality management. The Delegation noted that many countries pointed out that in addition to the legal stability of patent rights themselves, timeliness was also related to the quality of patents from the perspective of the process for acquiring patent rights. Furthermore the Delegation observed that also in Chapter 1, Part 7, of the PCT International Search and Preliminary Examination Guidelines, which dealt with the quality management system, it was stipulated that each International Searching Authority should have in place an appropriate control mechanism regarding fluctuations in demand and backlog. The Delegation concluded that effective work sharing not only directly contributed to improving the quality of patents themselves, but also positively impacted the quality of patents in terms of process for their acquisition. The Delegation reiterated that work sharing very useful in enhancing the quality of patents. Based on that understanding, the Delegation believed that the SCP should continue discussions on work sharing activities. Noting that the total number of IP offices participating in the PPH program had increased to 45 as of June 2017, while nine intellectual property offices had joined the PPH, in the Japanese fiscal year 2016, the Delegation stated that those figures clearly showed that the PPH had been well adapted as an effective cooperation framework. Furthermore, the Delegation was of the opinion that the PPH program did not affect independence of examinations at the participating offices. The Delegation mentioned that Japan, as one of the countries that most actively promoted the PPH program, had never received feedback from participating offices stating that PPH actually undermined the independence of the examination of any offices.

81. The Delegation of the United States of America expressed its wish to share its views on documents SCP/26/3 and 4. With regards to document SCP/26/3, the Delegation stated that improving the quality of issued patents was one of the top priorities of the USPTO. The Delegation observed that, as the responses to the questionnaire illustrated, that topic was also of great interest to many of the Member States of WIPO. Although the Delegation noted the considerable participation, it was however very disappointed that many offices that had shown a strong interest in defining what quality meant, had not provided answers to that questionnaire. The Delegation remained interested to learn how they defined the term and the measures they took to improve the quality of patent examination in their offices. The Delegation highlighted that according to its response to the questionnaire, one indication of a quality patent was one that was correctly issued in compliance with all the requirements of the US patent statutes as interpreted by their judiciary at the time of issuance. The Delegation explained that it meant in part that the application met the requirements of patentable subject matter, novelty, non-obviousness, and disclosure/enableness. The Delegation observed that USPTO's responses also recognized that, subsumed in such approach, there was the requirement that process for granting patents should meet high standards. The Delegation stressed that the USPTO continuously endeavored to strengthen and improve its products and work services at all stages of the patent process. The Delegation was encouraged by the fact that so many Member States responded to the questionnaire. In its opinion, that reflected common themes and views shared by many offices and could serve as a springboard for in depth discussion in future SCP sessions. The Delegation noted that large and small offices as well as offices with different levels of experience had reported similar themes on quality. For instance, the Delegation found common views that quality patents were patents that were in compliance with substantive legal criteria. In the Delegation's view, implicit in that statement was a general appreciation among Member States on what those criteria were, how to implement them in the examination process, and how they were scrutinized in judicial proceedings. The Delegation observed that as such, document SCP/26/3 reflected that there was a basic appreciation on the contours of various legal criteria, for instance, regarding inventive step. With regards to improving the patent process in order to facilitate the issuance of quality patents, the Delegation stated that document SCP/26/3 highlighted common themes among the submissions which included: (i) improving the search and examination process; (ii) timeliness of IP office actions and decisions; (iii) hiring of trained examiners; and (iv) applicants communication and transparency of processes. The Delegation agreed with those basic four themes pointed out in document SCP/26/3. The Delegation considered that, as such, those findings showed the need to address those topics. The Delegation specified that some of those themes were integral to work sharing programs and could be greatly enhanced by offices taking part in work sharing. The Delegation hoped in that regard that the Member States could build upon the very important findings on patent quality. With respect to document SCP/26/4, the Delegation stressed that the USPTO had been taking part in work sharing programs for many years, and had accumulated significant experience in working with other patent offices. The Delegation explained that current work sharing programs that it participated in, such as the PPH, the PCT collaborative search and examination and collaborative search and examination programs, had demonstrated the benefits that work sharing provided to offices and applicants. The Delegation pointed out that document SCP/26/4 summarized the submitted responses from IP offices of WIPO Member States as well as regional offices. The Delegation considered that the document made it evident that IP offices of many Member States already engaged in extensive cooperation with each other and that work sharing featured prominently in such cooperation. The Delegation observed that the following types of work sharing were highlighted in the document: (i) access to documents databases, search systems of other offices; (ii) use of search and examination products produced by other offices; (iii) collaborative search and examination; and (iv) carrying out search and examination for or by other offices. The Delegation noted that responses from the Member States showed that various types of work sharing models between IP offices were cross-cutting and encompassed countries in different

stages of development, IP offices of varying sizes and capabilities, and even legal systems with different traditions. The Delegation echoed the statement made by the Delegation of Japan by noting the widespread adoption of the PPH model across Asia, Americas and Europe. The Delegation also noted the widespread use of regional work sharing arrangement, such as PROSUR, CADOPAT, ARIPO and others, as well as the benefits that had been received in participating in those work sharing arrangements. The Delegation believed that the widespread participation in those arrangements, as well as the comments provided by several delegations, reinforced the view that patent work sharing was a good way to apply expertise in patent examination across a family of internationally filed applications to provide a higher quality examination and more efficient operations of the offices. The Delegation was of the opinion that, in that way, offices of more limited capabilities could carry out high quality searches and examinations which would otherwise be impossible or prohibitively expensive. Furthermore, the Delegation considered that the comments and strong participation also showed that countries did not see work sharing as infringing the sovereignty of any nation or imposing harmonization of laws upon them. In that regard, the Delegation referred to the statements contained in Argentina's submission that reuse of the work of other patent offices did not hamper the independence of patentability criteria. The Delegation observed that document SCP/26/4 reflected the view of many countries that collaboration and work sharing played a major role in making patent offices more efficient and improving patent quality.

82. The Delegation of Indonesia expressed its wish to share its view on the agenda item on quality of patents, including opposition systems. The Delegation considered that a precise definition and common understanding of the concept of quality of patents was extremely important to the SCP discussions. Furthermore, the Delegation believed that the problem of patent quality could not be resolved by simply adopting the practice of other IP offices or by collaborating with other offices through work sharing arrangements. In the Delegation's view, the concept of work sharing had little to do with patent quality. The Delegation was also of the opinion that the quality of prior art search and patent examination should be improved in conformity with the policy objectives of the country concerned. The Delegation reiterated that, without prejudicing the SCP discussions, it did not support the attempts of harmonization of patent law under the pretext of quality of patents. The Delegation stressed that one size did not fit all. Furthermore, the Delegation stated that there was diversity, including diversity in the use of flexibilities related to the scope of patentability in relation to public policy objectives, as well as diversity in the scope of patent protection. The Delegation therefore believed that work sharing would indirectly interfere with that diversity by leading to substantial harmonization of patent law. The Delegation was of the view that discussion on quality of patents should include discussion on opposition systems because the opposition systems had the objective of strengthening the quality of patents. The Delegation recommended that equal prominence should be given to opposition systems under that agenda item.

83. The Delegation of China thanked the Secretariat for the questionnaire and the explanation of its results. The Delegation believed that work would help to clarify the definition of patent quality and the scope of research. The Delegation also believed that sharing countries' practices would help countries to learn from each other. The Delegation considered those activities favorable for future SCP discussions. With regard to the quality of patents, the Delegation was of the opinion that the issue was related to innovation, examination, use and patent protection. The Delegation noted that the definition of quality of patents was complex. However, the Delegation observed that it could be measured by referring to several aspects, such as technological innovation, patent drafting, patent stability, patent utilization, etc. Noting that different countries were at different stages of development, and hence they faced different problems and concerns, the Delegation believed that discussion in that area should be open and inclusive, and should take into account the needs of different countries. With regard to work sharing, the Delegation suggested focusing on capacity building, such as the development of database, search tools and similar instruments, technical assistance to developing countries,

enhanced search and review, staff training and exchange. The Delegation considered training of patent examiners in developing countries very important for the quality of patents. It observed that in recent years, the Chinese State Intellectual Property Office (SIPO) had been providing different types of training to patent examiners, including those from foreign countries, in order to increase their skills. The Delegation pointed out that such initiative provided the examiners of other countries with the opportunity to share their experience and, at the same time, get trained. The Delegation specified that in 2016, SIPO provided training to 80 examiners from 20 developing countries. The Delegation stated that China was also actively considering the use of WIPO's China Trust Fund to work with WIPO to develop training for patent examiners in developing countries and to provide more training to developing country examiners. Furthermore, the Delegation pointed out that SIPO also paid attention to how work sharing could be implemented by developing the cloud patent review system to facilitate the sharing of documents and promote the exchange of information and communication. The Delegation stated that all those measures proved to be effective and expressed the wish to listen also to the other countries' experiences on those topics.

84. The Delegation of the Republic of Korea thanked the Secretariat for preparing the documents illustrating responses to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. Regarding documents SCP/26/3 and 4, the Delegation took note of the point that, in general, two main concepts, quality of patents itself and quality of patent granting process within that office had emerged from the responses on the terms of "quality of patents". The Republic of Korea was of the view that those two concepts were closely related, considering that the quality of patents itself was the outcome of a good patent granting process, including effective and efficient search and examination, as indicated in the documents. The Delegation believed that work sharing could be a powerful tool that could be instrumental in helping patent offices to grant high quality patents and in making their work more efficient and effective, thanks to the collaboration between patent offices in the search and examination process. The Delegation emphasized that work sharing was not related to the right to decide whether a patent should be granted or denied, which belonged to each patent office. The Delegation stressed that work sharing was only an instrument to help the granting decision of patent offices by providing useful information and reducing workload. The Delegation therefore supported the proposal made by the Delegation of the United States of America on the study of work sharing (document SCP/23/4). The Delegation requested that the Secretariat conduct studies on work sharing, including the circumstances and how the implementation of work sharing could assist enhancing the quality of patents.

85. The Delegation of Mexico thanked the Secretariat for its work. The Delegation expressed its wish to provide a brief summary of Mexico's responses to the questionnaire and its experience concerning the topics under discussion. The Delegation explained that the Mexican national legislation did not provide a definition of quality of patents. However, the Delegation specified that the Mexican Industrial Property Institute (INPI) considered that term to be a way of achieving the public policy objectives underlying the grant of patents. The Delegation further pointed out that it was considered to be an all-inclusive term which referred to all the elements that patents had to meet in order to ensure their contribution to innovation, technology transfer, economic development and the improvement of competitiveness and productivity in various sectors of industry. Furthermore, the Delegation highlighted that the aspects related to a clear legal framework comprising, *inter alia*, rules on education and professional skills of human resources working in IP office, the provisions concerning sufficient material resources to carry out tasks in the area of patent examination and related activities, were also included in those elements. The Delegation stated that the Mexican government wanted to grant patents on the basis of appropriate policies and procedures which would guarantee that the patent was of good quality and enforceable. INPI was of the view that the Mexican national legal framework needed to ensure quality of patents by making certain that patents were granted only for

inventions which contributed to the state of art and technological development without contrasting an objective of public interest. The Delegation highlighted that Mexico had put in place mechanisms to ensure such result. The Delegation further pointed out that in order to avoid unnecessary delay in granting a patent, it adopted administrative procedures that were as simple as possible. The Delegation stated that in addition, its rules and regulations provided clear criteria to grant a patent, which contributed to patent quality, such as: (i) substantive examination of patent applications; (ii) opposition systems; (iii) the concept of invention and patentable subject-matter; (iv) specification of subject-matters excluded from patent protection, by making use of the flexibilities contained in the TRIPS Agreement; (v) patent application requirements, including description of the invention; (vi) deadline to comply certain activities. Furthermore, the Delegation stressed that INPI constantly reviewed its procedures to make sure that they were as effective and efficient as possible. With that regard, the Delegation further pointed out that they tried to make sure that the wider public was aware of the criteria, rules and procedure to be complied with to obtain a patent. The Delegation mentioned that Mexico was trying to reach further agreements with other authorities working in that area to receive some help to achieve their goals, while some agreements had been already signed between INPI and other patent offices. The Delegation specified that thanks to those arrangements, they could take advantage of the search and examination work carried out by those patent offices and *vice versa*. The Delegation believed that such mechanism would help patent applicants to get a more rapid consideration of their application in accordance with the PPH agreements. The Delegation stated that technical assistance in respect of patent examination was done through the exchange of patentability opinions and search reports and that they were currently working with three patent offices in the region of Central America and the Caribbean. Concerning the documents SCP/26/3 and 4 and other research done by the Secretariat on those issues, the Delegation suggested continuing to work on issues related to cooperation among patent offices on search and examination. The Delegation supported the proposal made by the Delegation of Spain on the organization of sharing sessions and seminars, because they thought that it would be useful for SCP participants to share their experiences and to learn from other countries.

86. The Delegation of the Republic of Moldova expressed its wish to share the achievements of the State Agency on Intellectual Property of the Republic of Moldova (AGEPI) in respect of improving quality of patents. The Delegation stated that AGEPI had been using quality control mechanisms, in accordance with the ISO standards, to check the quality of patents for many years. The Delegation mentioned that they had a global approach to improve the qualifications of their specialists. The Delegation specified that they tried to improve the quality of work through the organization of various training seminars, also in cooperation with other countries of Europe. The Delegation explained that AGEPI carried out an examination on the inventive step, industrial application and all the other criteria applicable to patent quality. The Delegation highlighted that, in carrying out a prior art search, AGEPI used databases, *inter alia*, commercial databases, patent databases, as well as non-patent literature in various languages such as English, French and Russian. The Delegation stated that AGEPI had recently taken further steps to improve the quality of patents by signing an agreement with the Romanian Patent Office, which included the mutual recognition of search reports. The Delegation hoped that such measure would speed up the process of examination and that they would be able to carry on with that kind of cooperation in other areas for further achievements. The Delegation also expressed its wish to use WIPO CASE in the near future.

87. The Delegation of South Africa supported the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation raised the issue that while the Committee did not have yet a common understanding on the definition of the term "quality of patents", a quality patent was one that would withstand any revocation attempts. The Delegation specified that for that to be possible, a granted patent must meet the inherent patentability requirements which were the cornerstone of the patent system. The Delegation further observed that there must be a balance between the right granted and the disclosure to

the public, which could be reached by sufficient disclosure in the patent application. It was for that reason that the Delegation believed that disclosure was the bedrock of the patent system and that lack of transparency compromised patent quality. In its opinion, low quality patents inhibited research as well as knowledge building and dissemination, while also contributing to the loss of integrity and legitimacy of the system of patent rights and related duties. The Delegation therefore considered that the SCP's work on quality of patents should focus on attempting to shed some light on how the sufficiency of disclosure, the inventive step as well as opposition systems could be enhanced. The Delegation was of the opinion that although work sharing could ease the burden of patent examiners and avoid unnecessary duplication of work, that would not necessarily translate into quality of patents. The Delegation did not believe that patent quality could be simply improved by adopting the practices of other offices. In its view, work sharing could function if designed within a specific framework to enhance capacity building of offices along the lines proposed by the Delegation of Brazil.

88. The Delegation of Spain thanked the Secretariat for preparing documents SCP/26/3 and 4. The Delegation hoped that the analysis of the responses provided by Member States would make a contribution to better understand the concept of quality of patents and help the SCP to make headway on studying the various aspects of it. The Delegation noted that, as the responses to the questionnaire had shown, such concept was multi-faceted. Following the sharing session on the concept of inventive step at the previous session of the Committee, which the Delegation found very satisfactory, the Delegation had come to the conclusion that the time was ripe to make further progress on the study of that requirement. The Delegation suggested to carry out a study, in line with their proposal contained in document SCP/24/3, submitted at the twenty-fourth session of the Committee. The Delegation explained that such a study would be based on the contributions of Member States, which would like to participate, on some of the aspects identified in paragraph 8 of the proposal and others which might be suggested by other Member States. The Delegation specified that the study would look at the way inventive step was dealt with in various regions, and, if possible, examples and some jurisprudence would be integrated. The Delegation observed that at the twenty-fifth session of the SCP, the Committee had an exchange of experiences, and in particular, the Delegation of Spain had presented the view of Spain and of the European Patent Office on two issues, the general and common knowledge of the person skilled in the art and the assessment of inventive step with regard to biotechnology. However, the Delegation observed that they still did not know how those questions were tackled in other regions, while it was crucial for the Committee to know. The Delegation noted that if the SCP wanted to have a full picture of the issue, it was necessary to include experiences of other countries and regions in the study. The Delegation reiterated that at such a stage in the work of the Committee, harmonization was set aside. The Delegation stressed that the purpose behind its proposal was to obtain some information on how the assessment of inventive step was carried out in various regions. Furthermore, the Delegation highlighted that every state was free to set its own criteria for examination of inventive step and other substantive examination criteria, as allowed by the flexibility contained in Article 27 of the TRIPS Agreement. The Delegation recalled that, if the patent system was to achieve its social goal of promoting scientific and technological invention, it was essential to grant patents on only those inventions that deserved it. In its view, the inventions deserving patent protection were those which met the criteria of novelty, industrial applicability and inventive step, and it was essential that the application be sufficiently clear and complete in order to allow carrying out a proper examination. The Delegation believed that the better the knowledge of the substantive patentability requirements and the various methods of assessment and evaluation, the greater the likelihood of patents being granted for inventions that deserved to be patented. The Delegation was of the opinion that the proposed studies should be of interest of every country, independently of their level of development. The Delegation recalled that the first President of the EPO, Mr. Johannes Van Benthem, in his statement made on the occasion of the inauguration of the EPO, said that the success of the EPO would depend on whether its examiners were capable of assessing the inventive step

requirement in a correct manner. In the Delegation's view, no training on patentability requirements could be superfluous. The Delegation noted that many patent offices had large training departments that provided courses and upgraded the skills of their examiners. On the other hand, the Delegation observed that many small offices could not provide such training. The Delegation pointed out that, despite the lack of such training possibilities, those offices had to carry out a full and proper assessment of the inventive step requirement if they wanted to avoid granting patents to inventions which did not provide sufficient benefit to society and therefore did not deserve to be protected by exclusive rights. With that regard, the Delegation stressed the importance of the Committee, the only multilateral forum on patents, in carrying out studies on patentability requirements, particularly the inventive step requirement. The Delegation believed that if the SCP could provide studies on that issue, it could improve knowledge on patentability requirements worldwide, so that countries would be able to make better use of the flexibilities provided in the TRIPS Agreement. The Delegation pointed out some aspects that such study should cover as described in greater details in paragraph 8 of its proposal: (i) common general knowledge: Its combination with the state of the art; (ii) combination: juxtaposition vs synergic effects; (iii) the danger of hindsight analysis; (iv) secondary indicia; (v) selection inventions; (vi) problem invention; (vii) the assessment of inventive step in the chemical sector (Markush claims, enantiomers, etc.); (viii) the assessment of inventive step in other sectors which might imply a particular difficulty. The Delegation also illustrated further reasons why it considered additional studies on those issues extremely helpful. First of all, the Delegation observed that a considerable amount of work had already been done on those issues and it found regrettable to stop halfway without ending such work. Secondly, the Delegation believed that inventive step was clearly within the mandate of the SCP, being a matter of substantive patent law and therefore of interest to all Member States whatever their level of development might be. With that regard, the Delegation considered that such study would be of particular benefit to countries with small patent offices, which could not afford the luxury of having their own training department. Furthermore, the Delegation noted that one of the arguments put forward by certain states in respect of the proposals made on patent quality was that there could be interference with national sovereignty. The Delegation stated that such a risk was non-existent, since each patent office would prepare its own guidelines on examination, including aspects related to inventive step using the flexibilities provided by Article 27 of the TRIPS Agreement. The Delegation noted that the result of that study should be freely available and could be used by Member States if they considered it more appropriate. Noting the observation of some Delegation's that there was no consensus on the definition of quality of patents, while the Delegation agreed with such observation, it also noted that the responses to the questionnaire prepared by the Secretariat represented a step forward in that regard. The Delegation believed that thanks to an appropriate examination of inventive step, there would be benefits for society, since the risks related to an improper patent examination would be reduced. With regard to frivolous patents, the Delegation considered that such a problem could be avoided by an appropriate examination of the inventive step. The Delegation hoped that their proposal would be supported and included in the future work program of the Committee.

89. The Delegation of the United Kingdom thanked the Secretariat for producing the questionnaire and the Member States who responded to the questionnaire. The Delegation also encouraged other Member States that had not done so to respond to the questionnaire. The Delegation hoped that an additional opportunity to do so might increase the number of responses. The Delegation highlighted the information provided by the United Kingdom Intellectual Property Office (UK IPO) in response to the questionnaire, which also contained references to their quality assurance procedures. The Delegation hoped that information was of interest to other Member States and expressed their eagerness to learn from others' experiences. The Delegation believed that a definition could be useful in facilitating further work on the quality topic. The Delegation also stated that the information gained through the questionnaire was a good starting point. The Delegation noted that although there were differences in some of the responses, there were also some key themes that were reflected

throughout. The Delegation welcomed discussion on how to make progress on that point. For example, the Delegation suggested that that could be achieved through a seminar at the twenty-seventh session of the SCP. The Delegation observed that additional Member States might like to consider responding to the questionnaire so that their views on how quality was defined could be more easily taken into account. The Delegation also welcomed the opportunity to further discuss proposals relating to quality including, but not limited to, the proposals outlined in document SCP/18/9. In the Delegation's opinion, that paper included further questions which should form the basis of further work on quality. On cooperation and work sharing, the Delegation welcomed the responses to the questions relating to that topic in the area of search and examination, so that the SCP and other Committees could better understand what kinds of cooperation existed and what were their benefits. The Delegation noted that the responses to question 5 of the questionnaire made it clear that work sharing helped to improve quality and increase sufficiency. The Delegation was convinced that work sharing could ensure identification of relevant prior art, sharing best practices and reducing duplication, while at the same time allowing national and regional offices to continue to grant patents in line with their own national and regional law. The Delegation stated that that was their experience. The Delegation continued to support the proposal outlined in document SCP/20/11 REV. to hold an annual conference during the SCP week to share experiences regarding international collaboration. The Delegation believed that such a conference would help improve the usefulness of those work-sharing programs. The Delegation considered that quality and work sharing were crucial to ensuring the patent systems worked effectively for applicants, patent holders, IP offices and, more importantly, third parties. In its opinion, quality and work-sharing were essential to a well-functioning and appropriately balanced patent system.

90. The Delegation of the Russian Federation expressed its gratefulness to all countries participating in responding to the questionnaire prepared by the Secretariat on the issue of quality of patents. The Delegation also thanked the Secretariat for preparing documents SCP/26/3 and 4. The Delegation stated that the Federal Service for Intellectual Property (ROSPATENT) had been giving particular attention to the issue of quality of patents. The Delegation drew the Committee's attention to some activities that they had been conducting. The Delegation explained that the legislation of the Russian Federation did not have a definition of quality of patent as such. However, the Delegation specified that ROSPATENT was looking at the issue and understood quality of patents to mean the quality of state services provided to applicants for patent and the avoidance of duplication. The Delegation pointed out that such concept also meant full compliance with the administrative procedures set by Russian legislation, including meeting deadlines and enforcement. The Delegation believed that the quality of search and examination was also one of the important aspects that had to be taken into account when looking at defining quality of patent. The Delegation stressed that the quality of the services provided by the state was evaluated also by looking at the number of complaints received in relation to them, the number of oppositions to patent applications, and the number of cases on patent litigation brought before the national patent court. The Delegation mentioned that quality was a topic related also to the patent application and other documents submitted by the applicant, since those documents were taken into account when examining the patent application. The Delegation also stated that other factors to be taken into account were the filing of eventual oppositions by a third party, as well as sufficient interest in and benefit of the invention disclosed in the application for wider society. With regard to quality of patents and their reliability and enforceability, the Delegation explained that ROSPATENT had put into place a system of control carried out by the Quality Council, a new body that had been set up recently. The Delegation pointed out that the Quality Council had to undertake an objective assessment of the quality of the patent application and of the patent services provided by the state. The Delegation specified that the Council comprised two sections: one competent in aspects relating to the patent law, and the other competent in the technical aspects of the patent application. The Delegation observed that the questionnaire prepared by the Secretariat on that

issue did not seem to take into account ISO 9001 Standards and the extent to which offices had complied with it as an international standard. The Delegation considered that it would have been interesting to verify whether offices had the ISO certification or not, and if they did, the effect of that certification, if any, on the quality of the patents. The Delegation thus suggested that the Secretariat provide some information about the offices that were certified ISO 9001 and the effect that it had on the quality of patents, if any. The Delegation supported the proposal to have further discussion on opposition systems and the organization of a special session or seminar on that issue. The Delegation also agreed with the proposal about continuing discussion on the issue of work sharing, since ROSPATENT participated quite actively in cooperation with other countries in work sharing, particularly through the PPH program with around 22 patent offices. In addition, the Delegation expressed its support to the proposals put forward by the Delegation of Spain about further discussions on the questions of substantive patent law. In that regard, the Delegation believed that those topics were extremely relevant to, and for experts of, patent offices. The Delegation was of the opinion that the inventive step was particularly important, and should be discussed further, since the exchange of experience and gained knowledge on that issue could be useful to everyone.

91. The Delegation of Portugal thanked the Secretariat for delivering an important compilation of information on the questionnaire on the term “quality of patents” and for its effort to include their late response. The Delegation reiterated its support and commitment for advancing work on quality of patents and for all the proposals aiming at improving the overall efficiency of search and dissemination process. The Delegation also supported the proposal made by the Delegation of Spain contained in document SCP/24/3, and requested a study by the Secretariat on the assessment of the inventive step. The Delegation was of the opinion that the topic of the inventive step and non-obviousness was important for all Member States.

92. The Delegation of the United States of America expressed its wish to briefly address one of its earlier proposals relevant to the quality of patents. The Delegation stated it was encouraged by the interest shown in work sharing in SCP discussions and the quality questionnaire, but even more by actual participation of many patent offices in many different work sharing programs and arrangements, such as ARIPO, PROSUR, CADOPAT, PPH programs and several others. The Delegation observed that many delegations had stated that the benefits of work sharing could be especially significant when offices involved had different capabilities and strengths. However, the Delegation noted that even large offices like the USPTO could have difficulties in finding all relevant prior art on their own, particularly when it was in a foreign language and not located in national collections. The Delegation specified that that was the reason why they had proposed to work on that topic in document SCP/23/4. The Delegation was grateful that some aspects of the proposal had been carried out by the SCP and noted that several questions in the questionnaire on quality that was issued by the Secretariat addressed work sharing. While the answers to work sharing related questions in the questionnaire had been compiled in document SCP/26/4, the Delegation expressed its wish to have a more detailed look on how work sharing could be practically applied to achieve tangible results in improving quality. The Delegation believed that work sharing and international cooperation could be powerful tools that contributed to making the work of patent offices more efficient and effective and could be instrumental in amplifying the ability of patent offices to efficiently grant high-quality patents. The Delegation noted that they had seen that echoed in many responses to the questionnaire. The Delegation observed that those tools were especially useful when the offices involved had different capabilities and strengths, for example, offices that operated in different languages or had special expertise in different technical fields could help each other conduct a better search and examination. The Delegation considered that some offices could search and evaluate prior art relevant to certain patent applications more efficiently than others. The Delegation further noted that other offices could be able to amplify their capabilities by taking advantage of the work previously carried out in earlier searches and examinations. Recalling some of the aspects of its proposal contained in

document SCP/23/4, related to a better understanding of the potential of work sharing on the operation of patent offices, the Delegation proposed that the SCP direct the Secretariat to conduct a study of whether, under what circumstances and how the implementation of work sharing and international cooperation programs between patent offices could assist the collaborating offices in conducting more efficient searches and examination, and in granting high quality patents by leveraging the work carried out in other offices. The Delegation stated that although the Secretariat had already collected some information from Member States on their experience with work sharing programs, it wished the Secretariat to explore other sources of information on how limited capabilities of an office could be amplified through the use of work sharing. The Delegation suggested that for example, scholarly peer reviewed articles could be included and that the Secretariat request additional, more specific information from patent offices of the Member States by asking, for instance, what capabilities were available to them through work sharing which would not otherwise be available or would be difficult to obtain, in terms of areas of technology to be searched and examined, languages of prior art references, volume of work they were able to undertake and other aspects of their resources. The Delegation stressed that the study they had proposed also intended to address the tools that had been used by offices to share information such as, for example, WIPO CASE, the Global Dossier and others and what shortcomings and benefits the offices had encountered when using those tools. The Delegation recommended that the study investigate what types of shared work product had been found to be useful by examiners, and how to best share such work products. The Delegation noted that, for example, the Secretariat could indicate what tools could be used to share which types of work product, such as office actions, lists of prior art, classification of application, search strategies, etc., and could compile the results in a table showing what tools were used, which offices used them and for what purpose. To make a work sharing more concrete and understandable for the members of the SCP, the Delegation requested, that the Secretariat organize a practical demonstration of those tools when the completed studies would be presented. The Delegation recalled that an aspect of its proposal addressed prior art collections availability. The Delegation noted that while access to much of the relevant prior art was fundamental to carry out a high quality search, some prior art was only found in certain national collections which were not available to other offices. The Delegation therefore reiterated its proposal to study the benefits and possible impediments to making national collections of prior art available to all offices.

93. The Delegation of Japan, speaking on behalf of Group B, observed that some delegations had expressed the concern that work sharing was intended to harmonize substantive patent law. While noting the concern reflected in the answers to the questionnaire provided by some offices in low and middle income countries, the Delegation highlighted that work sharing was simply a means for Member States to share information relating to particular patent applications. The Delegation pointed out that work sharing allowed for a broader scope of prior art to be considered as part of the patent examination process, while reducing duplicated work by IP offices. The Delegation was of the opinion that the topic was a substantive aspect of patent law, rather than a procedural one, and therefore within the mandate of the Committee. The Delegation believed that the result of work sharing was a more accurate patent examination, which would ultimately lead to higher quality patents and a more efficient patent system. The Delegation hoped that the SCP could agree that such a result was beneficial to all Member States and offices, and did not constitute a step in the direction towards harmonization of substantive patent law.

94. The Representative of ARIPO supported the statement made by the Delegation of Japan. The Representative was of the opinion that work sharing could lead to a faster examination of patent applications. The Representative further believed that work previously carried out by other offices could provide a good basis for search in other offices, above all in developing and least developed countries. In the Representative's view, such information would help their offices in carrying out substantive examination and to grant quality patents. Furthermore, the

Representative stressed that such information was not binding for the patent offices that would use them and those offices were free to apply the patentability criteria in accordance with their applicable law. The Representative pointed out the importance of the work already carried out by other patent offices, information of which was very useful to all countries, especially for IP offices in developing countries and LDCs with scarce resources and tools. The Representative believed that work sharing would help the above-mentioned offices to improve the quality of the patents granted thanks to the availability of a good-quality prior art search which could lead to an appropriate examination of the patentability requirements.

95. The Representative of OAPI thanked the Chair and the Secretariat for their work. The Representative affirmed that OAPI did not receive the questionnaire and expressed the wish to contribute and reply to it. The Representative recalled the OAPI regional patent system, composed of 17 countries, where a single patent covered the territory of all its Member States. The Representative highlighted that under the OAPI system, there was no national patent office involved in the patent grant procedure. The Representative believed that the quality of patent was extremely important. He also stated that work sharing in the OAPI region had already occurred, and that they had some partners, such as the EPO, which helped them with prior art searches. With that regard, the Representative affirmed that such support did not jeopardize in any manner the independence of the OAPI, since their organization was free and independent in taking the final decision concerning the granting of the patent. The Representative noted that patent law, such as all intellectual property laws, was a territorial law: that implied the existence of as many patent offices as many countries/regions. The Representative believed that given that intellectual property was an instrument in favor of trade, IP rules tended to be more harmonized with globalization, in its opinion, harmonization of patent law, was the challenge that the SCP was facing.

96. The Representative of AIPPI noted that the question of sufficiency of disclosure had been raised several times during the SCP. The Representative recalled that the Delegation of the Russian Federation clarified further that the quality of a patent also depended on the quality of documents supplied by the applicant, and that aspect was strictly related with the one of sufficient description. The Representative reminded that the description had to be sufficient in order to enable a person skilled in the art to carry out the invention. The Representative stated that AIPPI had adopted several resolutions on sufficient disclosure and had studied the issue. The Representative mentioned that once the document was finalized, it would be transmitted to the Secretariat for possible distribution to the members of the SCP.

97. The Delegation of Zambia aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group regarding quality of patents and work sharing. The Delegation observed that the interventions made and the responses to the questionnaire focused on two different concepts related to that topic, namely an aspect concerning the quality of the patent itself and a second aspect concerning the patent grant process before the IP offices. The Delegation was of the opinion that the improvement of quality of patents could not be achieved by simply adopting the practices of other patent offices. The Delegation considered that the SCP should focus on other factors related to quality of patents, such as patentability criteria, which were within the purview of the national laws and the examination practices, including opposition systems. The Delegation stated that it had responded to the questionnaire, and reiterated that work sharing could be extremely relevant if it was analyzed in the right context. The Delegation was of the opinion that the right approach to work sharing should not focus on harmonization but on complementing the work done by examiners in their national offices using the national laws. The Delegation stressed that the information that was shared was non-binding and did not lead to harmonization if properly contextualized. The Delegation expressed its openness to hear the views of other delegations and have discussion on that topic.

98. The Delegation of the Russian Federation, referring to the statement made by the Representative of AIPPI regarding the sufficiency of disclosure, the Delegation stressed that it was a crucial issue for all patent experts in all patent offices. The Delegation explained that the Russian legislation had contained a requirement on the sufficiency of disclosure and its relationship with the granting of legal protection since October 1, 2014. Since the legal provision concerning sufficiency of disclosure existed in several patent laws, the Delegation believed that such requirement was understood by everyone to have more or less the same meaning. In its understanding, it related to a question of the nature of the invention being fully disclosed in the patent application to allow patent examiners to take their decision. The Delegation explained that the Russian legislation provided the possibility to challenge a patent granted on the basis of a patent application not complying with the requirement of sufficiency of disclosure. The Delegation pointed out that if that was proved, i.e. the sufficiency of disclosure was not met, the patent would be invalidated.

99. The Representative of ICC stated that their institution had been active in the intellectual property area for many decades, and that in such framework, ICC published on a yearly or three yearly intervals the so-called ICC Intellectual Property Roadmap for IP issues: the Current and Emerging Issues for Business and Policymakers. The Representative explained that patent quality was amongst the topics covered by that publication and proposed that copies would be made available for SCP participants.

100. The Representative of the GCC Patent Office thanked the Chair and the Secretariat for their efforts put into the work of the Committee. The Representative stated that the GCC Patent Office attached considerable importance to the work sharing program that they had been using, because such tool played an important role in ensuring the quality of patents. The Representative explained that the GCC Patent Office issued a regional patent that was enforceable across the six Member States of the Gulf Cooperation Council. The Representative hoped that they would improve the quality of patents in all GCC member countries. The Representative considered cooperation was important, and expressed its wish to increase it in respect of work sharing with, in particular, other regional offices and national offices of Member States of WIPO. The Representative pointed out that they were cooperating with some patent offices, for example, SIPO in the area of search and examination. The Delegation believed that such experience had taught them some useful lessons.

101. The Secretariat informed the SCP that, based on the information received by Member States, the SCP Electronic Forum web page regarding opposition and administrative revocation mechanisms, and international work sharing and collaborative activities for search and examination on patent applications, had been updated.

AGENDA ITEM 7: PATENTS AND HEALTH

102. Discussions were based on documents SCP/16/7, SCP/16/7 Corr., SCP/17/11, SCP/24/4, SCP/26/5 and SCP/26/6.

103. The Secretariat made a presentation on document SCP/26/5. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_26/scp_26_study_wipo.pdf.

104. The Delegation of Estonia, speaking on behalf of the EU and its Member States, reiterated their understanding of the challenges and constraints which might be faced by certain countries in handling public health problems. The Delegation stated that access to safe, effective, quality and affordable essential medicines and vaccines for all was a major challenge and a key SDG which must be supported by all. The Delegation stated that the EU and its Member States remained committed to increasing access to affordable medicines and to finding

solutions to the world's pressing public health challenges and inequities. The Delegation stated that as set out in the 2010 Communication and Council Conclusions on "The EU Role in Global Health", the EU pursued a human rights-based approach to health. The Delegation stated that strengthening all areas of a health system, including the availability of qualified health workers, the provision of affordable medicines and the adequate financing of the sector, was central to moving towards universal health coverage with quality health services which were accessible and affordable for all. The Delegation further stated that the quality and integrity of the pharmaceutical distribution chain was also essential in improving public health. The Delegation added that the current innovation model, including the role of trade related to intellectual property, had delivered consistent progress in global public health, and had led to key new and improved treatments as well as much extended life expectancy, both in developing countries and LDCs. The Delegation further added that such model already integrated a variety of tools, such as incentives for innovation based on intellectual property, public and private financing and awards or public research. The Delegation also added that such variety was necessary to address situations, where there was a functioning market or where there could be market failures. The Delegation recalled the important and authoritative contribution of the trilateral WIPO, WTO and WHO study entitled "Promoting Access to Medical Technologies and Innovation". The Delegation also recalled that discussions in the Committee could not go beyond the mandate of the SCP and the WIPO, and that the discussions which did not relate to intellectual property aspects of medicines should be left to more appropriate fora. The Delegation believed that any further work in the area of patents and health should reflect a balanced approach, taking into account the various factors of relevance to patents and health, such as the proposal made by the Delegation of the United States of America in document SCP/17/11. Lastly, the Delegation thanked the Secretariat for the preparation of document SCP/26/5 on constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impacts on access to affordable especially essential medicines for public health purposes in those countries, and welcomed the confirmation that "securing access to medicines was of multi-disciplinary nature". The Delegation took note of the suggestion contained in paragraph 56 of the document on additional reporting by Member States on implementation and use of patent flexibilities in their territories. The Delegation stated that it was ready to consider the suggestion, subject to further clarification of the type and method of reporting.

105. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Secretariat for preparing document SCP/26/5 which, in its view, contained very useful information on the current agenda item. The Delegation also thanked the independent experts and the WHO and the WTO for their contributions to the document. The Delegation claimed that the document was not a total examination of existing literature, but rather it looked at the law and the needs of Member States based upon the pertinent elements of international law, such as the TRIPS Agreement and the Doha Declaration. The Delegation stated that despite those rights, developing countries and least developed countries needed further flexibility in the patent system. The Delegation stated that the African Group recognized the importance of the work by the SCP, particularly in patents and health, which was considered by the African Group as a priority for the Committee. The Delegation further stated that they had requested a work program on patents and health since the fifteenth session. The Delegation stated that health was a fundamental human right, and had been a part of WIPO's development plan. The Delegation added that universal coverage and the SDGs for 2030, particularly number 3, recalled the universal character of that right. The Delegation stated that no part of the population should be deprived of that right, on which the economic and social development of Member States depended, particularly in consideration of the enormous cost of health care. The Members of the African Group were of the view that the question of patents and health must be discussed under the SCP, and that patents should not serve as an obstacle to access to quality medications and new technologies at affordable prices. The Delegation noted that it was clear that a perfect balance between patent holders and a general interest must be

considered and that patents had a direct effect on the severe conditions by which medicines could not be afforded by all. The Delegation stated that in all countries, both developing and developed, because of the spread of parasites and other pathogens situations such as the outbreaks of Ebola and Zika had been created. In its opinion, WIPO in general, and the SCP in particular, must stress the importance of human rights on the availability of medications. The Delegation stressed that issues of public health were very important regarding contagious and noncontagious diseases. The Delegation considered that bacterial infections and the neglected diseases were also a very important area of concern, and that during the preceding sessions, the African Group had made a proposal for its inclusion as a work program. The Delegation stated that the preparation of studies by independent experts at the request of the Secretariat after consultation with Member States was within the mandate of the SCP. The Delegation added that the exchange of views and information between Member States must be done in consideration of the United Nation's focus on the right to access to medicines, as established by the Human Rights Council. The Delegation explained that the three elements of the work program were interconnected, and thus should be simultaneously followed in order to succeed in the undertaking. The Delegation noted that their proposal was along the lines of the efforts made by the international community, particularly by the TRIPS Council, in order to prolong the transition period to 2023. The Delegation further noted that the proposal allowed WIPO to examine the issue as a specialized agency of the United Nations. The Delegation hoped that the current session of the SCP would reach an agreement on an ambitious work program on patents and health. Concerning document SCP/26/5, the Delegation expressed its commitment to discussing it in a constructive manner. Firstly, the Delegation thanked the Secretariat on behalf of the African Group for preparing the document. The Delegation recalled that, as stated in their statement, the document contained a wealth of information. However, in its opinion, the document as it stood did not cover all the concerns expressed by the African Group. The Delegation regretted that paragraph 5 of the study neither provided an in-depth analysis of the legal obligations, nor looked at special options that were available in those agreements. Furthermore, the Delegation noted that paragraph 5 did not examine the incidents of each of those options on the affordability of medications and the affordability of health. The Delegation stated that Member States needed to have additional information on the various options before them so that they could opt for the most appropriate option for them. The Delegation further stated that the document, unfortunately, only covered HIV AIDS and that the African Group wished to have more information about the medicines for various pandemics prevalent in Africa, particularly noncontagious diseases and neglected tropical diseases. The Delegation also wished to have a source of information, a reliable data bank, which was accessible and available to all Member States.

106. The Delegation of Paraguay, speaking on behalf of GRULAC, thanked the Secretariat for the preparation of the study on the difficulties encountered by developing countries and LDCs to make full use of flexibilities available in the area of patents and the consequent repercussions on access to affordable medication. The Delegation appreciated the work done jointly by WTO, WIPO, and WHO, as well as the contributions of the consultants for their inputs on the study. The Delegation stated that such type of collaboration was always useful when Member States needed to understand the difficulties encountered by Member States in ensuring the availability of medications in a sustainable manner. The Delegation stated that the debate on the relationship between health and patents was critical in order to promote the delicate balance which was required by the patent system. The Delegation noted that along those lines, they had a number of documents and proposals which could serve as a basis for the preparation of an ambitious work plan in the area. The Delegation noted that the Canadian proposal contained in SCP/26/6 was the most recent of those proposals. Consequently, the Delegation felt that they had a great deal of material which could allow the Member States to define a work program or agree on concrete points in that area.

107. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, wished to draw the Committee's attention to the UNHLP Report. The Delegation stated that the Report had specifically explored the policy and coherence between intellectual property rights, trade, and human rights and had made a number of recommendations in that regard. The Delegation stated that some of those recommendations were specifically addressed to WIPO, and were directly relevant to the SCP agenda on patents and health. The Delegation accordingly requested the SCP to initiate those exploratory discussions, based on the UNHLP Report. The Delegation stressed that in studies the constraints faced by developing countries and LDCs in making full use of patents flexibilities and their impact on access to affordable and essential medicines in developing countries and LDCs, the Committee must involve the UNDP which had facilitated the preparation of the UNHLP Report.

108. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Secretariat for the preparation and presentation of document SCP/26/5 and recalled the importance given to the issue by the Members of its Group. The Delegation believed that the issue was very complex and a holistic approach was obviously needed in order to resolve it. The Delegation noted that access to medicines was a major challenge, and that the CEBS Group was committed to participating in the initiatives that facilitated access to medicines. Recalling the trilateral WIPO, WTO, WHO study entitled "Promoting Access to Medical Technologies and Innovation" for discussions on the topic, the Delegation observed that duplication of work with other international organizations on the topic must be avoided. The Delegation stated that the CEBS Group was open to studies only in a balanced work program that would advance the common understanding of policies and initiatives for enhancing access to affordable medicines and health care technologies, through proposals similar to the one put forward by the Delegation of the United States of America in document SCP/17/11.

109. The Delegation of Japan, speaking on behalf of Group B, thanked the Secretariat for preparing document SCP/26/5 and making an informative presentation. The Delegation noted that as clearly indicated in paragraph 53 of the document, the factors that led to the individualized use of compulsory licenses were very complex. The Delegation reiterated that both innovation and access were equally important in the relationship between patents and health. The Delegation stated that as innovation was fostered by a patent system, intellectual property protection was crucial for the development of new medicines, including lifesaving ones. The Delegation also stated that when looking at the full picture of research and development in the field of pharmaceuticals, it was obvious that the incentive from patent protection was crucial in that sector. In the Delegation's view, it was of interest to the broader public to have private research and development on safe and effective medicines. The Delegation stressed the importance of not only focusing on the specific incremental patents, but also keeping the broader context in mind. The Delegation observed that the lack of availability of safe and effective medicines was a multifaceted problem which was related to many areas, such as inadequate financing for health care, a shortage or lack of access to trained health care personnel and adequate medical facilities, fragmented and unreliable procurement system and processes, a lack of infrastructure, conflicting policies that discourage market entry and competition of innovative drugs, failed management, poor visibility of demand, retail markups, taxes, tariffs, and so on. The Delegation recalled that the lack of access to medical technology was rarely due to a single isolated factor, as stated in the trilateral WIPO, WTO and WHO study on promoting access to medical technologies and innovations. The Delegation noted that an effective intellectual property system did not jeopardize access to medicines. On the contrary, the Delegation noted, it gave companies the confidence that their technology would not be unfairly used and thereby facilitated the early introduction of new medicines in developing markets. The Delegation stressed that calls to replace or undermine the intellectual property system with untested or impractical alternatives might have unintended consequences for patients and health care systems. The Delegation stated that Group B considered that before undertaking a new study in the SCP, there should be an inventory of studies and analysis

produced by other United Nations and multilateral fora in order to avoid unnecessary duplication with already existing work. The Delegation believed that the Secretariat, utilizing the existing collaborative relationship with the WHO and WTO, would be well placed to conduct such inventory of studies. The Delegation further stated that Group B was open to activities that would advance the common understanding of policies and initiatives that could enhance access to medicines and health care technologies. The Delegation felt that the work of WIPO, WTO and WHO's collaboration entitled "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade" could serve as a basis for productive discussions. The Delegation wished to consider the issue in a holistic manner, also including other related proposals such as those containing the document SCP/17/11. Although the Delegation took note of paragraph 56 of document SCP/26/5, it felt that the approach provided an incomplete look at the patent system. The Delegation observed that flexibilities was one of the possible tools that were appropriate as part of an effective regime of patent protection. The Delegation stated that only a balanced approach would bring the Committee forward and therefore, expressed its willingness to engage constructively on the matter in general. The Delegation also noted that certain delegations mentioned the proposal submitted by the African Group, namely document SCP 24/4. The Delegation felt that the African Group's proposal contained elements which were out of scope of the mandate of the Committee. The Delegation stated that with respect to paragraph 12 of the proposal, most additional incentives needed to improve research on AMR laid outside the patent system. Furthermore, the Delegation observed, with respect to paragraph 14, the UNHLP Report had not been a Member State driven process, had not reflected the opinion of Member States and had not been endorsed by the Member States. The Delegation stated that Group B was open to discussing access to medicines in a holistic manner and in accordance with the mandate of the SCP. However, the Delegation stressed that the UNHLP Report should not constitute the basis for discussions. The Delegation stressed that it was important that any discussion took into account the wide range of views and factors affecting access to medicines. The Delegation observed that with respect to paragraph 15, the mandate of the United Nations Special Rapporteur was probably inappropriate for discussion at the WIPO's SCP, which was a technical body. The Delegation stressed that paragraph 15, on the United Nations Special Rapporteur, was not acceptable to them. The Delegation thereafter noted that with respect to paragraph 16, any discussion on compulsory licensing should take into consideration the broader objectives of patent systems. The Delegation felt that a workshop focusing on compulsory licensing would lead to unbalanced discussions, particularly since the issue of exceptions and limitations were already on the SCP agenda. Finally, with respect to paragraph 20, the Delegation observed that WIPO and other intergovernmental organizations already provided robust assistance to Member States. The Delegation noted that the recent reports of different international organizations to the TRIPS Council provided an extensive list of already existing initiatives.

110. The Delegation of Iran (Islamic Republic of) appreciated the Secretariat's preparation and the study contained in document SCP/26/5. The Delegation extended its appreciation to the Delegation of Canada for the preparation of its new proposal. The Delegation noted that having access to essential medicines with affordable prices was a specific and important component for fulfilling the right to health as a fundamental and basic human right. The Delegation felt that WIPO, as one of the specialized United Nations agencies, should support Member States in addressing intellectual property related barriers impacting the availability, affordability and accessibility of medicines, treatments, and related technologies in low and middle-income Member States. The Delegation stated that in order to meet the public health requirements with respect to patented drugs and to provide them on affordable prices, it was essential that the Committee worked on effective utilization of compulsory licensing provisions under the patent laws and the conceptual impacts on the grant of compulsory licenses on the availability and price of patented drugs. The Delegation noted that at present, there was no other international forum where Member States were sharing experiences on the use of health-related patent

flexibilities. The Delegation noted that the work of the SCP in that area was vital. The Delegation was convinced that the SCP should identify a specific constraint in relation to the flexibilities that could be used to address public health needs, and thereafter discuss the same with a view to identifying action-oriented solutions. The Delegation highlighted the importance and relevance of the recommendations of the UNHLP Report, which had been published in September 2016. The Delegation firmly believed that it was an urgent need, to not only support, but also undertake follow-up activities and seriously consider the Panel's recommendation and act to make them a reality. The Delegation believed that the discussion on patents and health and future work program on the issue should assist Member States to adopt their patent law and make full use of the patent flexibilities in accordance with public health needs, in compliance with international obligations. The Delegation felt that such a work program should provide the possibility of analyzing the potential impediments and obstacles created by the system in accessing medicine such as the legal and contractual impediments and capacity constraints in making full use of flexibilities, and further analyze the means of overcoming those constraints. The Delegation stated that, based on those reasons, they continued to support the proposals made by the African Group and the Development Agenda Group for the future work program on patents and health. The Delegation hoped to see the recommendations contained in the proposals be operationalized within the Committee so that there could be a better understanding of the challenges and constraints in making full use of public health related patent flexibilities. In its opinion, undertaking an activity within the Committee based on the recommendations of the UNHLP Report was an important element and should be taken into account. The Delegation, with regard to the presentation and the new documents, thanked the Secretariat for the excellent presentation of the study. The Delegation felt that the study provided a general overview of the various constraints that were faced by developing countries and LDCs when implementing the patent flexibilities. The Delegation stated that since the study had been based on the limited number of sources of information, it could not be considered as being a comprehensive and inclusive study of the topic. The Delegation stated that bearing in mind the deficiencies of the document, some of which had been highlighted by the African Group, and the lack of credible conclusion due to lack of sufficient data, the study could be considered as a preliminary study and should be extended to cover the concerns of all Member States, in particular, the developing countries. The Delegation felt that another shortcoming of the document was that there was no concrete proposal as to the means that could be adopted by developing countries to overcome the constraints they were facing in using those flexibilities. The Delegation hoped that a further study would elaborate concrete proposals for Member States particularly the developing countries and LDCs in overcoming those constraints.

111. The Delegation of Argentina thanked the Secretariat for preparing document SCP/26/5 and its presentation. The Delegation, with regard to searching for relevant patents mentioned in paragraph 36 of the document, supported the importance of describing International Non Proprietary Names (INN) in patent applications and patents where the INN were available. In its view, in developing countries and LDCs the disclosure of INN could facilitate the Ministry of Health, NGOs, etc., to find out the situation of patented medicines through INN. Finally, the Delegation thanked the Delegation of Paraguay and expressed support for the statement it made on behalf of GRULAC.

112. The Delegation of South Africa thanked the Secretariat for preparing the document. The Delegation stated that patents were an important area for the African Group including South Africa. The Delegation further stated that the right to health was a fundamental part of human rights and was relevant to all countries, developing and developed alike. The Delegation observed that the recent pandemic outbreaks of Ebola and Zika virus showed that diseases did not respect tropical boundaries and did not distinguish between rich and poor, developed or developing countries. The Delegation noted that the global community took note of the above fact and reaffirmed the importance of health when it recognized access to public health as

Goal 3 of the SDG Agenda 2030. The Delegation further noted that Goal 3 was particularly important, because it recognized that there were large unmet health needs present in both developed and developing countries, and that there were significant health inequalities within countries themselves. The Delegation noted that SDG Target 3.8 required that the international community should strive to achieve universal health coverage, including access to quality and essential health care services as well as essential medicines and vaccines for all. The Delegation further noted that towards that end, all United Nations organizations had the responsibility, therefore, of working together to help achieve Goal 3. The Delegation stated that since access to safe and affordable medicines remained a fundamental challenge for developing countries and LDCs, the Committee could play an instrumental role as it was the nexus of patents and health. The Delegation believed that the African Group's proposal on patents and health could assist the Committee to attain the noble objective of access to health. The Delegation stated that, as previously articulated, the African Group's proposal contained three inter-linked web programs of studies, information exchanges, and technical assistance to be pursued simultaneously, with linkages to WIPO's Development Agenda recommendations 179, 14, 31, and 32. The Delegation observed that the African Group's proposal also included the request for the co-chairs of the UNHLP to share their views on the UNHLP's objectives, findings, and recommendations. The Delegation believed, and wished to remind other delegations, that although the UNHLP Report was initiated by the United Nations Secretary General, it was presented and adopted by the United Nations General Assembly, and was thus a United Nations Member State Report. The Delegation noted that the UNHLP Report was a rich repository and a reference document, and further believed that the discussion and implementation of the recommendations as well as other intellectual property and health-related recommendations had been articulated in the African Group's proposal. The Delegation stated that document SCP/24/4 had the potential to minimize an unfortunate situation where women and babies were imprisoned in prisons, because they could not afford to pay their medical bills. The Delegation further stated that WIPO and its Member States could not afford to stay silent in the face of such longstanding questions and challenges on the role of patents on health technologies, especially as they affected life and the right to human dignity and good health in a safe environment.

113. The Delegation of the Holy See expressed its appreciation to the Chair for its guidance in the Committee. The Delegation believed that the work of the Committee could be advanced under the guidance of the Chair. The Delegation also thanked the Vice-Chairs and the Secretariat for their efforts in preparing for the current session and, in particular, for preparing document SCP/26/5. The Delegation supported the work of the SCP and attached great importance to the mandate of the Committee. The Delegation noted that according to paragraph 53 of the document, "the use of compulsory licenses, the factors that determine the individual use of such licenses were very complex". The Delegation stated that policy coherence in reaching the twin goals of access to medicines and medical innovation were vital to achieving the aim of the 2030 Agenda to improve the health and well-being of all people at all ages and had been articulated in several SDG Targets. The Delegation noted that SDG Goal 3 specifically required conducting more holistic situation assessments, prioritizing the most pressing public health needs by the founders of health research and development, having equitable and sustainable financing, as well as more prudent and strategic use of public and private resources. The Delegation added that as clearly stated in the 2013 Trilateral study, the Doha Declaration had served as a catalyst for developing coherence at an international level, at both a legal and policy level, by placing a multilateral trade agreement within a public health context, and dealt directly with the interplay between public health policies and intellectual property. The Delegation felt that the Doha Declaration in paragraph 4 confirmed that the TRIPS Agreement did not and should not prevent Members from taking measures to protect public health and that the Agreement should be interpreted and implemented in a manner supportive of the right of WTO Members to protect public health and, in particular, to promote access to medicines for all. The Delegation stated that access to affordable medicines was no

longer a challenge just for the least developed and other developing countries; it had also become an increasingly urgent issue for developed countries as well. The Delegation concluded that the challenge of developing and implementing effective and equitable policy measures for innovation and access to meet public health needs was dynamic in nature, and was evolving with the disease burden as well as progress in technology and diversification of innovation systems. The Delegation felt that adaptive solutions would be needed to address changing and diversified needs. The Delegation further believed that adaptive solutions will be needed for changing and diversified needs. The Delegation believed that regular reporting might assist a better understanding of the dynamic factors involved in making full use of flexibilities. The Delegation stated that as appealed by Pope Francis to the pharmaceutical industry leaders who were convened at the Vatican previous years, Member States had to continue their action on access to medicine until, the technical expertise, the resources and the methods that provided access to diagnosis and treatment would be available to all, and not simply to a privileged few, for there was no human life that was more sacred than another one. The Delegation assured the Chair of the constructive spirit and the support of the Holy See.

114. The Delegation of Chile took the opportunity to refer to document SCP/26/5. The Delegation, firstly, thanked the Secretariat and the experts who worked on the preparation of the document. The Delegation noted that the document clearly illustrated the relationship between the international patent system and the challenges associated with local implementation. The Delegation further noted that maintaining a space for public policy decision-making and making possible access to medicines and procedures was one of the main challenges faced by governments in that area. The Delegation recognized that the reasons that led to success on a particular medicine policy depended on multiple variables. The Delegation stated that it was undoubtable that the intellectual property system of each country was one of the major aspects within that equation. The Delegation felt that the Secretariat's document had put forward a series of challenges that needed to be part of the discussions of the Committee. Among those aspects, the Delegation felt that, firstly, there was a need to create technical capacity on intellectual property, which would enable agencies charged with public policy linked to access to medicines to have full knowledge of the obligations on protection and flexibilities which would assist formulating their national public policy on medicines. Secondly, the Delegation considered it necessary to continue going into great depth on transparency of the system of patents with regard to both the examination of patents and the way they were used. The Delegation felt that that would give clarity with regard to status of patents at a local level. Thirdly, the Delegation hoped to continue seeing the development of a technical assistance program which would enable countries to implement, within their own legislation, in an effective manner, exceptions and limitations to patent rights. With regard to measures going into greater transparency of the patent system, the Delegation highlighted the work carried out by the Medicines Patent Pool, particularly MedsPAL, which was a tool that would help make concrete progress in that area. The Delegation also supported the statement made by Argentina on the importance of including INN when patents were granted. The Delegation felt that the Committee needed to continue being a space where Members could be regularly informed and could also give information about the challenges and the development of public policy in all the Member States.

115. The Delegation of Brazil thanked the Secretariat for the presentation on constraints faced by developing and least developed countries in making full use of flexibilities. The Delegation aligned itself with the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation also appreciated the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation stated that the topic of patents and health was important for every Member State represented at the SCP, without exception. The Delegation believed that market driven research and development had led to a large number of important technologies that had improved health conditions worldwide. The Delegation believed that sometimes that was the result of purely private undertakings, while at other times, was the outcome of

successful partnerships of private businesses with the academia or the public sector. The Delegation believed that the Bayh-Dole Act in the United States of America and similar initiatives elsewhere had encouraged such efforts with excellent results. The Delegation believed that all Member States would acknowledge, however, that gaps persisted in the incentives created by the patent system, particularly in areas where the market alone might not provide adequate incentives. The Delegation felt that such was the case, for instance, of treatments for neglected diseases. The Delegation felt that the gaps and failures in addressing disease burdens and access to treatments remained a challenge everywhere in the world. The Delegation believed that Member States should not lose sight that many international treaties and national constitutions had enshrined the fundamental right to health and the right to share in the benefits of scientific advancements. The Delegation also believed that such was also the case of the United Nations SDGs; for the attainment of which WIPO had an important role to play. The Delegation noted that those fundamental rights could be pursued in harmony with the free enterprise system within the existing multilateral rules. In its opinion, an inclusive, balanced, and effective patent system was a system which promoted and rewarded innovation, without erecting undue barriers to public access to health. The Delegation believed that in the area of health, a well-functioning patent system also contributed to preserving fair competitive conditions, which was a basic tenet of a healthy, capitalist society. The Delegation believed that the international community had a responsibility to develop creative solutions which expanded access to health and, at the same time, maintained a respect for intellectual property rights. The Delegation acknowledged that it was a complex challenge, but one which needed to be overcome to build and nurture a legitimate, strong, and sustainable patent system. The Delegation stated that far from undermining the system, those initiatives actually reinforced it and ensured its long-term survival and prosperity. The Delegation believed that solutions and ways forward would be found only if Member States engaged in discussions in good faith without prejudging the outcome of those discussions in any way. The Delegation was convinced that the SCP, by its very nature and mandate, could not evade the responsibility of dealing concretely with those issues. The Delegation looked forward to making concrete and constructive proposals in the session in line with both the African Group proposal and the Canadian proposal and the recent statement by the Delegation of Chile. The Delegation thereafter proceeded to make a few comments on some parts of the study. Firstly, the Delegation mentioned that they had had a different data concerning the number of medicines under patent protection in the WHO model list of essential medicines. According to the Delegation, the latest percentage of the number of medicines under patent protection in the WHO model list of essential medicines was 15%, not 5%. The Delegation felt that the difference seemed to result from an upward trend caused by the changed criteria of inclusion of new medicines in the list. According to the Delegation, the criteria for inclusion in the list no longer took low prices into account. With respect to the conclusion of the study that more data was needed to make credible conclusions on the use of flexibilities, the Delegation firstly stated that Member States were never going to have all the data they wished. The Delegation stressed that it was important that there was enough data to make credible, empirical, and sound statistical analysis. Secondly, the Delegation suggested that the WIPO's Economics and Statistics Division could be consulted to have a second opinion and as well as to exchange ideas on the way to move forward. Furthermore, the Delegation added that the issue regarding the lack of institutional capacity for Member States to implement the flexibilities currently implemented by Member States, which was an additional conclusion of the study, should be studied in more detail. The Delegation felt that the term 'extrinsic influences', used in the study, was very diplomatic and that the topic had not received enough attention in the study. The Delegation acknowledged that while the topic was contentious, yet it should be more carefully

examined in the future work program of the SCP. The Delegation reaffirmed its support for document SCP/24/4 which it considered to be a balanced basis for discussions. The Delegation also thanked the Delegation of Canada for showing a constructive spirit in submitting a proposal contained in document SCP/26/6. The Delegation reaffirmed that it would continue to work hard to find common ground between Member States and have a work program on the current agenda item which could benefit all countries, irrespective of their level of development.

116. The Delegation of Ecuador thanked the Secretariat for preparing and presenting the study on LDCs and developing countries on the use of flexibilities in patents, particularly where essential medications were concerned. The Delegation thanked the Delegation of Canada for the proposal contained in document SCP/26/6. The Delegation wished to establish a balance between patents and access to medications and, to that end, had sought to use the flexibilities particularly regarding compulsory licensing. The Delegation noted that compulsory licenses had allowed Ecuador to manage medications and had strengthened national production, particularly of essential medications. The Delegation stated that in 2009, through a presidential decree, the national government had decreed that it had been in national interest to have access to medications which had affected the population of Ecuador. The Delegation informed that 34 applications for compulsory licenses had been filed in Ecuador for medicines used by human beings. The Delegation further noted that there had been a particular concern for medications for catastrophic diseases such as cancer and AIDS. According to the Delegation, in the latter case, there was a 78% reduction in the cost of the medicine, which had benefitted the neediest sectors of the population. The Delegation noted that the use of flexibilities in Ecuador presented a number of challenges which were mentioned in the study of the Secretariat. The Delegation stated that the work done by the SCP in the area of health and patents would remain critical for access to medications. The Delegation reiterated its support for the African Group's proposal contained in document SCP/24/4. It agreed with the delegations that had stated that the SCP must take into account the UNHLP Report. The Delegation felt that WIPO, as a specialized agency, must bear in mind all the work which had been undertaken within the United Nations system. The Delegation, along the lines of the intervention made by the Delegation of Argentina, agreed with use of INN in applications for patents if they had been identified. In addition, the Delegation also supported the intervention made by the Delegation of Paraguay on behalf of GRULAC.

117. The Delegation of Indonesia thanked the Secretariat for preparing document SCP/26/5. The Delegation noted that patents and health was a topic of great importance to all Member States. The Delegation further noted that providing access to essential and life-saving medicines at an affordable price was in the interest of all Member States. The Delegation stated that the sustainable development goals recognized and affirmed the importance of public health. The Delegation believed that the objective of the exercise on patents and health in the SCP was to develop a work plan for WIPO to improve its assistance towards Member States in understanding and using the flexibilities in the TRIPS Agreement for public health. The Delegation recalled that there was a co-operation agreement for technical assistance between WIPO and WTO, which clearly had given the mandate to WIPO to offer assistance on intellectual property related matters that were also covered by the WTO agreements. The Delegation drew attention to the UNHLP Report published in September 2016. The Delegation noted that the UNHLP Report had the same focus as the exercise on patents and health in the SCP. The Delegation stressed that, therefore, it was critical that the recommendations of the UNHLP Report constituted the basis for further discussions on patents and health in the SCP, including the recommendation that governments should draft national law in a way that facilitated prompt and expedient use of a compulsory license or government use of a patent for non-commercial purposes, including the criteria for determining the remunerations for the right holder. The Delegation supported the African Group's proposal as contained in document SCP/24/4 for the work programs on patents and health. The Delegation believed that the document offered a balanced proposal. The Delegation also thanked the Delegation of Canada

for submitting a new proposal to the SCP. In addition, the Delegation thanked the Secretariat for the study and presentation thereof (on the constraints on the full use of patent flexibilities). The Delegation was concerned that no credible conclusion could be drawn on the impact of full use of patent flexibility on access to medicines. The Delegation stressed that the current agenda item was important, not only for developing countries and least developed countries, but for all people to have access to affordable, especially essential, medicines wherever they might live. The Delegation stressed that the agenda item and the study by the Secretariat could not stop at the present juncture. The Delegation was also concerned that no credible conclusions could be drawn due to the lack of sufficient data which prevented an empirical impact analysis and stressed on the need for having more data. The Delegation was also concerned that the study did not refer to the UNHLP Report which, in its view, was a good basis for understanding issues regarding patents and health. The Delegation proposed that the Secretariat should advance the study by working closely with the Member States, international organizations, NGOs and IGOs to have more information on the specific challenges encountered in implementing flexibilities and thereby have a better understanding of the impact of flexibilities on access to medicines.

118. The Delegation of Nigeria supported the African Group's proposal contained in document SCP/24/4. The Delegation reiterated the call for an ambitious work program, keeping in mind the significant impact of health-related patents in the lives of people, especially in developing and least developed countries. The Delegation hoped that the Member States were prepared to take bold steps in that regard. The Delegation counted the flexibility and the will of Member States to ensure a productive conclusion of the work of the Committee.

119. The Delegation of Uganda commended the Chair and the Vice-Chairs for their dedication to the work of the Committee. The Delegation also thanked the Secretariat for the organization of the session. The Delegation aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation noted that although scientific and technological innovation had contributed to significant improvements in health conditions, the emergence of global challenges to public health, including pandemics such as the Ebola virus and influenza which had the capacity to transcend continental borders, demanded a shared, coordinated and cooperative international response. The Delegation acknowledged that access to affordable and essential medicines depended on numerous factors. The Delegation however felt that the high prices of patented drugs constituted one of the major obstacles which should be addressed in a comprehensive and sustainable manner. The Delegation stated that the patent system had been designed to promote innovation and, at the same time, offer a mechanism to ensure that the fruits of that innovation were accessible to the society. The Delegation noted that, in general, the development of new drugs required heavy investment and long-term research, coupled with expensive clinical trials and regulatory approval procedures. The Delegation additionally noted that the exclusive right conferred by a patent had been one of the incentives for developers of new drugs in making necessary investments into that research. The Delegation felt that the current patent system did not adequately address public health crises. The Delegation noted that the commercial incentives provided by the patent system were not sufficient to ensure the development of new products in certain areas, for example, neglected diseases, and patent rights, which were enforced on the basis of commercial and market-based considerations, prevented access to, or increased the prices of, essential medicines. The Delegation stated that the findings and recommendations of the UNHLP Report were consistent with the Global Commission on HIV and the Law, an earlier United Nations report issued in July 2012, proving that the over-reach of intellectual property protections impeded the production and distribution of low-cost generic drugs and thereby impeded access to affordable and essential medicines. The Delegation stated that the Committee had the duty to ensure an optimal balance between the rights of patent owners, who provided technological innovations to improve health conditions, and the needs of the general public. The Delegation further stated that the Committee had the mandate to discuss matters regarding development of

patent laws and related issues. The Delegation recalled that, to that end, Development Agenda Recommendation No. 45 enjoined WIPO to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, among others. The Delegation stated that the African Group's proposal on patents and health, aimed at addressing such and other constraints in the patent system that had been identified above, provided a solid basis for the Committee to continue future work on the current agenda item. The Delegation stated that it was optimistic that, in contrast with the previous session of the SCP, the SCP would be able to reach a consensus towards a development-oriented work program on the present agenda item at the present session and be able to contribute meaningfully to the implementation of relevant Development Agenda Recommendations. The Delegation looked forward to fruitful discussions in the SCP.

120. The Delegation of China thanked the Delegation of Canada for its new proposal. The Delegation believed that Member States should strengthen the protection for the innovators while remaining concerned about public health interests. The Delegation felt that the research of the SCP on patents and health was very useful. The Delegation further felt that the Member States should help developing countries to understand the current issue and help them in overcoming the obstacles for using those provisions. The Delegation suggested that the SCP should continue to carry out studies and information sharing sessions so that all parties can better understand the provisions thereby perfecting the legislation and practices for promoting the access to medicines and other public interests.

121. The Delegation of the United States of America thanked the Secretariat for preparing and presenting document SCP/26/5. The Delegation found the report to be thorough and complete in addressing the constraints in the implementation and use of exceptions and limitations to patent rights by Member States and by users within the Member State. The Delegation agreed with the indication given in the report that many of the constraints faced by governments could be alleviated by seeking technical assistance from WIPO, keeping in mind the circumstances and needs of specific countries, and assessing and applying the available options in diverse ways resulting from different outcomes in international patent laws. The Delegation agreed that, as stated in the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, there was no-one-size-fits-all solution in the use of flexibilities by each Member State. The Delegation also agreed with the study's indication that many of the constraints faced by stakeholders were not related to the patent system, and that the use of exceptions and limitations to patent rights alone was often ineffective in improving access to medicines. The Delegation believed that the current document was complete with respect to the topic of exceptions and limitations to patent rights. The Delegation pointed out that exceptions and limitations were not the only tools available to countries in deciding the manner to develop their laws. The Delegation believed that Member States also had the flexibility to promulgate legal provisions that provide more extensive patent protection than the minimum standards set by international agreements. The Delegation noted that many countries had already adopted such enhanced provisions in order to achieve their economic goals. The Delegation further noted that those provisions were only hinted at in paragraph 21 of the present document. The Delegation believed that they merited being addressed in a more thorough manner. The Delegation believed that those provisions might include, for example, extensions of patent terms, exclusivity, patent linkage and others. The Delegation thus believed that any further expansion of the study in the Secretariat's report beyond what had already been addressed by the Secretariat should also include information on those additional tools to enlighten as to the reason why many Member States found it beneficial to include those provisions in their law and consequently be able to provide a complete picture of the options available to Member States.

122. The Delegation of the United Kingdom thanked the Secretariat for its study in document SCP/26/5, which they found was an informative summary of the issues faced by developing and least developed countries in making full use of patent flexibilities. The Delegation supported the Doha Declaration on Public Health and in line with the Doha Declaration, supported the use of flexibilities under the TRIPS Agreement by developing countries in the case of national emergencies. The Delegation stated that the study had usefully highlighted many of the issues faced by developing countries in implementing flexibilities such as inadequate technical capacity or infrastructure. The Delegation agreed with the conclusion of the study that it was important to have an understanding of the issues in a specific, national context, taking into account the manner in which each Member State applied the available options according to their domestic policies and their ongoing socio-economic developments. The Delegation agreed with the views expressed by the Delegation of the United States of America, and stated that any future work should take a more balanced view on patent flexibilities. Additionally, the Delegation believed that it was important for the SCP to complement the work on flexibilities with efforts to strengthen the quality of patents. The Delegation considered that a strong and fair intellectual property system supported the use of flexibilities while promoting innovation.

123. The Delegation of Brazil stated that all Members States recognized that the identification of the status of a patent was of utmost importance to all countries. The Delegation further stated that the knowledge of the status of a patent was critical for stakeholders to make informed, as well as legally responsible, decisions. The Delegation stated that as an example, before deciding to manufacture or import a pharmaceutical patent, it would be important to find out the relevant patents covering that product. The Delegation stated that the information was not easy to obtain, especially in developing countries. The Delegation further stated that although the information was available in intellectual property offices, the information gathered was restricted to the country where the search was made. Additionally, the Delegation added that the language used by Intellectual Property offices was not easily understood by normal human beings. The Delegation wished to make a suggestion to benefit all Member States in understanding the ongoing work undertaken to improve the situation. The Delegation believed that it would be very useful to all Member States if the Medicines Patent Pool could make a detailed presentation about its database and also exchange ideas with the Member States on the means of collaborating with them in improving this important tool going forward. The Delegation informed that the Medicines Patent Pool, which was usually known as MPP, was a United Nations backed public health organization that worked to increase access to HIV, hepatitis C and tuberculosis treatments in low and middle income countries. The Delegation further stated that through its innovative model, the MPP partnered with governments, industry, civil society, international organizations, patient groups and other stakeholders to forecast, prioritize, and license the needed medicines. The Delegation stated that the MPP encouraged generic manufacture and the development of new formulations through patent pooling. The Delegation further informed that the MPP was founded, and remained funded, by UNITAID. The Delegation informed that the MPP's license database was called MedsPal. The Delegation informed that the MedsPal provided information on the patenting and licensing status of selected HIV, hepatitis C and tuberculosis medicines in low and middle income countries. The Delegation informed that MedsPal allowed searching of patents and medications by the countries and medicine's name. The Delegation further informed that the database also enabled free text searches. The Delegation gave examples of free text searches which could be used in the MedsPal, such as, by patent number, product, brand name, applicant name, patent status or any combination of those. The Delegation stated that whenever a patent had been applied for or granted in a given jurisdiction, the database provided detailed information about the patent application and also gave links for further information. The Delegation further informed that wherever a license had been signed for a specific medicine, the database provided detailed information about the license agreement in relation to the product and countries that were searched. The Delegation noted that the MedsPal database covered most HIV medicines, in particular those that were included or had been included in the WHO model

list of essential medicines or in the WHO treatment guidelines. The Delegation further noted that, in relation to tuberculosis and hepatitis C, the database also included new patented medicines present in the WHO's Essential Medicines List (EML), or WHO treatment guidelines. The Delegation additionally noted that, for all the three diseases, promising new medicines or medicines at a late stage development were also included in the database. The Delegation apprised Members that the database was periodically updated to include new HIV, hepatitis C, or tuberculosis medicines, as they were developed or included in the WHO EML or relevant guidelines. The Delegation also apprised Members that currently, MedsPal was working to expand all patented medicines included in the WHO model list of essential medicines. The Delegation noted that since MedsPal presented information in a very friendly manner, it added value to the work of the Member States, because the database was understandable not only for patent examiners or experts but for public health representatives, procurement agencies, patent groups, international and national public health organizations as well as for normal human beings. The Delegation felt that it was important to recall recommendation 9 of the WIPO Development Agenda which stated that, "Request WIPO to create, in coordination with Member States, a database to match specific intellectual property related development needs with available resources, thereby expanding the scope of its technical assistance programs, aimed at bridging the digital divide." The Delegation opined that given the scarce resources and the need to avoid duplication of work, it would be unreasonable to request WIPO to create something that already existed and worked fairly well. The Delegation believed that it would be very useful to all Member States if the Medicines Patent Pool could make a detailed presentation in the current session about its database so as to exchange ideas on collaborating with them for this database going forward. The Delegation also thanked the Chair, Vice-Chairs and all delegations who supported them in presenting their proposal. The Delegation made a special thanks to the Delegation of Chile and said that they had always been a very supportive partner.

124. The Delegation of Ireland stated that the presentation proposed by the Delegation of Brazil on the MPP was an interesting idea. The Delegation stated that sharing of patent information generated by national offices with a central agency, whether it was WIPO or any other agency, was a very difficult technical undertaking. The Delegation informed delegates about the attempts by the EPO to provide up-to-date information on EPO patents, which later became national patents. The Delegation stated that the EPO was started in 1978 and presently had 38 Member States. The Delegation informed that currently only 18 Member States were providing up-to-date patent information on the EPO federated register. The Delegation informed that the project had been ongoing for a number of years and that there were huge technical problems. The Delegation stated that most patent offices developed their own information technology systems and had different ways of producing their data. The Delegation stated that getting the data to the EPO in a format that could be readily made available was a very challenging technical undertaking. The Delegation stated that the IT staff in the EPO had stated that they had to cope with over 70 different data formats to process the data that had been coming in from different offices. The Delegation stated that while the IT staff in the EPO had been trying to standardize data collection, that required enhancements and developments at the national office, which were quite costly. The Delegation cautioned that while the recommendation of having a worldwide database was seen in a number of reports, and was a lovely idea, it would not be ready next year or in five years because it was a massive undertaking.

125. The Delegation of Chile thanked the Delegation of Brazil and the Delegation of Ireland for the proposals put forward by them. The Delegation stated that as their industrial property office had signed a memorandum of understanding a year ago with the MPP, they were able to share their experience with Member States. The Delegation noted that their experience on updating information with the MPP had been quite different from the experience of the EPO with its national offices. The Delegation stated that the updating of information with the MPP had been

quite simple. The Delegation preferred to wait and see if MPP was able to give a presentation themselves. The Delegation stated that once the presentation by the MPP had been made available, they would be interested in sharing their own experience. The Delegation thought it was preferable to hear MPP's experience instead of getting into the details of the manner in which the Industrial Property Office of Chile worked together with the MPP. The Delegation of Chile was ready to give information of their own experience during the current session, if it was felt appropriate by Member States.

126. The Delegation of Switzerland thanked the Secretariat for preparing all the work for the meeting and also thanked the Chair for its commitment to the Committee and for helping delegations in finding a good work program. The Delegation also thanked the Delegation of Brazil for its proposal on the presentation of MPP's database. The Delegation further thanked the Delegation of Chile and the Delegation of Ireland for their comments on the possibilities of creating such a database. The Delegation stated that Switzerland was currently financing a feasibility study which was conducted by the MPP on potentially expanding the MPP beyond its current focus of diseases, namely, HIV, tuberculosis, and hepatitis C. The Delegation supported the proposal made by the Delegation of Brazil regarding the presentation of MPP's database. The Delegation believed that the presentation would provide Member States with more insights in the creation of the database and the progress of the work. The Delegation believed that the presentation would address concerns on status of patents which had been expressed within the SCP and had been mentioned by several delegates.

127. The Delegation of Zambia congratulated the Secretariat for the presentation and thanked the delegations that spoke before him. The Delegation aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation believed that public health was critical as health did not respect geographical boundaries. Regarding the issue of patents related to medicines as well as data on those patents, the Delegation supported the views expressed by the Delegations of Iran (Islamic Republic of), Brazil, the United Kingdom, and Canada. The Delegation believed that the African Group's proposal on patents and public health could assist the Committee in obtaining a noble objective of access to medicines by all, as envisioned by the discussions and findings in the UNHLP Report. The Delegation reaffirmed its support to the African Group's proposal and remained open to hearing views by other Member States on the subject.

128. The Delegation of Argentina thanked the Delegation of Brazil for its proposal on MPP's database. The Delegation supported the proposal, since it would contribute to the debate in the Committee. The Delegation noted that paragraph 37 of document SCP/26/5 mentioned the difficulties encountered by the Member States in obtaining information on the legal status of pharmaceutical products. The Delegation thanked the Delegation of Ireland and the Delegation of Chile for sharing their preliminary experience in that area.

129. The Representative of the WTO appreciated the opportunity to cooperate with the WIPO Secretariat in a practical way on the current agenda item. Regarding the work that had been discussed in the Committee, the Representative stated that the work aimed at informing members of the nature of the international legal framework and also to create a forum for the sharing of experiences and the collation of empirical data to support informed policymaking. The Representative apprised that one such framework for collaboration was the trilateral framework which had been discussed. The Representative added that there was a far broader range of collaboration across the multilateral system, and the key motive had been to respond to the increasingly focused and diverse requests for information. The Representative stated that in the context of the ongoing work in the current agenda item, he would be happy to follow up and comply with any proposals for cooperation and future work that were discussed in the Committee.

130. The Representative of KEI stated that since the African Group and Development Agenda Group had first tabled their proposals on a work program on patents and health in May 2011, much had happened. The Representative recalled that at 2017 World Health Assembly, the Delegation of Portugal had stated that “All regions of the world face, at different levels, insufficient access to medical products. In recent times, the dramatic increase of prices of new and innovative medicines made them unaffordable to large segments of the population also in rich countries, while threatening the sustainability of health care systems. In too many countries, prices of new medicines to treat hepatitis C and cancer, for instance are particularly shocking. The sustainability of health systems is a constant concern and objective. However, it has been threatened by the exorbitant prices by some innovative medicines that made them inaccessible to large segments of the population.” The Representative noted that the United States of America was among the many countries that were struggling to address high drug prices. The Representative recalled a statement made on the microblogging website Twitter by Dr. Scott Gottlieb, the head of the US FDA, on June 27, 2017: “No patient should be priced out of the medicines they need, we must do our part to help patients get access to the treatments they require.” The Representative thereafter proceeded to list the things that needed to be done to address the issue. The Representative recalled that as noted by former United Nations Secretary Ban Ki-Moon while appointing a High-Level Panel on Access to Medicines, the challenge in making drugs more affordable and access more equal and fair was the policy incoherence between intellectual property rights, innovation, and affordable access to medicines. According to the Representative, the challenge included, but was not limited to, the policies relating to patents. The Representative stated that at present, the primary global policy to induce investments in biomedical research and development was to grant a temporary monopoly on a medical invention, which enabled the holder of a patent to charge high prices that undermined affordability and access. The Representative stated that it was hardly surprising to observe high prices and unequal access to medicines when high prices were the primary instrument to finance innovation. The Representative stated that a growing number of governments, policy experts and stakeholders were recognizing the need to change the current system, so that the financing of research and development, including the incentives to private investors, were progressively delinked from the prices of products. The Representative stated that to accomplish such delinking, governments and international norm setting organizations had to enhance and expand the mechanisms for funding research and development which did not rely upon high drug prices, and additionally ensure that laws on patents and other intellectual property rights were consistent with such reforms. The Representative further recalled that in 2017, in the United States of America, 16 US Senators and 14 Members of the US House of Representatives had called upon the National Academies of Sciences, Engineering, and Medicine to conduct a study to examine the use of innovation inducement prize funds and push financing mechanisms as a way to stimulate investments in biomedical research and development that delinked costs from product prices. The Representative also recalled that in May 2017, the World Health Assembly (WHA) had approved a resolution on cancer that had given the WHO a sufficient mandate to undertake a feasibility study of the delinkage as it related to the development of new drugs for cancer. The Representative also recalled that in 2014, WIPO had published a study on alternatives to the patent system to support R&D efforts, in CDIP/14/INF/12. The Representative suggested that the study be presented at SCP/27 under the agenda item on Patents and Health. The Representative stated that it was working with several other groups and governments to host technical meetings on the terms of reference for feasibility studies on delinkage, particularly as it related to new drugs for antibiotics, cancer, HIV and rare diseases. The Representative welcomed engagement in its work. The Representative proposed that WIPO should have an instrument that created reciprocal rights in government funded inventions, so that the Member States that were a member of any such agreement would have agreed to the terms and modalities under which they could share access to government funded inventions. The Representative took note of the Canadian proposal for conducting a review of existing research on patents and access to medical products and health technologies. The Representative felt that the study should

provide information about all of the cases where non-voluntary use had been allowed as a limitation on remedies, including, for example, the recent limitations on remedies for infringement of patents on medical diagnostic tests and medical devices in the United States of America, the use of competition law in Italy, compulsory licensing of medical patents in Germany, and the use and impact of compulsory licensing of patents on drugs for HIV, cancer and heart disease in developing countries. In addition, the Representative suggested that the Canadian proposal be expanded to address issues relating to transparency as they related to patent landscapes on biomedical inventions, including biologic drugs and vaccines, litigations over patent validity and scope, the growing state practice of limiting the grant of injunctions when infringement occurred, and the economic aspects of drug development and commercialization, including the costs of research and development and the prices and revenues of products, as well as the utilization and gaps in access for new drugs. Lastly, the Representative urged the SCP to schedule a presentation by experts on the legal basis as well as the experience of Member States in permitting the non-voluntary use of patents on medical inventions as a limitation on the remedies available in Part III of the TRIPS Agreement, including specifically cases of running royalties for infringement of medical devices and diagnostic tests, and the export of those products outside the framework of Article 31 *bis* of the TRIPS Agreement.

131. The Representative of MSF appreciated the efforts of the Committee in continuing to discuss and work on the issue of patents and health. The Representative thanked the Secretariat for its presentation of document SCP/26/5 on the constraints in making full use of patent flexibilities by developing countries and LDCs. The Representative welcomed the rights enjoyed by Member States in using the flexibilities of the TRIPS Agreement to address the challenges facing the accessibility and affordability of medicines, such as those stated under the Doha Declaration. The Representative additionally wished to share few specific observations and possible improvements that could be made in a future study and also to the work of the Committee on the current agenda item. The Representative noted that the conclusion of document by stating that there wasn't enough empirical data to map the constraints of the use of flexibilities was a limitation of both the methodology used by the study and the manner in which some of the literature was cited in the study. The Representative noted that for instance, while citing the UNHLP Report, the document omitted the important observations and recommendations made by the HNHL report specifically concerning the constraints in using flexibilities, as well as the enhancements which could be made by WIPO to its own work and through collaboration with other multilateral organizations. Additionally, the Representative noted that paragraph 29 and footnote 38 of document SCP/26/5 cited page 24 of UNHLP report which stated the need to improve national capacity in the context of using flexibilities. The Representative noted that the same page 24, together with other relevant sections of Chapter 2 of the report, gave the exact examples of obstacles in using flexibilities by developing countries, and also provided the corresponding recommendations. The Representative recommended that the Secretariat, when following up the current document SCP/26/5 in the future, ought to better review of available literature where cases, analyses and recommendations had been made in the context of the constrains in using flexibilities by developing countries. Additionally, the Representative noted the study commissioned by WIPO to University of Ottawa on the patent status of medicines on the WHO Model List of Essential Medicines (EML), cited in paragraph 42 of document SCP/26/5, was methodologically and empirically contestable. The Representative noted that the study was based on an old version of WHO EML while the WHO had been reluctant to include patented and more costly medicines in its list in the first place. Moreover, the Representative noted, the EML selection had evolved in recent years, and new medicines included in EML for treating diseases, such as cancer and hepatitis C, were more likely to be patented and expensive in many Member States. The Representative additionally noted that the study commissioned by WIPO was not mandated by Member States, and also failed to include Member States' verification and input on its data collection and analysis. The Representative noted that in a recent official press conference held by WHO on the revised

EML in June 2017, the WHO had announced that 15% of the 433 medicines included in the EML were still under patent protection in some parts of the world. The Representative encouraged the Secretariat to take into account the evolving feature of the global burden of diseases in its future study on the issue. The Representative felt that it was sensible for the Secretariat and the Committee to continue working on the current agenda item and recommended the following steps. Firstly, the Representative recommended that the Committee should invite the co-Chairs of the UNHLP to present the UNHLP Report, as well as hold transparent discussions on its findings and recommendations as they related to WIPO's work. The Representative noted that the issues and recommendations in the UNHLP report had been discussed in a number of major multilateral platforms including TRIPS Council of the WTO, WHO, UNAIDS, and the United Nations Human Rights Council, and left WIPO as the last multilateral agency which remained reluctant to discuss the findings and recommendations of the Report in a transparent manner. Secondly, the Representative, regarding the recommendations in document SCP/26/5 concerning the future work on the current agenda item, supported the statement made by the Delegation of Brazil on acting upon good enough and credible data rather than waiting for full data. Additionally, the Delegation noted that further literature review should be able to expose the Secretariat to existing credible data on the challenges of using patent flexibilities for access to medicines in developing countries. The Representative observed that such literature and data might not exist only within the conventional patent law literature or SCP statements, but also in the literature documented by civil society organizations on the ground, and also the literature related to the political economy of patent norm negotiations in the context of trade and investment treaty negotiations. The Representative hoped that the Secretariat could draw attention to those sources in its future examination of the current issue. Lastly, the Representative supported the statement made by the Delegation of China that the future work on the current agenda item should include concrete recommendations, which could be implemented by Member States and which could also be integrated in the technical assistance provided by WIPO.

132. The Representative of IFPMA thanked the Chair for the opportunity to provide an input on the discussions on patents and health within the SCP. The Representative informed the delegates that IFPMA represented leading research-based pharmaceutical companies as well as national and regional industry associations across all five continents. The Representative believed that sustainable access to quality medicines could only be achieved by creating the necessary incentives for medical innovations and ensuring appropriate levels of health care infrastructure and financing. The Representative stated that if those factors were not in place, or failed to operate effectively, then the objective of access to medicines was significantly undermined. The Representative cautioned that the erosion of intellectual property rights through mechanisms such as compulsory licensing could jeopardize the availability of medicines, including generics. The Representative further cautioned that innovative companies might be less likely to quickly introduce products in certain markets if they feared that their intellectual property rights would be disrespected. The Representative stated that it was evident that without local launch and development of the market by the originator, generic companies had far less incentives to go through the expensive process of obtaining market approval and investing in the outreach to healthcare professionals. The Representative cautioned that weakening the national intellectual property system might therefore deny or delay patients' access to innovative products, and also hinder the introduction of good quality generic versions in the longer term. The Representative regretted that a part of the discussion in the Committee had focused on the UNHLP Report. The Representative stated that improving access to medicines across the world was one of the greatest challenges of our time, yet, as was referenced by many Member States since its publication, the Panel's mandate was too narrow and was based on a false premise. The Representative felt that the Report had failed to address the genuine barriers to access that were critical in meeting the targets of the UN's Sustainable Development Goals and was hence a missed opportunity. The Representative felt that the recommendations of the UNHLP Report were consequently based on assertion rather

than evidence. The Representative also felt that the recommendations failed to recognize the complexities around pharmaceutical research and development and the importance of strong intellectual property rights to the development and diffusion of medicines to patients. The Representative noted that the panelists of the UNHLP Report had expressed strong divergence in their commentaries and that the United Nations Secretary General had not endorsed the report. The Representative stated that neither the report nor its recommendations could be a sound basis for further consideration for action by either the WIPO or the United Nations system. The Representative noted that the improvement of global health was a shared commitment by the research-based pharmaceutical industry and WIPO's Member States. The Representative apprised that IFPMA affiliated companies had undertaken numerous multi-faceted initiatives to facilitate development of medicines and improve access. The Representative stated that those practical measures included providing training in clinical trials and manufacturing processes, the training of health care professionals, providing educational grants, and supporting regulatory and health care infrastructure development. The Representative further stated that in relation to immediate access to medicines, numerous initiatives had been developed and deployed, such as preferential pricing, donations, voluntary licensing and capacity building. The Representative urged a visit to IFPMA's health partnership directory for an extensive list of such initiatives. The Representative wished that the Member States would be able to find a reasonable compromise on the current agenda item at the current session of the SCP.

133. The Representative of MPP agreed that it was fundamental to have transparency of information in the status of patents. The Representative noted that reliable patent information was often hard to come by, but was useful, not only to MPP which was trying to improve access to medicines, but also for governments, procurement agencies and other public health organizations engaged with intellectual property and access to medicines. The Delegation noted that in October 2016, at the WIPO General Assembly, the MPP had launched MedsPal, its database on patents and licenses of medicines, which included comprehensive information on the patents and licensing status of HIV, hepatitis C and tuberculosis medicines. The Representative apprised that MedsPal provided transparency on the status of HIV, tuberculosis and other medicines in developing countries, and also included information on patents, license and data exclusivity protection in over 100 developing countries. The Representative thanked the support of the EPO and other national patent offices such as these of Chile, the Dominican Republic, Ecuador and South Africa and others, with whom MPP had collaboration agreements, she also thanked a large number of civil society groups, patent experts and companies for helping MPP to compile the data for their public resource, MedsPal. The Representative informed that MedsPal currently included more than 60% of the patented essential medicines in the current WHO EML. In addition, the Representative noted that due to recent Swiss government collaboration, the MPP had started a feasibility study on the possible expansion of its mandate to cover all patented essential medicines in the WHO EML. The Representative informed that patent data was being collected for that study, and hopefully could be added to MedsPal as early as October 2017. The Representative stated that if there was an interest, MPP could work with Member States to identify patented medicines in their national EML and include the information in MedsPal. The Representative invited other patent offices to contribute to the MedsPal database so as to allow key new medicines to become available in all low and middle income countries at affordable prices. Finally, the Representative informed that the MPP remained at the disposal of the Member States to make the detailed presentation as was requested by the Delegation of Brazil and was supported by the Delegations of Chile, Switzerland, and Argentina. The Representative also informed that it was willing to provide any further clarifications and to work together with Member States, regional groups, WIPO, WHO and other stakeholders in order to further strengthen MedsPal to meet the needs of the stakeholders.

134. The Representative of JIPA informed the Committee that it comprised of about 900 major Japanese companies as its members. The Representative further stated that it made its statement in conjunction with Japan Pharmaceutical Manufacturers Association (JPMA) which comprised of 72 pharmaceutical companies. The Representative further noted that its statement was also supported by IFPMA. The Representative believed that it was important for SCP to agree that the provision of quality medicines to many patients in the world was a mission of the governments and companies in both developed and developing countries. The Representative was of the opinion that the discussion on the methods and means for accomplishing that mission must take place after long and careful analysis of the causes of the existing problems. The Representative noted that according to the report titled "Medicines in Development" by PhRMA in 2015, which had been mentioned at twenty-fourth SCP, the role of intellectual property as an incentive for innovation and long-term access was well known. The Representative stated that the research and development by the pharmaceutical industry had contributed to nearly every important medicine over the past century, including antibiotics, vaccines, HIV and HCV treatments, as well as cancer and cardiovascular medicines. The Representative noted that the industry had developed over 550 medicines in the last 15 years for the world's emerging health needs, including in the areas of oncology, cardiovascular diseases, and diabetes. The Representative noted that currently, the industry continued to be instrumental in exploratory research, as well as in translating research into patient-ready treatments, with more than 7000 medicines in development across all therapeutic fields. According to the Representative, launching a new medicine into a country had significant costs for the originator company. The Representative therefore added that in order to successfully distribute medicines to patients in a new country, companies had to first bear the cost of conducting additional clinical trials to meet local requirements, obtain local regulatory approval, setup local distribution and marketing networks, educate healthcare providers about the benefits of the new product, and also undertake post-marketing research and surveillance. The Representative noted that intellectual property rights provided an opportunity to recoup all those costs by a company that was financing the launch of a new medicine before a generic competitor entered the market. The Representative also noted that as stated in the report titled "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry (2005)", a number of studies had confirmed the importance of intellectual property in accelerating the global diffusion of new medicines. The Representative noted that the 2005 study, which had covered a large number of developed, as well as developing countries, had found that in those Member States which had stronger patent protection there had been an increase in the speed of new drug launches. The Representative further, noted that the report titled "Patents and the Global Diffusion of New Drugs (2014)", which was a comprehensive study of drug launch data of over 600 drugs in almost 80 countries from 1983-2002, showed that robust patent protection accelerated new product launches in higher and lower income countries alike. The Representative was therefore convinced that the patent system was a vehicle for commercialization of new technologies. The Representative believed that a fair patent protection of pharmaceutical technology would allow pharmaceutical companies to continuously carry out research and development of new drugs for patients in developing countries. The Representative also informed that Japanese pharmaceutical companies had also been seriously working on the issue of access to medicines in developing countries. The Representative thereafter proceeded to introduce their activities for access to medicines. The Representative informed that the Japanese pharmaceutical company, Takeda, had officially joined the WIPO Re:Search Consortium on September 25, 2015 in order to contribute to the development of drugs, vaccines and diagnostics for HIV AIDS, malaria and tuberculosis by providing the company's assets such as proprietary compounds, study data, and technologies. The Representative informed that Takeda was the second Japanese pharmaceutical company to join the Re:Search Consortium after Eisai. The Representative stated that as reported in the WIPO Re:Search homepage, Takeda had provided Prof. Conor Caffrey, Center for Discovery and Innovation in Parasitic Diseases at the University of California, San Diego, with a targeted set of compounds to screen against *Schistosoma mansoni in vitro*. The Representative also

added that Takeda had provided Professor Yossef Av-Gay, Division of Infectious Diseases at the University of British Columbia, with a targeted set of compounds to screen against *M. tuberculosis* residing within macrophages. The Representative thereafter stated that in August 2016, Takeda had publicly launched its new access to medicines strategy. The Representative stated that Takeda's Patient Assistant Programs were designed to ensure that patients, whose ability to pay the full cost of treatment was limited, were able to access the full course of treatment through affordability-based approaches in regions such as Sub-Saharan Africa. The Representative stated that Takeda's Patient Assistant Programs would be tailored to address local needs via different collaborative cost-sharing models between patients, Takeda, and at times, charities, medical societies and other parties. The Representative stated that Eisai was also committed to improving the affordability of its products. To realize their commitment, Eisai had introduced strategies for affordable pricing for countries outside of those defined as high-income for selected products as well as had introduced tiered pricing that involved establishing multiple price burden levels, from full payment by the patient to free of charge, to enable patients who needed their medicines to receive treatment regardless of their income level. The Representative also informed that Astellas Pharma did not file or enforce patents in countries with significant economic challenges with a view to improving access to health. The Representative further informed that Daiichi Sankyo flexibly filed and enforced patents on a per-country basis with due consideration given to improving access to medicines. The Representative thus concluded that Japanese pharmaceutical companies had been making efforts to provide new drugs for patients in developing countries. In addition, the Representative noted that six Japanese pharmaceutical companies, Astellas, Chugai, Daiichi Sankyo, Eisai, Shionogi and Takeda, participated in the Global Healthcare Innovative Technology Fund (GHIT), which had been established by Japanese pharmaceutical companies, the Japanese government and the Bill & Melinda Gates Foundation, in order to promote development of pharmaceuticals via global cooperation. The Representative also stated that other JPMA's activities for access to medicines in developing countries were mentioned in JPMA's internet homepage. The Representative believed that, regarding access to medicines in developing countries, it was necessary to promote research and development of medicines centering on patent systems. The Representative was convinced that the patent system promoted public health in both developed and developing countries.

135. The Delegation of Canada thanked the Member States and the Secretariat for the support of its proposal. The Delegation stated that, to foster a robust pipeline of new innovations, governments followed a variety of approaches in trying to strike the right balance. The Delegation further stated that the relationship between patent rights and public health outcomes had been a longstanding topic of discussion in the SCP and it was clear that there were a diversity of views and a vigorous debate on that relationship. The Delegation believed that the discussions would be enriched by having a document that had a common understanding on the state of research of the patents and access to medical products and health technologies. The Delegation stated that its proposed review was intended to summarize existing high-quality research in a factual manner. The Delegation anticipated that the review would capture research representing all sides of the debate. The Delegation stated that it would be for Member States to determine the best manner for interpreting and applying that research. Nonetheless, the Delegation believed that its proposal could serve as a valuable first step in building trust and establishing a productive way forward on the topic and could be supported by all Member States. The Delegation stated that in the interest of time, it did not wish to walk through its proposal line by line, but wished to draw attention to a few specific points. Firstly, the Delegation believed that its proposal could move forward in parallel with other work on the current agenda item. At the same time, the Delegation stated that Member States could take account of the results of its proposal when making decisions about topics of any other research that Member States might wish to commission. Secondly, the Delegation believed that while much of the discourse on patents and public health technologies focused on medicines, achieving a positive public health also depended upon access to a wide variety of other

technologies such as vaccines, diagnostic equipment, and medical devices. The Delegation stated that Member States would be doing themselves a disservice by focusing on exclusively on medicines, if they wished to approach the issue in a holistic manner. Thirdly, the Delegation stated that, in identifying specific topics of research to be captured by the review, it had tried to strike a balance, recognizing that there were many points of view on the relationship between patents and health. The Delegation believed that its proposal represented one possible reflection of that balance but that they were open to working with Member States on potential changes. The Delegation stated that, as that was an area where countries were still trying to strike a balance, it was important to recognize that if Member States were able to agree on a proposal, it would not look like one that any of the Member States would have drafted in their own individual capacity. The Delegation stated that it would be pleased to answer any questions Member States had on its proposal.

136. The Delegation of Japan, speaking on behalf of Group B, appreciated the constructive effort by the Delegation of Canada to foster a meaningful discussion. The Delegation took note of the proposal and stated that the proposal required further discussion.

137. The Delegation of Senegal, speaking on behalf of the African Group, thanked the Delegation of Canada for their proposal. The Delegation welcomed the proposal and the spirit behind the proposal. The Delegation considered that as stated by the Delegation of Canada, its proposal was just a first step aimed at establishing trust among the various stakeholders and Member States. The Delegation believed that the proposal made by the Delegation of Canada could be taken alongside other proposals, including the proposal made by the African Group. The Delegation however felt that the proposal was limited with regard to their expectations under the agenda item. In its view, that the African Group proposal, which was articulated around three different points, and which the African Group wanted to deal with in the whole, included studies and sharing sessions on information and technical assistance. Therefore, the Delegation expressed its preference to maintain the African proposal.

138. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Delegation of Canada for putting forward its proposal to conduct a review of the preexisting analysis and research on the topic of patent protection and access to medical products and health care on the agenda of patents and health. The Delegation took note of the proposal, and sought some clarifications for improving the text. The Delegation agreed that policymaking within the SCP should rely on quality evidence and agreed with the Delegation of Canada that a review was a good possibility to build upon existing research. While the Delegation welcomed the inclusion of the studies prepared by WIPO, WHO, and the WTO, but it stated that inclusion of studies carried out by other organizations would need more consideration. Therefore, the Delegation suggested further exploration of the scope of the review. Furthermore, the Delegation expressed its reservations on including non-patent barriers and the availability of essential medicines within the proposal, because the mandate of the SCP was limited to patent law. The Delegation also felt that the scope of the terms “medical products” and “health technologies” used in the proposal was unclear. That being said, the Delegation stated, the CEBS Group could consider the Canadian proposal as a topic for future discussion.

139. The Delegation of Estonia, speaking on behalf of the EU and its Member States, thanked the Delegation of Canada for trying to bring the Committee’s work forward on the topic of patents and health with its proposal to conduct a review of preexisting analysis and research on the topic of patent protection and access to medical products and health technologies. The Delegation saw merit in studying those issues and was prepared to discuss and develop the proposal further. The Delegation stated that, however, based on the language used in the proposal, they had some reservations which did not enable them to fully support the proposal as it stood. While the Delegation agreed with the Delegation of Canada that the SCP was mandated to focus on patent law, it questioned as to how could the study, on one hand, comply

with the mandate of SCP and, on the other hand, consider the question in the broader context of access to medicine, which clearly fell outside the remit of the Committee. The Delegation, however, agreed with the Delegation of Canada that, in addition to the patent system, there were a variety of other factors, both on the supply and demand side that affected the availability and affordability as well as the other access dimensions of medical products and health technologies. The Delegation stated that paragraph 2 of the proposal contained a non-exhaustive list of relevant examples of such factors. The Delegation stated that, if the purpose of the intended inclusion of non-patent barriers in the review was to indirectly identify the impact of patents on availability and accessibility in the short term, then a possible alternative could be to look at the situation of accessibility of medicines in environments without patent protection. The Delegation noted that, as referred to in paragraph 42 of document SCP/26/5, research had shown that of the medicines of the WHO EML, the vast majority, approximately 95% of the medicines were not under patent protection in most lower-income countries. The Delegation further stated that studies which looked into the factors influencing the accessibility of such medicines in those countries could perhaps help in better understanding the role of patent system in ensuring the availability and accessibility of medicines. The Delegation agreed with the Delegation of Canada that work of the SCP must rely on the quality evidence. Therefore, the Delegation believed that it was important that the proposed review would build on existing high-quality research and that the studies were conducted by neutral and objective parties. The Delegation welcomed the reliance on studies prepared by United Nations Organizations such as WIPO, WHO as well as the WTO. The Delegation believed that, with regards to academic research, there was a need to ensure a high level of rigor, independence, and relevance of the subject matter. The Delegation sought clarification of the central terms used in the proposal. The Delegation stated that as an example, the scope of terms “medical products” and “health technologies” was presently unclear. In general, the Delegation welcomed the fact that the intention of the final report of the review was not to make an original recommendation, but rather to provide a factual synopsis of the analysis and the key conclusions of the recommendations of the existing body of research. The Delegation saw the role of the potential review as a collection of information and the documents supporting future discussions and did not see it as an outline of different policy options for WIPO.

140. The Delegation of Brazil reaffirmed their appreciation of the constructive spirit shown by the Delegation of Canada, and stated that the Delegation saw merit in the proposal made by the Delegation of Canada. The Delegation stated that it had been in touch with the Delegation of Canada, and had informed them that it would react and might make suggestions in the near future. The Delegation believed that the proposal was an effort to build bridges, which was thus commendable by itself. The Delegation clarified that its support for the proposal did not, in any way, affect its continued support for the proposal by the African Group and for any other initiative that aimed at bringing Member States closer.

141. The Delegation of Australia thanked the Chair for its leadership in the Committee and looked forward to working with the Chair in advancing the work of the Committee during the week of the SCP. The Delegation also thanked the Secretariat for its work in preparing for the Committee. The Delegation welcomed the discussions on access to medicines. The Delegation believed that the discussion required a holistic approach, which was cognizant of all factors affecting access to medicines. The Delegation also believed that it was important to take account of the existing work on the current agenda item in WIPO and other relevant fora. The Delegation welcomed the proposal made by the Delegation of Canada for the review of existing research on patents and access to medical products and health technologies. The Delegation looked forward to constructive discussions on the proposal with the Delegations of Canada and other Member States. The Delegation also noted the proposal made by the Delegation of Brazil on the presentation by the MPP, and stated that it was open to such a presentation.

142. The Delegation of Singapore expressed its appreciation for the Chairs' continued leadership in the Committee. The Delegation thanked the Delegation of Canada for its efforts in preparing document SCP/26/6, and expressed its support for the proposal. The Delegation noted that the issue of the relationship between patents and health was not new, and that they were of the view that the proposed literature review was a meaningful exercise to help Member States understand the stock of knowledge in terms of existing research, prior to making commitments to commence further studies. The Delegation stated that the review should also have a summary of the key themes, findings and recommendations that were common to the various studies, in order to help the Member States in coming to the right conclusion on the work that was still needed to be done. The Delegation felt that in order to achieve a balanced work program, in addition to the topics that were contained within the current proposal, there was scope and merit to consider incorporating some of the elements that were within the African Group's proposal, as highlighted in document SCP/24/4.

143. The Delegation of Chile thanked all delegations that had made proposals for the future work of the Committee on the current agenda item. The Delegation noted that the African Group's proposal suggested three areas: studies, exchange of information, and technical assistance. The Delegation believed that a comprehensive work program in that area should certainly look at those three pillars as the framework for its work. The Delegation also thanked the Delegation of Canada for their proposal contained in document SCP/26/6. The Delegation stated that the proposal focused on the first pillar of the African Group's proposal on the current agenda item i.e., studies. The Delegation believed that the compilation of information from other fora and the contribution of experts would certainly be an important reference material for future debates of the Committee. The Delegation stated that, however, as to the exchange of information, which was the second pillar of the African proposal, they were very grateful for the shared information on the MPP. The Delegation felt that the information about the database was of the greatest value, because otherwise it was very difficult for users to be informed about the patents covering a particular medication. The Delegation noted that the Chilean Institute of Intellectual Property understood the importance of the MPP's initiative and had signed a cooperation agreement to provide relevant information. The Delegation believed that patent offices could take more responsibility regarding the public information dealt by them, particularly regarding sending the information to MedsPal. The Delegation stated that it would support the work of the MPP and also felt that patent offices of the Member States should work together to create a better, more valuable database. Hence it welcomed the proposal made by the Delegation of Brazil on the presentation by the MPP, which, if not in the current session, would be presented in the future sessions, and would facilitate the cooperation. The Delegation believed that the presentation would be a way of drawing a path for the second pillar. The Delegation stated that the experience of their patent office showed that it was possible to contribute to MedsPal without increasing the burden of the daily work of the Office.

144. The Delegation of Iran (Islamic Republic of) extended its appreciation to the Delegation of Canada for the preparation and presentation of its proposal. The Delegation stated that it preferred to reach a consensus concerning the future work of the Committee on the current agenda item. The Delegation was concerned that as the proposal by the Delegation of Canada was only an overall literal review of the studies and other activities, which had already been undertaken by the Committee, the proposal might delay the action for the future. The Delegation sought information from the Delegation of Canada of the value addition by the proposal to the discussions in the Committee on the current agenda item. The Delegation stated that the proposal by the Delegation of Canada was one of the proposals among the many proposals on the table and that their preference was still to see some elements of the African proposal be operationalized in the future work of the Committee. The Delegation sought a clarification concerning the duration or the time period of 2005-2016 mentioned in the proposal. In addition, the Delegation wished to know whether the time frame mentioned in the proposal, till the end of the 2016, would include the UNHLP Report in the proposed review.

145. The Delegation of the United States of America thanked the Canadian Intellectual Property Office for their proposal for a review of the research. The Delegation felt that a survey of the research carried out on the topic would be very useful as long as proper fact-checking was carried out to ensure its accuracy. The Delegation wished to have more details on that aspect of the proposal. The Delegation felt that it would be useful to consider the effects between various non-patent barriers and the availability and accessibility of essential medicines as had been proposed by the Delegation of Canada. The Delegation felt that the SCP would not be able to directly affect some of those barriers, if they fall outside the SCP's mandate. The Delegation however believed that learning about those barriers was crucial in understanding the extent of impact by the patent system on access to medicines. The Delegation felt that similarly, it would be important to consider all factors that facilitated or impeded the role of the intellectual property systems in fostering knowledge, spillovers, and technology transfer in the medical product and health technology sector. The Delegation believed that factors such as technical absorption capacity, manufacturing capabilities as well as other factors should also be considered.

146. The Delegation of the Republic of Korea recognized that agenda item "patents and health" were one of the difficult items to discuss, among others. The Delegation expressed its support to the proposal by the Delegation of Canada. However, considering the workload of the Secretariat, the Delegation suggested that the SCP consider whether such a study should be presented to the twenty-eighth session of the SCP.

147. The Delegation of China thanked the Delegation of Canada for its proposal and remained open to discuss it. The Delegation stated that although the patent system was one of the important factors influencing the accessibility of medicines, there were other factors, and the Secretariat's study seemed to have such a conclusion. The Delegation continued that, therefore, a comprehensive review and analysis of the issue would be valuable. In this opinion, however, the focus of the proposed review should be on how to improve accessibility to medicines, which was the primary goal for that topic.

148. The Delegation of Indonesia thanked the Delegation of Canada for its proposal to conduct a review of existing research on patents and access to medical products and health technologies. Noting that the content of such a review would include such topics as, voluntary licensing mechanisms, patent pools and non-patent barriers, the Delegation noted that the timing of submission of the proposal was not right. The Delegation shared the concern that the Canadian proposal would delay the development of an action-oriented program on patents and health. Noting that the SCP had moved forward in considering specific aspects of the relationship between patents and access to medicine, the Delegation stated that it did not see merit in a general literature review as proposed by the Delegation of Canada. The Delegation was also of the view that the proposal had some limitations, both, in scope and format. The Delegation explained that the proposed review would be limited in scope, as it could not possibly include rich empirical analysis and studies by global health community, including global health initiatives and NGOs working on the topic "patents and health". On the other hand, the Delegation stated, the proposal by the African Group offered a concrete and balanced work program, on which, unfortunately, discussions had not been finished since sixteenth session of the SCP. In conclusion, the Delegation stated that, at that stage, it could not support the proposal by the Delegation of Canada, as it did not see a value from it to the expected progress of the Committee.

149. The Delegation of the United Kingdom thanked the Delegation of Canada for its proposal and stated that the proposal had a potential to avoid duplication of existing studies and that it could help to structure the future work on that agenda item. The Delegation placed increased importance on making use of the expertise and research of WIPO, WHO, and WTO, and urged for the study to only reference high-quality and evidence-based research. The Delegation

supported the statement by the Delegation of Estonia, on behalf of EU and its Member States, as regards reviewing the issue of accessibility of medicines in countries without patent protection.

150. The Delegation of Mexico recognized the complexity of the issue and the necessity of seeking a balance between the patent protection and the issue of access to medicines. The Delegation supported a proposal of organizing a sharing session where Member States could share their experiences on public policies, the flexibilities contained in the TRIPS Agreement, as well as legal status of protected medicines, among others.

151. The Delegation of Switzerland noted that all Member States agreed that public interest and access to medicines was a very important topic. The Delegation stated that the current system of IP protection fully integrated a balance between private and public interest, and that patents were so-called “negative rights”. The Delegation further stated that it was inherent to the system that investment in R&D and marketing of innovative medicinal products were financed through the patent system through revenues from enforcing patent rights, which, in the short- to medium term, was reflected in the prices of the medical products. The Delegation noted that, in the longer term, it had a pipeline of new medical products which usually become available after the patent protection period had expired and at a lower price. The Delegation stressed that reliable and solid rules on IP protection provide for the necessary legal certainty to encourage not only the investment in new and better drugs for unmet medical needs but also to allow for the licensing of technology innovation of any products, including medical products. The Delegation further stated that in the mid- to long-term, the IP system played an essential role with regards to availability and accessibility of medical products and was, therefore, affirmative of the right to health. The Delegation was aware that a good IP framework was not only the requisite for foreign direct investment. The Delegation noted that the IP system was not a panacea for solving all aspects in the challenge for better access to medical products and that there might be policy and market failures that needed to be addressed. The Delegation wished to highlight that access to medical products constituted one of the main objectives of its foreign health policy. The topics of strengthening global health research, protection of IP, and promotion of human rights were priorities that were stipulated as explicit goals in that policy. The Delegation stated further that, based on its foreign health policy and the 2030 Agenda of Sustainable Development, Switzerland fostered a number of initiatives aiming at improving access to medicines. For instance, the Delegation stated, the Swiss government provided technical and financial support to the WHO to set up a public observatory where research and development activities were monitored worldwide and gaps identified. The Delegation further stated that the Swiss government supported that the Committee prioritized research needs. The Delegation further informed the Committee that Switzerland had also given technical and financial support for a Voluntary Fund to finance priority research and development initiatives. The Delegation noted that, however, funding of the selected innovative demonstration projects remained insufficient. The Delegation stated that the Swiss Matching Fund to provide complementary contributions from low- and middle-income countries had not been fully used by those countries. To date, the Delegation noted, it had only been able to disburse 700,000 USD out of two million USD. The Delegation continued that, Switzerland also invested in public-private partnerships for the research and development of medical products, so-called “product development partnerships”, especially in the area of poverty and neglected tropical disease. That included, for example, the Drugs for Neglected Diseases Initiative (DNDi) or the Global Antibiotic Research and Development Partnership (GARDP). The Delegation further informed the Committee that Switzerland was among the core funders of product development partnerships, such as DNDi or the Foundation for Innovative New Diagnostics (FIND). The Delegation also highlighted that its government supported the MPP by financing its feasibility study, which would look into the challenges and opportunities of potentially expanding the business model of the MPP beyond the current disease areas of HIV, tuberculosis and hepatitis C. The Delegation stated that, in summary, instead of advocating the use of

exceptions and limitations as a solution, it strongly believed in the promotion of initiatives and approaches which would incentivize research and development and by the same token, improve access to medicine products for people in low- and middle-income countries, and that was one important example of how the IP system served the public interest. The Delegation was of the view that building on voluntary and inclusive efforts, such as the MPP, or the Global Funds eProcurement platform, or WIPO Re:Search was the way forward and that it corresponded to the collaborative spirit of the 2030 Agenda for Sustainable Development. Further, the Delegation stated that the issue of access to medicines was a very complex one, and that IP rights played a crucial role in incentivizing research and development. While noting that governments were free to use the flexibilities contained in the TRIPS Agreement, the Delegation stressed that a systematic weakening of IP rights risked to eventually discourage biomedical innovation. The Delegation supported a more holistic approach in the discussions on the topics of patents and health: one that would balance the public and private interests. In that regard, the Delegation stated that a proposal of the United States of America (document SCP/17/11) contained elements that could serve that purpose. Referring to important work already under way at other international organizations, such as the WHO, which was the United Nations lead agency on access to medicines, the Delegation stated that duplication of that work should be avoided. In that respect, the Delegation welcomed and supported the proposal put forward by the Delegation of Canada to conduct a review of existing research on innovation and access to medicinal products and health technologies. The Delegation noted that the proposed study would shed light on efforts and work undertaken in that area and would provide a clearer understanding of the current state of knowledge. Considering the already existing extensive high-quality research, for example, of WHO, WTO and WIPO, and the renowned academic researchers, the Delegation believed that the review of such rich documentation was a logical and constructive step forward before entering in further work on the topic of patents and health. With respect to the non-patent elements included in the Canadian proposal, the Delegation was of the view that such elements set the issues of patents and health in its broader context, and would not engage WIPO in working on those elements.

152. The Delegation of Canada thanked the delegations for their interest and engagement in its proposal. With regards to some points raised by the delegations, the Delegation made the following clarifications. With regard to the non-patent barriers, the Delegation considered that most agreed that patents were simply one of many factors in the question of access to medical products and health technologies. On the other hand, the Delegation noted that the mandate of the Committee was limited in scope to patent law, and therefore it was a challenge to try to engage on that topic in light of those facts. The Delegation continued that in order to be able to understand the effect of patents on availability and accessibility, one could not look at them in a vacuum and that all other factors affecting access and availability needed to be examined in order to determine the precise effect of patents, relative to the other factors. The Delegation noted that it would not expect the SCP to take action on non-patent elements as a result of the proposed review. They would simply be considered as part of the review in order to better elucidate the effect of patents relative to other factors. In that regard, the Delegation observed that much of the literature on that topic did not look at patents in isolation, but along with other non-patent elements. Therefore, the Delegation considered that even if it would remove that element from its proposal, it was likely that many of the same studies would still be captured. However, on that point, the Delegation remained open to discuss the issue, if the views of other Member States were that it was inappropriate to have that element in the proposal. As regards the academic research, peer-reviewed research and the need to ensure that high-quality research was captured, the Delegation expressed its full confidence in the ability of the Secretariat to undertake that exercise and to identify high-quality research. The Delegation further stated that, on the scope of medical products and health technologies, the WHO defined "health technology" as the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. The Delegation stated that, in the context of the patent system,

devices, medicines, vaccines and diagnostic systems would be the most relevant elements of that definition. As regards the proposal to incorporate some of the elements of the proposal by the African Group, the Delegation explained that its proposal was not intended to replace the African Group proposal, and therefore, the Delegation did not have the idea of incorporating specific elements of the African Group proposal in its proposal. In that regard, the Delegation noted that the different nature of the exercises proposed: the African Group's proposal was aimed at conducting original research, whereas its proposal was aimed at conducting a review of existing research. Nevertheless, the Delegation noted that some overlap might exist in terms of topics covered by both proposals, such as compulsory licensing and the transfer of technology. The Delegation stated that it was not aware of any previous exercise along the lines of its proposal being undertaken in the recent past. As regards the 2005 to 2016 time period, the Delegation explained that it limited the research to that specific time period in order to limit the amount of research to a manageable scale. The Delegation further explained that it chose the year 2005 as the start date, since from that year, developing countries had had to provide product patent protection for pharmaceuticals in accordance with the TRIPS Agreement. The Delegation stated that it was open to consider alternative time periods, bearing in mind that the overall scope of the project remained manageable. Further, the Delegation noted that the UNHLP Report would fall within that time frame and the scope of that exercise. The Delegation further stated that it would reflect on the suggestion on reviewing the issue of accessibility of medications in countries without patents. As regards the question of whether the research by the NGO would be included in the literature review, the Delegation noted that the reason for limiting the scope of the review in the manner currently reflected in the proposal were twofold: first, the Delegation wanted to ensure that the body of research captured and summarized would be manageable for the Secretariat; and second, such review should assemble a body of high-quality rigorous research. In that regard, the Delegation stated that research conducted, or commissioned by relevant international organizations, or peer reviewed academic research would most likely to be of high quality. The Delegation believed that those categories would give a clear guidance on what work should be included in the review. The Delegation further explained that considering those aspects, in the interest of balance, if it were to include the NGO research, it would have to include research by the private sector and that would become a broad scope of work. The Delegation supported the proposal by the Delegation of Brazil to invite MPP to give a presentation on its database.

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

153. The Secretariat informed the Committee that the SCP web page on the confidentiality of communications between clients and the patent advisors had been updated based on the information received from the Member States.

154. The Delegation of Indonesia noted that Patent Attorneys Associations had adopted various resolutions encouraging countries and regions to provide the protection of legal professional privilege for the communications between clients and the IP practitioners. The Delegation also noted that an international instrument in the form of a model law had also been suggested by such bodies. In that regard, the Delegation pointed out that the Paris Convention expressly left the issue of administrative and judicial procedure to be regulated under national law, and that no other international treaty regulated the issue of client-attorney privilege. Therefore, the Delegation stated that it would prefer to discontinue any further discussions on that issue.

155. The Delegation of Japan, speaking on behalf of Group B, stated that its Group attached high importance to the topic of confidentiality of communications between clients and their patent advisors. The Delegation stated that users of the patent systems from different regions including Canada, Switzerland, Brazil and India, continued to stress the need to address the subject at the international level. Noting that patents had become more globalized and that patent holders might require legal advice regarding patents in various nations worldwide, the Delegation stressed that there was a need to address the lack of adequate protection of legal IP advice at the international level. The Delegation continued that Group B believed that the issue, in particular, the aspect of the obligation of holding patent advisors' privilege, should be addressed at the SCP. In particular, the Delegation was of the view that the Committee should take substantive steps to address the issue in the manner which leave enough space or flexibility for Member States, in light of the differences in legal systems around the subject matter. The Delegation continued that, in that context, a soft law approach should be pursued. The Delegation stated that as the issue was critically important from the viewpoint of the practitioners, Group B expected that the Committee could respond to the voices of the market, and contribute to the business environment for innovation. Further, the Delegation expressed its belief that court cases regarding different national legal systems the confidentiality of communications would provide resourceful material for Member States, and would contribute to important discussions. Recognizing that the different opinions had been presented on the issue during the previous sessions, the Delegation invited all Member States, particularly those opposed to further work, to approach the problem and difficulties in a more objective manner, and to foster a discussion on what could be accomplished. The Delegation stated that, for example, a study based on the questionnaire could be prepared, as well as further compilation of the court cases could be continued.

156. The Delegation of Georgia, speaking on behalf of the CEBS Group, stated that its Group attached a great importance to the continuation of the work under that agenda item. The Delegation was of the view that the issue was relevant to the work of the Committee as it had a cross-border dimension. The Delegation reiterated that soft law approach could be pursued and effectively applied in that area.

157. The Delegation of Senegal, speaking on behalf of the African Group, reiterated its position on the issue of the confidentiality of communications between clients and their patent advisors. Specifically, the Delegation remained convinced that the issue fell outside the mandate of the SCP. In its opinion, it was a matter of private law and the regulation of professional services, particularly in respect of codes of practice and ethics. The Delegation continued that, in many jurisdictions, the question of confidentiality of communication between clients and their patent advisors was governed by the law of evidence. Therefore, the Delegation did not consider the issue to be a substantive aspect of patent law. The Delegation stressed that it was up to each of the Member States to decide how it should deal with and regulate the issue under its national law. The Delegation stated that, instead of trying to protect those communications by confidentiality, it would be better to employ transparency-related measures, encourage disclosure and issuance of high-quality patents meeting specific patentability criteria. Finally, the Delegation stated that its Group did not wish to discuss the matter internationally.

158. The Delegation of Iran (Islamic Republic of) continued to believe that the issue was not a substantive patent law issue and that it fell outside its scope and, therefore, should be treated under the national laws as a matter of private law and the regulation of professional services. The Delegation did not see any added value from further discussion of the issue.

159. The Delegation of Switzerland stated that increase of international trade led to internationalization of IP rights, and that innovators were increasingly faced with IP prosecution and disputes across multiple jurisdictions. The Delegation stated that, therefore, legal advice regarding a patent was often sought in various nations worldwide. The Delegation noted that,

many jurisdictions did not provide protection of the confidentiality and professional advice. Free and frank communications between clients and attorneys were essential to produce good and clearly articulated patent applications and increase the certainty and the validity of granted patents. Noting that legal advice was often provided by non-lawyer patent attorneys with special training in IP law and technical qualifications, the Delegation stated that many jurisdictions did not include those professionals in the legal protection of clients from disclosure of IP advice. The Delegation continued that, in addition, many jurisdictions did not provide protection of communications between clients and foreign non-lawyer patent attorneys. Thus, innovators who sought patent protection abroad could not be certain and confident that their communications, even with their local IP advisor, would be protected against disclosure in foreign court proceedings. The Delegation further stated that confidentiality of communications between patent advisors and their clients had national and transnational aspects, and that there was a need to address the lack of adequate national protection and of protection abroad. The Delegation recalled that during the twenty-first session of the SCP, practitioners from several countries, including Canada, Switzerland, Brazil and India, had underlined the importance and urgency to find a solution to a cross-border protection of secrecy. With respect to the concern raised on transparency, the Delegation stated that the disclosure of an invention in a patent application needed to be distinguished from the disclosure of communication between a patent advisor and his client within a discovery procedure. The Delegation stated that the national laws required an applicant to describe his/her invention in a clear and complete manner so that the person skilled in the art could carry it out. The Delegation continued that, in consequence, the applicant was obliged to disclose all information necessary to fulfill the enabling disclosure requirement. The Delegation further explained that that requirement was not compromised by professional secrecy, and that it continued to apply even if what had been discussed between patent advisors and the client during the preparation of the patent application could be kept confidential. Referring to document SCP/22/4, the Delegation noted that patent laws varied on the details of the enablement requirement. The Delegation stated that, however, those requirements were unrelated to the issue of confidentiality of communications between patent advisors and their clients. In its opinion, the issue of confidentiality of communication concerned patent advisors of all Member States. Therefore, the Delegation encouraged all Member States to enter into discussions on how their patent professionals could receive protection of professional secrecy at the national level and abroad. The Delegation reminded the Committee that, in the SCP, Switzerland had proposed to address that issue through a non-binding soft law mechanism. The Delegation stated that such instrument would recognize a confidentiality of protection in the context of professional advice in patent matters and set minimum standards for the confidentiality protection in cross-border situations. In addition, being widely flexible, it would allow Member States to adapt their national legislations according to their own legal backgrounds and needs.

160. The Delegation of Japan supported its statements made on behalf of Group B, as well as the statements made by the Delegation of Georgia on behalf of the CEBS Group and the Delegation of Switzerland. The Delegation wished to reiterate that appropriate protection of communications between patent advisors and their clients was extremely important to ensure honest and frank communications between both parties. Therefore, the Delegation was of the opinion that each country should extend the attorney-client privilege to its patent advisors. In addition, the Delegation wished to repeat that the issue had to be discussed in terms of its cross-border aspects. The Delegation was of the view that, in order to resolve the issue, it was essential to establish a highly feasible framework, which would be acceptable to the greatest number of countries. Therefore, the Delegation requested the Committee to continue discussions of the issue toward establishing such a framework.

161. The Delegation of Estonia, speaking on behalf of the EU and its Member States, extended its appreciation to the Secretariat for preparing a compilation of court cases with respect to client-patent advisor privilege based on the information provided by members and observers of

the SCP, presented in document SCP/25/4. In regard to the issue, the Delegation suggested that tangible action should be taken towards a concrete mechanism to address the recognition of foreign patent advisors' privilege. The Delegation wished to reiterate that a soft law approach should be considered and work on a non-legally binding instrument would be beneficial to all the Member States, aiming at conferring in Member States the same protection to communications between a client and its foreign patent advisor as that applicable under national law to communications between a client and its national patent adviser. The Delegation noted that that should be without prejudice to existing national legislation and should ensure optimal flexibility. The Delegation concluded by stating that the convergence of existing diverse systems in the area of confidentiality of communications between clients and patent advisors among WIPO Member States would be beneficial for users of the patent system, irrespective of the level of development of individual WIPO Member States.

162. The Representative of the AIPPI requested the SCP to continue the discussion on that subject. The Representative stated that the relationship between the client and the advisor must be a relationship of trust so that the advisor could have all available information from the client in order to give the best possible advice on, for instance, preparing an application for a patent. In his view, the confidentiality of communications contributed to the quality of the patent, and that could only occur if the confidentiality was respected. The Representative stated that the confidentiality would not hide from the examiner any information which would conceal possible non-compliance with, e.g., the inventive step requirements. The Representative noted that, certain countries, such as the United States of America, obliged the applicant to make available all information which could possibly affect the patentability of his/her invention, the failure of which would result in the annulment of patent protection. The AIPPI was of the view that protection of communications between patent advisors and their clients would provide security for all concerned, be they representatives of developing countries, LDCs, or developed countries.

163. The Representative of JPAA wished to emphasize the importance of maintaining discussions on that subject in the SCP. Especially, the Representative hoped that the issue would be approached from the standpoint of users or clients, rather than representatives or patent advisors, since the privilege belongs to clients and not to patent attorneys. In that connection, the Representative wished to point out that JPAA comprised Japanese patent attorneys, including in-house attorneys which accounted for about 30% of the total number of Japanese patent attorneys. The Representative stated that in-house attorneys might be deemed to be "clients" relative to outside counsels. On the other hand, the Representative stated, in-house attorneys might also be "patent advisers" toward the corporate officers, managers, inventors or others in the same company. The Representative continued that, according to the recent questionnaire survey of JPAA, quite a few in-house attorneys were concerned with confidentiality of communications, not only between the in-house attorneys as a client and their outside counsels, but also between the in-house attorneys as a patent advisor and a person concerned in the relevant company. The Representative observed that due to the increased globalized economic activities, they were involved in more cross-border legal cases. He noted that, under such circumstances, more and more users, including patent attorneys, had become aware of the risks, or legal uncertainties involved in the communications in their global activities. The Representative was of the view that the same treatment should apply to all countries where economic activities were expanding globally, regardless of whether the countries were developed or developing. Therefore, the Representative stressed that it was becoming increasingly important for that subject to be discussed in the SCP, as the only formal body handling substantive patent law internationally. The Representative reiterated his view that a non-binding soft law approach would be a good solution, considering the cross-border aspect of the client-attorney privilege issue.

164. The Representative of the ICC maintained its earlier expressed view that the issue was important cross-country issue which needed to be further discussed and resolved in the Committee.

165. The Representative of the EPI supported the statement made by the Representative of the AIPPI and stressed that the protection of confidentiality should improve the quality of advice to the client.

166. The Representative of the APAA stated that though that agenda item had been discussed since a long time, there were still different understandings of the issue among Member States. The Representative expressed its strong belief that more time was needed to understand the importance of the issue for the patent system, patent holders as well as the public before taking further steps in the discussion. Therefore, the Representative supported a proposal to study the current situation and court cases and any obstacles for implementing any laws or regulations on protection of communication between clients and patent advisors among WIPO Member States in both domestic and cross-border issues in order to set a minimum international standard or other possible remedies for protecting such communications against forcible disclosure.

AGENDA ITEM 9: TRANSFER OF TECHNOLOGY

167. The Delegation of Paraguay, speaking on behalf of GRULAC, stated that GRULAC positively considered the sharing session on the relationship between patent systems and transfer of technology, which had been held during the previous session of the Committee. The Delegation noted that the question of the sufficiency of disclosure was considered fundamental for the dissemination of knowledge in developing countries. The Delegation stated that, indeed, that matter had been raised in the debates regarding the quality of patents. The Delegation expressed its belief that the current agenda item should be maintained, and that the SCP should study cases and examples in which disclosure permits and facilitates the transfer of technology and innovation, and the manner in which such information is made accessible to the public.

168. The Delegation of Georgia, speaking on behalf of the CEBS Group, wished to reiterate the importance it attached to the current agenda item and acknowledged the role of WIPO in promoting the transfer of technology. The Delegation believed that the transfer of technology was an enabling factor in fostering development. The Delegation stated that, in that regard, the nineteenth session of the CDIP had discussed two proposals on IP and technology transfer demonstrating the role of WIPO in that area. The CDIP had agreed to continue discussions on the issue in the future. The Delegation continued that, the proposal of South Africa had been adopted and the compilation of the national, regional and international technology licensing platforms would be prepared by the Secretariat for the following session of the CDIP. In that line, the Delegation concluded that any new activity under the current agenda item should take into account the work carried out by the CDIP and avoid any duplication.

169. The Delegation of Senegal, speaking on behalf of the African Group, reiterated the importance it attached to the question of transfer of technology. The Delegation stated that, indeed, transfer of technology promoted creativity, innovation and provided access to knowledge. The Delegation noted that Development Agenda for WIPO, specifically, recommendations from 24 to 32 expressly dealt with the transfer of technology. The Delegation wished to quote recommendation 25 which stated “[t]o explore intellectual property-related policies and initiatives necessary to promote the transfer and dissemination of technology, to the benefit of developing countries and to take appropriate measures to enable developing countries to fully understand and benefit from different provisions, pertaining to flexibilities provided for in international agreements, as appropriate.” Further, the Delegation expressed its

support for the work program which would include the issue of sufficiency of disclosure and research on agriculture where patents were concerned. The Delegation remained convinced that the SCP should bear in mind the Development Agenda for WIPO, as well as the work undertaken in other Committees.

170. The Delegation of Estonia, speaking on behalf of the EU and its Member States, noted that the transfer of technology was an important factor in fostering development. The Delegation stated that, however, considering that the CDIP had produced an excellent overview of the work of WIPO on the issue, its position was that the SCP should avoid duplicating the efforts of the CDIP in that respect. The Delegation noted that the nineteenth session of the CDIP had adopted a proposal by South Africa entitled "Project on Intellectual Property Management and Transfer of Technology: Promoting the Effective Use of Intellectual Property in Developing Countries, Least Developed Countries and Countries with Economies in Transition", contained in document CDIP/19/11. Noting further that, according to the decision of the CDIP, the Secretariat would prepare and make available for the next session of the CDIP a compilation of existing national, regional and international technology exchange and technology licensing platforms, as well as of challenges related thereto, facing in particular developing countries and LDCs, the Delegation stated that it looked forward to that document and constructive engagement on its basis. Further, the Delegation expressed its support to updating of WIPO webpage on transfer of technology regarding information of the national, regional and international technology exchange and technology licensing platforms.

171. The Delegation of Japan, speaking on behalf of Group B, reiterated the importance it attached to the transfer of technology, and WIPO's work on promoting and facilitating technology transfer as well as capacity building and training activities in that area. The Delegation expressed its strong belief that IP helped to promote technology transfer on voluntary and mutually agreed terms and the wide dissemination of new technologies for the benefit of society. The Delegation wished to highlight that WIPO had been actively involved in the wide range of technology transfer-related activities that had benefited developing countries, LDCs, as well as countries with economies in transition. The Delegation noted that WIPO's work on facilitating technology transfer had been discussed extensively at the CDIP. Specifically, the Delegation stated that, the nineteenth session of the CDIP discussed two proposals on technology transfer that were presented within the framework of the project on IP and Technology Transfer. The Delegation stated that the joint proposal by the United States of America, Australia, and Canada that had focused on concrete steps that WIPO should undertake in order to ensure the sustainability of the results of the project on IP and Technology Transfer had been approved, for the most part, at the eighteenth session of the CDIP. Further, the Delegation stated that the proposal by South Africa had also been adopted with amendment, and that the CDIP had agreed to continue the discussion at the next session on the issue. The Delegation further observed that the CDIP had decided that the Secretariat would prepare and make available at the following session of the CDIP a compilation of existing national, regional and international technology exchange and technology licensing platforms, as well as of challenges related thereto, facing in particular developing countries and LDCs. In addition, the Delegation noted that WIPO had continued its work on WIPO GREEN, WIPO Re:Search, and WIPO Match. Consequently, the Delegation was of the view that concrete issues and activities related to the role of WIPO in transfer of technology should be discussed at the CDIP rather than at the SCP, since CDIP was better equipped to handle concrete projects and in order to avoid duplication of work. Noting that concrete issues relating to the role of WIPO in technology transfer was within the competency of the CDIP, the Delegation reiterated that it did not wish to create any duplication or prejudice the outcome of the CDIP on the topic. The Delegation continued that, the SCP should not consider future work relating to transfer of technology in general. In its opinion the CDIP should remain the only platform to discuss the issue.

172. The Delegation of Japan, speaking in its national capacity, stated that existing patent system had been implemented, taking into account the balance between the incentive for inventors and the third parties' use of those inventions. The Delegation stated that such balance was achieved by the disclosure requirement. The Delegation did not support any work that might undermine that balance.

173. The Delegation of Iran (Islamic Republic of) stated that transfer of technology was a significant subject in the agenda of the SCP. Consequently, the Delegation stated that the SCP should play an important role in understanding the challenges faced by technology transfer in enhancing free flow of technology, and promoting science and technology innovation, by holding discussions and sharing information. The Delegation was of the view that in order to carry a balance of rights and obligations, the protection and enforcement of patent rights *vis-à-vis* the technological content of the patent specification should be beneficial to social and economic development. The Delegation continued that the requirement of sufficiency of disclosure had the potential to play a basic role in innovation systems, and it was a crucial component of transfer of technology and the proper functioning of the patent system. The Delegation stated that bearing in mind the differences between the subject of transfer of technology in the CDIP and the SCP, it continued to believe that the work on transfer of technology should be maintained in the agenda of the SCP.

174. The Delegation of Indonesia stated that the promotion of transfer of technology was important in reaching the objective of Indonesia's national IP policy. The Delegation attached great importance to that agenda item. It was of the view that discussions under that agenda item had an important and positive role in understanding the opportunities and challenges facing technology transfer to promote the effective free flow of technology as well as that of innovation, in all countries. Regarding the competency of the SCP on the issues of transfer of technology, as during the previous sessions, the Delegation stated that, while the CDIP had discussed transfer of technology, the issue of patents and transfer of technology should be discussed within the SCP. The Delegation further wished to highlight the importance of discussions on the requirement of sufficiency of disclosure, which had a key role in their national innovation system and had played a crucial part in the proper functioning of the patent system. The Delegation looked forward to hearing the update from the Secretariat on the transfer of technology website, as well as to a sharing session in order to gain insights on the relationship between patent systems and transfer of technology.

175. The Delegation of Brazil aligned itself with the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation stated that the topic of transfer of technology provided many opportunities to explore. The Delegation stated that IP rights, and particularly, the patent system, rested on a compromise, a temporary monopoly on the economic exploitation of a patent in exchange of disclosure of its underlying technology to advance knowledge for the benefit of society as a whole. The Delegation continued that the idea of advancing knowledge and technology had been recognized as a core goal of the IP system. The Delegation noted that, indeed, the TRIPS Agreement in its preamble recognized the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives." The Delegation stated that, although many different elements affected technology transfer, the patent system played a key role in it. The Delegation referred to Article 7 of the TRIPS Agreement which acknowledged that "[t]he protection and enforcement of Intellectual Property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology []." The Delegation further stated that, in addition, Article 66.2 of the TRIPS Agreement should inspire Member States to take action on the matter, which stated "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." Further, the Delegation referred to

recommendations 25, 28, 29, 30, and 31 of the WIPO Development Agenda, and highlighted that the transfer and dissemination of technology should be in a manner conducive to social and economic welfare. The Delegation stated that, Brazil's experience with technical cooperation had been instructive in that regard. The Delegation continued that, in almost every single case, Brazilian technicians learned much from the receiving country and brought valuable knowledge back home. The Delegation stated that the transfer of technology was a two-way street. Further, the Delegation stated that, to remain within the mandate of the SCP, it wished to suggest that WIPO conduct a review of preexisting analysis and research as well as an exchange of views and experiences on the following topics: (i) collaborative and open innovation, which would include the contribution of patent pools and international co-patenting to innovation; (ii) sufficiency of disclosure, which lies at the core of the patent system, and the SCP members should engage in discussions to ensure that patent applications always disclose information in sufficient detail to allow a person skilled in the art to carry out the invention; and (iii) the role of IP in agriculture and the food system. The Delegation stated that innovation could be a key to maintaining the productivity growth required to meet the rising demand for food in a sustainable fashion, and it could help to enhance the networks that integrate food systems. In conclusion, the Delegation stated that those initial ideas were open to contributions from all SCP members.

176. The Delegation of China thanked the Secretariat for its continued attention and efforts on the issue of transfer of technology. The Delegation stated that free flow of technology was conducive to the promotion of national scientific and technological innovation, economic development, and, therefore, was in the public interest with significant positive impact. The Delegation expressed its hope that the SCP would be able to further strengthen its research and focus on the difficulties faced by developing countries in transfer of technology, seek solutions in promoting technology transfer, and to form operational rules for the promotion of technology transfer. The Delegation stressed that there was a unique advantage of discussing the issue and encouraged the SCP to continue its work in that regard.

177. The Delegation of the United States of America supported the statement made by the Delegation of Japan in their national capacity on the topic. The Delegation stated that the enabling disclosure in exchange for receiving exclusive rights was part of the bargain of the patent system. The Delegation stated that the disclosure allowed the public to learn about the most recent technical developments and freely use the teachings after the expiration of the patent. The Delegation continued that, if an invention was not sufficiently disclosed, the public might not be able to derive the benefits intended by the patent system. The Delegation stated that from the patent examination point of view, if an invention was not sufficiently disclosed under the patent law of most jurisdictions, including its own, a patent might not be granted. Referring to documents SCP/22/4, entitled "Study on the Sufficiency of Disclosure", the Delegation stated that the document addressed the important questions that arise when evaluating the requirements for enablement, claim support, and written description, and provided a thorough analysis of the issues. Further, the Delegation agreed with the view stated in paragraph 31 of that document, which stated "[s]ince the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features should be given, but the description must disclose any feature essential for carrying out the invention in sufficient details to render it apparent to the skilled person how to put the invention into practice without undue burden or experimentation and without needing inventive skill." The Delegation also agreed with paragraph 44 of the document which stated "[i]n general, the term "a person skilled in the art" refers to an ordinary skilled person who has good knowledge and specialization in the relevant field but who is not necessarily an expert in the field. This allows for a simplified description since it can be assumed that the reader will be an informed reader having the background knowledge which makes it unnecessary to describe every basic detail of the invention." The Delegation concluded that, in view of the work on the

topic of the sufficiency of disclosure, the Delegation did not support any additional work to be carried out on it. In addition, regarding the work on the topic of technology transfer in general, the Delegation agreed with those delegations which had stated that such work should take place in the CDIP.

AGENDA ITEM 10: PROPOSAL OF THE GROUP OF COUNTRIES OF LATIN AMERICA AND THE CARIBBEAN (GRULAC) ON THE REVISION OF THE 1979 WIPO MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS

178. The Delegation of Paraguay, recognizing that no consensus on its proposal had been reached, stressed that the essential element of the proposal was legislative assistance and training. The Delegation stated that, in that context, its Group was exploring alternative proposals, which it wished to raise in the framework of informal consultations.

179. The Delegation of Senegal, speaking on behalf of the African Group, supported the GRULAC's proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions which would take account of changes which had occurred in patent law since 70s, particularly due to the entry into force of the TRIPS Agreement in 1995. The Delegation was interested to hear the alternative proposals considered by GRULAC.

180. The Delegation of Estonia, speaking on behalf of the EU and its Member States, recalled that the topic had not been on the work plan of the SCP. The Delegation reiterated that tailor-made and demand-driven technical assistance had been already being provided by the Secretariat along the lines of the Development Agenda recommendations. The Delegation stressed that the Secretariat's technical assistance took into account country-specific needs and situations in a much more comprehensive manner than would be possible by applying the Model Law. The view of the Delegation was that, by revising the Model Law a "one size fits all" approach would be promoted. The Delegation noted that no convincing arguments for such revision had been presented and thus there was no need to further discuss the proposal. In conclusion, the Delegation emphasized that the SCP should not attempt to interpret the provisions of the TRIPS agreement.

181. The Delegation of Japan, speaking on behalf of Group B, underlined that the discussion on the topic was unproductive and adversely affected the balance of the work program, since the topic was not part of the five subjects forming the body of the agenda. The Delegation recognized the importance of the legislative assistance provided to developing countries by the Secretariat for the purpose of establishing or improving patent systems in those countries. The Delegation continued that, WIPO's assistance was very important in order to have a patent system that functioned as a driving force for innovation and economic development. In its view, rather than one-size-fits-all model, a tailored approach of legislative assistance was more comprehensive and effective, based on the circumstances, needs, priorities, and development level of individual countries. The Delegation stated that such approach would also comply with the Development Agenda recommendation 13 on the features of WIPO's legislative assistance. The Delegation further noted that there was no indication that such legislative assistance by WIPO to individual Member States had been inadequate or unavailable. The Delegation stated that, in addition, there was a wealth of information on the national patent system that countries could use, such as WIPO Database on Flexibilities in the Intellectual Property System, which provided information on Member States' provisions on exhaustion of rights, research exceptions, compulsory licenses and government use, patentability or exclusion from it. In the view of the Delegation, should the discussions were taken forward, a revision would lead to substantive harmonization of patent laws, which it suspected was not the intention of the proponents of revising the Model Law. Noting that the revision of the Model Law would be a normative exercise, the Delegation wished to stress that the Committee had agreed that the

work of SCP would not be of a normative nature. The Delegation continued that if the SCP would agree to continue the normative work with the Model Law as an outcome, a Substantive Patent Law Treaty could also be another outcome. Noting that the resumption of harmonization was clearly in line with the mandate of the SCP, the Delegation reiterated its readiness to revert to normative mandate of the SCP and commence the normative work. However, the Delegation understood that the other Groups did not share that interest. In addition, the Delegation noted that a revision of the Model Law would likely involve significant resources of the Secretariat.

182. The Delegation of Georgia, speaking on behalf of the CEBS Group, aligned itself with the statement made by the Delegation of Estonia on behalf of the EU and its Member States in respect of the GRULAC's proposal to revise the 1979 WIPO Model Law for Developing Countries on Inventions. The CEBS Group wished to stress that it was not in favor of discussing the document as it would create an imbalance in the SCP discussions not being the part of the five main topics agreed by the Committee. Additionally, the Delegation considered that the Secretariat had already provided tailor-made and demand-driven technical assistance under the Development Agenda recommendations.

183. The Delegation of Iran (Islamic Republic of) was of the view that after the adoption of the Development Agenda recommendations for WIPO's technical and legislative assistance, and in order to ensure that developing countries were able to fully utilize available flexibilities in an updated manner, the revision of the 1979 WIPO Model Law for Developing Countries on Inventions was a required exercise for Member States and the Organization. The Delegation expressed its belief that such a revision should be fully development-oriented and should provide the legislative and policy options for developing countries to fully utilize the flexibilities. The Delegation reiterated its support for the revision of the Model Law and looked forward to the informal consultation where the alternative proposals would be discussed.

184. The Delegation of China stated that the revision of the Model Law could provide practical policy and legal assistance to developing countries, which would be within the mandate of the SCP. Such a revision, the Delegation stated, would also be a useful attempt to advance the work of the SCP. The Delegation recommended the SCP to listen to all Member States' needs, especially developing countries' needs regarding the Model Law so that it could form a basis for future work and revision. The Delegation noted that the provisions of the future Model Law would not necessarily be a one-size-fits-all approach, and the various provisions might be optional, allowing countries to implement it in accordance with their national circumstances.

185. The Delegation of Indonesia supported the proposal by GRULAC to revise the 1979 WIPO Model Law for Developing Countries on Inventions, and noted the importance of continuing the discussions on the issue. Specifically, the Delegation noted that such a revision would be a useful exercise and should be development-oriented as well as in line with the Development Agenda recommendations. In addition, the revision of the Model Law would provide legislative and policy options for developing countries to fully utilize the TRIPS flexibilities. The Delegation wished to stress that such a revision should take into account the differences in the level of development and avoid substantive harmonization approach. The Delegation stated in conclusion that, in principle, it welcomed the proposal by GRULAC that the request to revise the Model Law be directly addressed to the Secretariat.

186. The Delegation of Brazil aligned itself with the statement made by the Delegation of Paraguay on behalf of GRULAC. The Delegation did not agree with those views which stated that the discussion of the revision of the Model Law would create imbalance in the work of the Committee. In its view, on the contrary, such discussions would bring more balance to it.

187. Following some discussions and consultations with the regional coordinators and Member States, the Committee decided that, as the final deliberation of the proposal by GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions (document SCP/22/5), the Secretariat would organize, at the next session of the SCP, an informative session on legislative assistance in the field of patents and related capacity building.

AGENDA ITEM 11: FUTURE WORK

188. The Delegation of Georgia, speaking on behalf of the CEBS Group, stated that the agenda of the Committee was, on the one hand, mix of the important and complex issues of the international patent system, but on the other hand, it reflected the priorities of different regional Groups. The Delegation recognized that Member States had a complex task ahead in order to retain the delicate balance. The Delegation stated that its Group attached a great importance to the issue of quality of patents and it believed that the issue was at the core of the patent system. The Delegation stated that the high quality patents would enable the intellectual property to fulfil its functions and that the work sharing exercise was one of the instruments for the patent offices to facilitate high quality patents and help them to improve the efficiency of examination process. The Delegation was convinced that the work in that direction would benefit all Member States. In respect of the topic on confidentiality of communication between clients and their patent advisors, the Delegation wished to continue work and see advancement on the recognition of foreign patent advisor's privilege through a soft law instrument, and it welcomed studies in relation to that topic. The Delegation also welcomed continuation of discussions on the topic of exceptions and limitations to patent rights taking into consideration that the balance between the interests of right holders and the general public was maintained. In relation to the future work on patents and health, the Delegation could only discuss the balanced approach as it was reflected in the proposal put forward by the Delegation of the United States of America in document SCP/17/11. As regards the transfer of technology, the Delegation was in favor of avoiding any duplication in discussing the issue in the CDIP and SCP. The Delegation was ready to continue deliberations on the five main core topics under the agenda.

189. The Delegation of Paraguay, speaking on behalf of GRULAC, stated that the SCP had a range of various proposals and documents which should be used for the basis of a preparation of a wide-ranging work program or at least to reach agreement on specific activities to be undertaken under the various agenda items. The Delegation stated further that, at the current session, it had listened to new proposals being tabled on the various issues which should be examined in a constructive spirit, with flexibility and a realistic viewpoint. The Delegation stated that on the topic of exceptions and limitations to patent rights, it supported the proposal by the Delegation of Brazil, contained in document SCP/14/7, and the development of a non-exhaustive manual on the subject. On the topic of patents and health, as a preliminary opinion, the Delegation could assess the proposal made by the Delegation of Brazil concerning the presentation by the MPP. On the issue of the transfer of technology, the Delegation remained open to the exploration of specific proposals made in the course of that session.

190. The Delegation of Estonia, speaking on behalf of the EU and its Member States, stated that the current work program contained significant and complex topics of the international patent system, while at the same time reflecting a balance of priorities of different regional Groups. The Delegation noted that in order to take the SCP's work forward, it was of utmost importance to retain that delicate balance. The Delegation further listed the priorities of the EU and its Member States regarding future work. In particular, the Delegation attached a considerable importance to advancing work on the issue of quality of patents. The Delegation remained convinced that investing time on that issue was beneficial to all Member States, as it could enhance international cooperation and improve the knowledge of patentability

requirements, thus ensuring a more efficient, effective, and higher quality patent system. The Delegation appreciated interesting and fruitful sharing session held during the previous SCP sessions as well as several good proposals on the table regarding work sharing, assessment of inventive step and improving the quality of search and examination. Regarding the future work on the topic, the Delegation stated the following: a study on inventive step and the evaluation methods used in the WIPO Member States, as proposed by the Delegation of Spain in document SCP/23/4, would allow for the improvement of understanding of the requirement. On work sharing programs, the Delegation thanked the Secretariat for maintaining and updating a dedicated page on the WIPO website for work sharing activities which would improve awareness of existing initiatives and enable patent offices to collaborate more efficiently. On that point, the Delegation also added that annual conferences on the margins of the SCP sessions would allow for the sharing of experiences on work sharing programs and explore ways to improve the usefulness of those programs to IP offices, users of the IP system, and the general public, as suggested in document SCP/20/11 Rev. The Delegation also supported a study to be undertaken by the Secretariat on how different laws and practices limit the potential for work sharing, and what voluntary measures could be put in place to address any problems at the international level. The study could identify areas where initiatives could be undertaken to improve the efficiency and quality of the patent system. The Delegation also welcomed the discussions on other key aspects of substantive patent law in relation to quality of patents. Regarding the topic of confidentiality of communication between clients and their patent advisors, the Delegation remained committed to continuing work on the issue, as convergence of differing provisions would be of benefit to users of the patent system. The Delegation stated that the time was ripe to address the recognition of foreign patent advisor's privilege through a soft law instrument and it also welcomed further studies on that topic. Further, the Delegation expressed its readiness to continue discussions on exceptions and limitations to patent rights. In that context, the Delegation emphasized the utmost importance of striking an appropriate balance between work on exceptions and limitations to patent rights and on the legal standards used to determine whether an invention was patentable, such as novelty, inventive step, and industrial applicability. The Delegation underlined that those two topics were closely interlinked, and that an appropriate balance between the interests of rights holders and the general public should be maintained. The Delegation noted that, in the past, sharing sessions on case studies had proved to be a useful source of knowledge and understanding of that topic. While noting the interest of developing countries and LDCs to maintain the topic of patents and health in the work of the Committee, the Delegation emphasized that the mere existence of IP rights on a product was not a barrier to, nor its absence a guarantee of, access to that product. Therefore, the opinion of the Delegation was that the possible future work on patents and health should reflect a balanced approach and could, for instance, draw inspiration from the proposal made by the Delegation of the United States of America, contained in document SCP/17/11 and the proposal by the Delegation of Canada, contained in document SCP/26/6. The Delegation continued by stating that, similarly, possible further activities of the Committee in relation to the transfer of technology should be balanced, objective, and considered in light of many examples of the benefits of the patent system to technology transfer. The Delegation remained committed to consider any proposals to deepen the understanding of the impact of patent disclosure on transfer of technology, and confirmed its suggestion to update the existing WIPO web page on transfer of technology. Further, the Delegation suggested carrying on discussions on the basis of the five main topics in the agenda. The Delegation did not support the discussions on the 1979 WIPO Model Law for Developing Countries, as that exercise would take the SCP away from a balanced work program reflecting different regional priorities. Furthermore, the Delegation wished to emphasize that the Committee should not engage in interpretation of provisions of the TRIPS Agreement. In conclusion, the Delegation stated that it remained committed to discussing key aspects of substantive patent law, with the aim of international patent law harmonization.

191. The Delegation of Japan, speaking on behalf of Group B, stated that any future work with respect to exceptions and limitations to patent rights should be conducted in a balanced manner, shedding light not only on the interest of general public but also on the interest of the right holders. In addition, the Delegation stated, any possible future work should be based on the extensive documentation elaborated by WIPO, and the outcome should be factual and should not be prejudged. In the view of the Delegation, creation of any manual, handbook or prototype would prejudice the outcome and represent a one-size-fits-all approach, and therefore was not acceptable. The Delegation noted that the use of exceptions and limitations should be judged on a case-by-case basis. With respect to agenda item on quality of patents, the Delegation looked forward to further work on substantive issue, and wished to see a further study by the Secretariat on the assessment of the inventive step, based on the proposal made by the Delegation of Spain in document SCP24/3. With respect to work sharing and collaboration activities, the Delegation stated that its Group continued to believe that, given the importance of such activities to many Member States, their further discussion and exchange of views would be valuable. The Delegation highlighted the proposal contained in document SCP/20/11 Rev. for an annual work sharing event. The Delegation noted that the event would be a productive forum for sharing experiences on best practices and would also allow participants to identify ways to increase the usefulness of work sharing and collaboration programs. Further, the Delegation noted that some delegations had expressed concerns on how to define the quality of patents. In that regard, the Delegation found the responses to the questionnaire as a positive step towards finding such a definition, and welcomed further discussion on that point by incorporating the questionnaire in document SCP/18/9, possibly in the form of a seminar at the following session of the SCP. The Delegation stated further that finding the definition of the term “quality of patents” was useful but not essential to working on quality. In the view of the Delegation, it was important not to just talk about the definition of quality itself, but to consider the best possible ways to enhance the quality from various points of view. The Delegation therefore reiterated that the future work in that area should also incorporate the questionnaire set out in document SCP/18/9. With respect to the agenda item on patents and health, Group B considered that before undertaking a new study in the SCP, there should be an inventory of studies and analyses produced by other organizations of the United Nations and multilateral fora in order to avoid unnecessary duplication with already existing work. The Delegation believed that the WIPO Secretariat, utilizing the existing collaborative relationship with the WHO and WTO, would be well placed to conduct such inventory of studies. In that regard, the Delegation noted that the trilateral study of WIPO, WTO, and WHO entitled “Promoting Access to Medical Technologies and Innovation”, could serve as the basis for productive discussions. The Delegation stated that Group B wished to consider that issue in a holistic manner, including other related proposals such as those contained in document SCP/17/11. While noting paragraph 56 of document SCP/26/5, the Delegation stated that its Group was of the view that the suggested approach provided an incomplete look at the patent system: flexibilities were one of the possible tools that were appropriate as part of an effective regime for patent protection. Group B was of the view that only a balanced approach would bring the Committee forward. Further, the Delegation commended on the specific elements of the African Group proposal, contained in document SCP/24/4. In particular, the Delegation stated that the proposal contained elements which were outside the mandate of the Committee. Specifically, the Delegation stated that paragraph 12 of the proposal, additional incentives needed to improve research on Anti-Microbial Resistance (AMR), lied outside the patent system. With respect to paragraph 14 of the proposal, the Delegation noted that UNHLP Report had not been a Member State-driven process, had not reflected the opinions of the Member States and had not been endorsed by the Member States. While Group B was open to discuss access to medicines in a holistic manner and in accordance with the mandate of the SCP, the Delegation stressed that the Report should not constitute the basis for that discussion. It was important for the Delegation that any discussion would take into account the wide range of views and factors affecting access to medicines. With respect to paragraph 15 of the proposal, the Delegation stated that the UN Special Rapporteur had a different mandate and

parameters that would be inappropriate for a discussion at the SCP, which was a technical body. Therefore, paragraph 15 of the proposal was not acceptable to the Delegation. Turning to paragraph 16 of the proposal, the Delegation stated that discussion on compulsory licensing should take into consideration the broader objectives of the patent system. A workshop focusing on compulsory licensing would lead to unbalanced discussions, particularly since the issue of exceptions and limitations to patent rights were already on the SCP agenda. With respect to paragraph 20, the Delegation noted that WIPO and other intergovernmental organization had already been providing robust technical assistance to Member States. The Delegation also stated that the recent reports of the different international organizations to the TRIPS Council provided an extensive list of already existing initiatives. The Delegation noted that it was not aware of complaints regarding the inadequacy or unavailability of WIPO on the technical assistance area. Regarding the issue of confidentiality of communications between clients and their patent advisors, the Delegation believed that court cases in different national legal systems in the field of the confidentiality of communications would provide resourceful materials for Member States and would contribute to discussions. Recognized that different opinions had been presented around the issue in the previous sessions, the Delegation invited all Member States, particularly those opposing further work, to approach the problems and/or difficulties they saw in conducting that work in a more objective and precise manner to foster discussions of what could be accomplished. For example, the Delegation suggested that a study based on a questionnaire could be carried out. The Delegation also stated that the study of the collection of court cases should be continued allowing Member States to submit relevant court cases. Regarding the agenda item on transfer of technology, Group B believed that the Committee should not consider future work relating to transfer of technology in general; rather the CDIP should remain the only platform to discuss the issue. Finally, with respect to the revision of the Model Law, the Delegation reiterated that the topic was not part of the five subjects forming the body of the agreed balanced agenda and that the continued discussion on the topic would be unproductive and adversely affect the balance of work program. With respect to the new approach on technical assistance stated by GRULAC, the Delegation expressed its appreciation of the constructive approach and remained ready to engage in the discussion.

192. The Delegation of Senegal, speaking on behalf of the African Group, reiterated that its priority was on the issue of patents and health, and specifically on the activities contained in its proposal (document SCP/24/4). The Delegation recalled that its preference was in organizing a half-day information exchange with the United Nations Special Rapporteur on the Rights to Health to present his report on Intellectual Property Rights and Access to Medicines. As regards the transfer of technology, the Delegation stated that there were three proposals on the table. The first proposal was to carry out a detailed study by independent experts on the relationship between the patent system and transfer of technology. The second proposal was related to the study on the sufficiency of disclosure and how the insufficient disclosure might limit technology transfer towards developing countries. And the third proposal was on the policy initiatives on patents which were necessary to promote the transfer and dissemination of technology for developing countries and LDCs, including the implementation of rights and obligations to understand the use of flexibilities provided for in the TRIPS Agreement. In addition, the Delegation expressed its support to the proposal made by the Delegation of Brazil on conducting a study on the role of IP in agriculture and the food system. As far as exceptions and limitations to patent rights were concerned, the African Group endorsed the continuation of the work towards the third element of the proposal by the Delegation of Brazil, i.e., the development of an exceptions and limitations manual. In conclusion, the Delegation stated that its Group did not favor continuing discussions on the issue of confidentiality of communications between clients and their patent advisors, and, in general, any attempt to harmonize the patent system.

193. The Delegation of Iran (the Islamic Republic of) stated that patents and health was its priority, since it affected directly the basic human right to access to medicine. The Delegation supported the proposal made by the African Group, and hoped to see some elements of that proposal to be included in the future work. The Delegation further stated that having information exchange with the participation of WHO and co-chairs of the UNHLP, and exchange of national experience regarding the use of public health flexibilities was one of other preferences of the Delegation. On the issue of exceptions and limitations to patent rights, the Delegation was in favor of seeing the third phase of the proposal of the Delegation of Brazil to be included in the future work. On the issue of the transfer of technology, the Delegation urged the Secretariat to continue analyzing the relationship between the requirement of sufficiency of disclosure and the transfer of technology, and to prepare a study on the relationship between patent system and technology transfer to identify possible difficulties faced by developing countries in the promotion of technology transfer. With regard to the GRULAC proposal, the Delegation expressed its hope to see some new action-oriented activity. On the issue of quality of patents, including opposition systems, the Delegation wished to see equal prominence and action-oriented activity with regard to the opposition system in the future work.

194. The Delegation of Spain stressed the importance of the SCP as an only multilateral forum on patents and requested the delegations to keep that in mind in discussing the future work. Further, the Delegation expressed its appreciation to the work being produced by the SCP. In particular, the Delegation stated that participants of various trainings organized in some Latin American countries had provided positive feedback on the studies produced by the SCP as they allowed them to get familiarized with the practices in other regions. The Delegation expressed its hope that the SCP would be able to agree on the work of substantive nature for the following session. Specifically, the Delegation stressed the importance of having technical discussions within the SCP, such as on the inventive step requirement. In that regard, the Delegation made the following suggestions: firstly, a study to be carried out by experts from various regions, similarly to the one produced in 2010 regarding the subject of exceptions and limitations to the rights, which had been coordinated by Professor Bently from the University of Cambridge. Secondly, the Delegation wished to have a compilation of information on the practices of various offices on the assessment of inventive step requirement. Thirdly, the Delegation wished to have exchange of experiences by different Member States on the inventive step requirement, on the basis of which the SCP would produce a document. Finally, the Delegation called the attention of delegations to the fact that patent examiners from various offices wish to have something useful for their daily work which would reflect the practices of different regions.

195. The Delegation of Mexico stated that the SCP agenda had various issues that reflected the interest of all members of the Committee. The Delegation agreed with the Delegation of Spain that, for patent examiners it would be useful to know the practices of other offices in various areas of their work. Therefore, the Delegation suggested organizing the sharing sessions on different topics on the agenda. The Delegation was ready to share its own experience in the areas of quality of patents and patents and health. In addition, the Delegation welcomed the proposal by the Delegation of Brazil to invite the representative of the MPP to make a presentation on its database.

196. The Delegation of China attached great importance to the role of SCP as the only multilateral forum in the field of patents. The Delegation stated that the topics discussed by the SCP included important issues in the patent system, reflecting the different concerns and needs of the Member States. The Delegation recommended that the Committee continue to maintain the balance and continue to advance the discussion of the issues. The Delegation expressed its particular interest in the issues of exceptions and limitations to patent rights, patents and health, and transfer of technology, among others. In the view of the Delegation, those issues were important to ensure the balance of the patent system. As regards the other topics, the Delegation was also willing to participate actively in the discussions. In addition, the Delegation

stated that, although it believed that the SCP was not the best forum to discuss the issue of confidentiality of communication between clients and patent advisors, it was willing to show maximum flexibility and listen carefully to the concerns expressed by advocates. The Delegation expressed its hope that the SCP could make strides of the current agenda items and help Member States understand the practices of other Member States and commonly promote the continuous improvement and refinement of the patent system.

197. The Delegation of Brazil stated that it came to that session with a constructive spirit and with a goal of helping to move discussions forward on many issues. Therefore, the Delegation did not hesitate to show approval or appreciation for various ideas which were in line with its views. The Delegation expressed its belief that it was possible to make progress on many topics on the agenda. The Delegation looked forward to engaging with other delegations to ensure that the future work of the SCP reflected a broad range of interests and views. To help in that effort, the Delegation wished to recap some of its proposals. Specifically, the Delegation reiterated that on the topic of patents and health, it had suggested the presentation by MPP on their database. Further, while reaffirming its full support to the African Group proposal, the Delegation wished to make it clear that such support did not affect its appreciation for the proposal by the Delegation of Canada. On the issue of exceptions and limitations to the rights, the Delegation wished to see its proposal on the production of a non-exhaustive manual reflected in the future work of the Committee. Finally, with regard to the issue of transfer of technology, the Delegation wished to work on three topics: collaborative and open innovation, sufficiency of disclosure, and the role of IP in agriculture and the food system.

198. The Delegation of the United States of America stated that, in addition to its proposal on the study on work sharing, contained in document SCP/23/4, it was also interested in the other previous proposals it had made on the topic of quality of patents. Specifically, the Delegation referred to the proposals contained in documents SCP/17/10, SCP/20/11 and SCP/19/4. As regards the topic of patents and health, the Delegation reiterated its proposal contained in document SCP/17/11, which was essentially directed to looking at other reasons why medicines might not be accessible in some countries, as well as at the positive impact of the patent system on the availability of medicines in those countries.

199. The Delegation of the Russian Federation emphasized the great importance of achieving a consensus on the future work of the Committee. Further, the Delegation briefly highlighted the main areas that should be included in the future work. On exceptions and limitations to patent rights, the Delegation supported the proposal by the Delegation of Brazil on the preparation of a non-exhaustive manual on that topic. On the issue of quality of patents, including oppositions systems, the Delegation supported the continuation of the discussion in all aspects of the quality of patents. The Delegation was also of the view that particular focus should be placed on the issue of opposition systems. The Delegation was also interested in studying the issue of the ISO certification, as it had expressed during the discussion on that agenda item. On the issue of patents and health, the Delegation expressed its support to the proposal by the Delegation of Spain on the study of inventive step requirement. The Delegation further expressed its support to the exchange of experiences and court cases on the issue of confidentiality of communications between clients and their patent advisors. In its view, the soft-law approach would be appropriate. Finally, on the issue of transfer of technology, the Delegation supported the continuation of discussion within the Committee.

200. The Delegation of Canada, on the issue of patents and health, remained interested to further discuss its proposal contained in document SCP/26/6.

201. After some consultations conducted by the Chair, the Committee decided on its future work as follows:

- The non-exhaustive list of issues will remain open for further elaboration and discussion at the next session of the SCP.
- Without prejudice to the mandate of the SCP, the Committee agreed that its work for the next session be confined to fact-finding and not lead to harmonization at this stage, and would be carried out as follows:

Exceptions and Limitations to Patent Rights

- The Secretariat will prepare a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection, which will contain the following elements for each exception and limitation: (i) the description of the exception and limitation; (ii) its objectives and goals; (iii) national/regional implementation; (iv) challenges faced by Member States in its implementation; and (v) results of its implementation. The Secretariat will make use of all information available from the SCP activities. As a first step, the draft reference document will cover the exception regarding acts for obtaining regulatory approval from authorities, and will be submitted to SCP/27. The Secretariat will invite Member States to send any additional inputs for the preparation of the draft reference document.

Quality of Patents, including Opposition Systems

- The Secretariat will update a summary of the responses to the Questionnaire on the Term “Quality of Patents” and Cooperation between Patent Offices in Search and Examination, taking into account the additional responses to be submitted by Member States and regional patent offices.
- With a view to preparing a further study on inventive step to be submitted to SCP/28, a sharing session will be held on further examples and cases relating to assessment of inventive step, giving a particular attention to the topics suggested in paragraph 8 of document SCP/24/3 (Proposal by the Delegation of Spain).
- The Secretariat will continue to update and present the webpage on opposition and administrative revocation mechanisms, based on inputs received from Member States and regional patent offices [http://www.wipo.int/scp/en/revocation_mechanisms/].
- A half-day information exchange session on cooperation between patent offices in search and examination will be held. The session will address, among other issues, the effects of such cooperation on the patent granting process and capacity building.

Patents and Health

- The Secretariat will supplement the study (document SCP/26/5) with inputs from members and observers of the SCP with respect to the constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs.
- A half-day information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines will be held. The Chair will invite a representative of the WHO to make a presentation on this topic and a representative of

the Medicines Patent Pool (MPP) to make a presentation on its Medicines Patents & Licenses Database (MedsPaL). The session will address, among other issues, practical utilization of those databases and the issues addressed in paragraphs 18 and 19 of document SCP/24/4 (Proposal by the African Group for a Work Program on Patents and Health).

- The Secretariat will update the feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and patents (document SCP/21/9), to be submitted to SCP/28.
- A sharing session among Member States on patents and other related issues on access to medicines will be held. The Secretariat will invite experts from the WHO and WTO to present the issues regarding the availability of generic medicines in developing countries and LDCs.

Confidentiality of Communications between Clients and Their Patent Advisors

- A sharing session on the experiences of Member States in implementing the confidentiality of communication between clients and their patent advisors through national legislation, including cross-border issues will be held.

Transfer of Technology

- A sharing session on patent law provisions that contributed to effective transfer of technology will be held.

AGENDA ITEM 12: SUMMARY BY THE CHAIR

202. The Chair introduced the Summary by the Chair (document SCP/26/7 Prov.).

203. The Summary by the Chair was noted by the Committee.

204. 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 on by the SCP during 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, during its following session.

AGENDA ITEM 13: CLOSING OF THE SESSION

205. The Secretariat congratulated the Chair for her efficient and skillful conduct of the meeting and commended the hard work of all delegations. It thanked the Chair for her outstanding work and wished the delegations safe journey home. It expressed his willingness to see them all again in December at the next session of the SCP.

206. The Delegation of Paraguay, speaking on behalf of GRULAC, thanked the Chair for the work carried out under her leadership, which had enabled the Committee to achieve a positive result. It stated that GRULAC had made constructive comments on the various topics of its interest, and noted that concrete work on three areas of exceptions and limitations and patents and health had been decided upon. With regard to transfer of technology, the Delegation

expressed its hope that, in the future session, the Committee would come up with greater options for work on that key area for innovation. With regard to the revision of the Model Law, GRULAC felt that an informative session on legislative assistance in the field of patents and related capacity building would provide greater clarity to Member States when they put forward their requests for support and cooperation to the Secretariat. In its view, it would facilitate the provision of technical assistance, which would enable Member States to adapt their laws and regulations on patent matters in a manner that would facilitate the spread of knowledge and innovation. The Delegation further welcomed the dedication and professionalism of the Secretariat.

207. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, thanked the Chair and the Vice-Chairs for their advice and guidance as well as the Secretariat and all the interpreters, for their hard work and efforts. The Delegation also commended all delegations for their flexibility and constructive spirit shown during the meeting. The Delegation expressed its delight that all Regional Groups and Member States had managed to build a consensus and had agreed on the future work that was balanced and served as a good basis to guide the Committee's work in the upcoming session. Acknowledging the fact that the issues facing the Committee were challenging, the Delegation stated that it was important to constantly remind itself that the SCP had been created in 1998 to serve as a forum to discuss issues, facilitate coordination and provide guidance concerning international development on patent law by dealing with interlocking issues rather than on a single issue in the isolated manner. In its opinion, the WIPO mission was to lead the intellectual property system that enabled innovation for the benefit of all, including the development objectives that constituted important factors of a balanced and effective international system. The Delegation wished the delegations best wishes for their future and for the future of the Committee.

208. The Delegation of Indonesia, in its national capacity, conveyed its sincere appreciation to the Chair and Vice-Chairs for their able leadership as well as to the Secretariat and the interpreters for their hard work. The Delegation further expressed its sincere gratitude to all Regional Coordinators and Member States for their constructive engagement. The Delegation welcomed the future work agreed by the Committee. It noted that, although it was not as ideal as it had proposed, in the spirit of flexibility, the Delegation could live with it. While the Delegation supported and endorsed the future work, it wished to put on the record its attention to the UNHLP Report published in 2016. The Delegation was still of the view that the UNHLP Report and the SCP focused on the same issues as regard patents and health. Therefore, in its opinion, it was critical that the recommendations of the UNHLP Report would constitute the basis of further discussions on patents and health in the Committee, including the recommendation that governments should track national law in a way that it would expand the use of compulsory licenses or government use of a patent for noncommercial purposes, including the criteria to determine the remuneration for the right holder.

209. The Delegation of Senegal, speaking on behalf of the African Group, expressed its gratitude to the Chair for her commitment and professionalism. The Delegation also thanked the Vice-Chairs and the Secretariat, who had not spared any effort to ensure that the twenty-sixth session of the SCP be crowned with success. The Delegation particularly welcomed the positive contributions from the various delegations which showed a constructive spirit of consensus and commitment throughout the week. The African Group hoped that that spirit would continue in all of the other Committees of WIPO. The Delegation stressed the importance of patents and health, and particularly the African Group proposal contained in document SCP/24/4. Even though not all of its proposals had been taken up in the future work, the African Group supported the program of future work in the spirit of compromise. The Delegation stated that it would await with interest the implementation of the future work. In addition, the Delegation reiterated the importance it attached to the work around exceptions and limitations and transfer of technology. The Delegation was pleased that the Committee had

come up with a balanced and highly valuable program of work. In conclusion, the Delegation congratulated the Chair and the Vice-Chairs as well as the Secretariat, and expressed its gratitude for the interpretation service throughout the meeting.

210. The Delegation of Georgia, speaking on behalf of the CEBS Group, thanked the Chair for her excellent work and skillful guidance, which had led to the outcome of the session. The Delegation also thanked the Secretariat for invested efforts in the preparation of the session, and all Regional Coordinators and Member States for their openness and the constructive spirit to advance the challenging exercise. The Delegation congratulated all with the positive outcome and looked forward to continuing deliberations in the next session of the SCP with the approved future work with greater enthusiasm.

211. The Delegation of Iran (Islamic Republic of) thanked the Chair and the Secretariat for the smooth handling of the session. The Delegation emphasized the importance of the agreement reached after several sessions of debates and negotiations on future work. The Delegation also appreciated the constructive engagement of all delegations in the course of the Committee's deliberations. In its view, the success owed to the joint efforts by all. It hoped that such a positive atmosphere prevail at all future meetings.

212. The Delegation of Japan, speaking on behalf of Group B, congratulated the Chair and the Secretariat on the positive outcome. The Delegation welcomed the successful outcome on future work. The Delegation was very pleased that during its twenty sixth session, the Committee had had useful technical discussions which had enabled delegations to better understand substantive issues. The Delegation therefore looked forward to the technical discussions during the future sessions as well. Regarding the agenda item 10, the Delegation stated for the record that Group B had accepted the GRULAC's alternative proposal, based on the understanding that the discussion on that item would come to close. The Delegation thanked all Regional Coordinators and Member States for their tireless efforts, especially during the informal consultations, and stated that Group B would work constructively in future sessions.

213. The Delegation of Estonia, speaking on behalf of the EU and its Member States, congratulated the Chair for taking the work of the Committee forward. It noted that her contribution was especially significant on the topic of future work of the SCP. In its opinion, the Chair's draft had incorporated the various proposals and the different positions of WIPO Member States in a balanced and forward looking manner. The Delegation added that, for future sessions, it recommended that informal consultations be as inclusive as possible and involve all major stakeholders to represent the views of Member States. The EU and its Member States considered the twenty-sixth session of the SCP successful, as the Committee had had interesting discussions on the five main topics on the agenda of the SCP and the new proposals had been made, explained and discussed. The Delegation welcomed further discussions based on the existing proposals relating to quality of patents, and remained committed to advancing the work of the Committee under the agreed work program. The Delegation was glad that the Committee had reached a consensus on its future work. It reiterated the considerable importance it attached to advancing work on the quality of patents. The Delegation welcomed the decision of the Committee to have a sharing session at the subsequent session of the SCP on examples and cases relating to assessment of inventive step, and to give particular attention to the topics suggested in the proposal of Spain contained in document SCP/24/3. The Delegation believed that the sharing session could be helpful in preparing a study on inventive step for the twenty-eighth session of the SCP. The EU and its Member States looked forward to making a contribution to that work. The Delegation also welcomed the possibility given to submit additional responses by Member States and regional patent offices to the Questionnaire on the Term "Quality of Patents" and Cooperation between Patent Offices in Search and Examination. The Delegation found the questionnaire and the compilation of answers prepared by the Secretariat helpful in gaining a better understanding of

those topics. In its opinion, contributions from other Member States besides the 57 that had already responded to the questionnaire would increase the weight and value of the outcomes of the questionnaire. Furthermore, the EU and its Member States welcomed the decision to update and present the web page on opposition and administrative revocation mechanism by the Secretariat. The Delegation considered that it would help delegations to enhance understanding on the different models available. On the topic of patents and health, the Delegation welcomed the evidence-based approach of the Committee. In its view, supplementing existing studies with inputs from members and observers of the SCP and holding information and sharing sessions were a good way to work on the topic, as it would enable to have a better understanding on the role of patents in health-related issues, including the many benefits to innovation. The Delegation stated that the EU and its Member States were committed to contribute to those discussions. Regarding the proposal by GRULAC, the Delegation welcomed the alternative approach that had been agreed on. It believed that addressing the problems raised by GRULAC in the form of individual and tailor-made technical assistance would enable the Secretariat to take into account country-specific needs, and thus was more efficient than a one-size-fits-all approach. The Delegation hoped that the informative session help the Member States to understand the various types of assistance provided by WIPO and how those measures could be used to meet their needs. As for the long-term work of the SCP, the EU and its Member States expressed their wish to see more discussions on the issues relevant to harmonization of substantive patent law.

214. The Delegation of Tunisia supported the statement made by the Delegation of Senegal on behalf of the African Group. The Delegation thanked the Chair and all Member States for their constructive commitments in order to enable the Committee to come to the consensus solutions around the various subjects under consideration. The Delegation expressed its satisfaction with the progress the Committee had achieved: the elaboration by the Secretariat of a reference document on exceptions and limitations would have particular importance for all Member States; and the exchange of experiences on quality of patents should enable the delegations to have mutual enrichment and contribute to the improvement of work procedures of patent offices. The Delegation further noted that the future work on patents and health would facilitate the understanding of the issues by the Committee. In its opinion, the agreed future work was concretization of the objectives of the Committee. Before concluding, the Delegation welcomed the efforts by the Secretariat that had contributed to facilitating the work of the Committee.

215. The Delegation of China thanked the Chair for her meticulous work leading to the successful outcome of the meeting, especially during the informal consultations on future work. The Delegation stated that the Chair had done an excellent job with a lot of wisdom, reflecting many concerns and needs of the Member States in the future work. Noting that not all the concerns of all the Member States had been reflected in the future work, the Delegation thanked the Member States for their flexibility shown and the excellent work of the Regional Coordinators. The Delegation was pleased to see that under the leadership of the Chair and Vice-Chairs, the SCP was advancing. In its view, since the SCP was the only forum that discussed patent issues, its role was irreplaceable. The Delegation wished that it would actively participate in the deliberation of future work. Before concluding, the Delegation also expressed its appreciation to the interpreters for their hard work.

216. The Delegation of Brazil stated that the outcome of the twenty-sixth session had been the result of hard and committed work. It thanked the Chair for her wise, fair, and firm guidance. The Delegation also thanked the Secretariat for their outstanding preparation of the session and for their continued support to Member States at all times during the session. The Delegation further expressed its appreciation to other Member States in all regional groups which had

engaged in the discussions constructively and in the spirit of dialogue and flexibility. The Delegation observed that it had learned something new from each and every delegation. It asked the Chair whether there was anything that Member States could do for the Chair to continue chairing the SCP.

217. The Delegation of South Africa aligned itself with the statement made by the Delegation of Senegal on behalf of the African Group. It congratulated the Chair for her efforts in steering the work of the Committee towards the successful adoption of future work. The Delegation also thanked the Chair for the professional and committed manner in which she had presided over the SCP's deliberations. The Delegation further thanked the Secretariat for its tireless efforts in preparing the documents for the meeting. While the adopted work program did not speak to all of its priorities, the Delegation nevertheless believed that the spirit of constructive compromise had prevailed. In its opinion, that was a step in the right direction, which assured that the critical work of the SCP would move forward. The Delegation observed that the implementation of those important outcomes would be supportive of the successful achievement of its national priorities. In particular, the Delegation looked forward to a reference document on exceptions and limitations, discussions and study on inventive step, and the work on patents and health, including part of the African Group's proposal that it fully supported. The Delegation reiterated that South Africa was grappling with those issues, and noted that it would take into account the outcomes of the SCP discussions in formulating its national policy. The Delegation looked forward to the future work of the SCP, and stated that it would continue participating in the activities of the SCP actively. The Delegation believed that the success of the SCP was in the interests of all Member States.

218. The Delegation of Mexico thanked the Chair for her wisdom, and congratulated her on achieving an adoption of balanced future work that included very diverse topics. The Delegation also thanked the Secretariat for all the work it had carried out, particularly with regard to the documents that they had prepared for the meeting. The Delegation observed that those documents had been very useful for it to learn about the diversity of different systems. The Delegation further expressed its appreciation to all Member States for their very constructive attitude, which had enabled the Committee to adopt the future work program and to ensure that delegations would continue sharing experiences and deepening their understanding about different national practices and views. The Delegation expressed its commitment to actively participating in the sharing sessions to be held at the next session of the Committee.

219. The Delegation of Japan, speaking in its national capacity, expressed its satisfaction with the fact that the Committee could reach an agreement on the future work, which had not been possible at the previous session. The Delegation expressed its appreciation to the Chair, the Secretariat, and the delegates from all Member States who had demonstrated their determined effort, patience and flexibility. The Delegation noted that, through the discussion during the session, it had seen a ray of light in the future of the Committee, since there had been several interventions in which it had felt the pure enthusiasm for making patent systems better, setting aside politics. The Delegation hoped that such a positive atmosphere would continue to grow so that future meetings of the SCP would be more constructive and productive.

220. The Delegation of Spain thanked all participants, particularly the Chair and the delegates who had participated in the informal consultations, for their flexible and constructive attitude which had enabled the Committee to achieve the great results on a number of activities.

221. The Delegation of India stated that it should congratulate the Committee for achieving what it had not been able to achieve at the previous session. The Delegation however noted that India would have liked a reference to the UNHLP Report. In the good spirit in the room, the Delegation expressed its wish to take the discussion forward, seeing the possibility of discussing that report in the remits of the future work on patents and health. The Delegation

clarified that it was agreeing to the future work program in that spirit. The Delegation stated that it went along with the future work, and expressed its hope that, in the subsequent SCP session, delegations would be able to bridge their gap. The Delegation observed that there was a big gap among the positions of Member States, especially on the UNHLP Report, which had been politicized. In its view, however, the SCP was a forum where the recommendations of that report should be discussed, as there were specific recommendations for WIPO. The Delegation expressed its hope that it would be able to find ways to discuss those issues without disturbing the political sensitivities in other countries. The Delegation thanked the Chair and stated that the agreed future work program was a welcome step.

222. The Delegation of the United States of America thanked the Secretariat and all of those who had been involved in putting together the meeting and helping to make it a success. In particular, the Delegation thanked the Chair for doing a very nice job in coming up with a balanced and fair result, agreeable to everybody in the end. The Delegation thanked all delegations for their spirit of cooperation and looked forward to more of the same spirit of cooperation in future meetings of the SCP.

223. The Representative of OAPI fully supported the statement made by the Delegation of Senegal on behalf of the African Group. The Representative thanked the Chair, and expressed its gratitude to WIPO for inviting OAPI to the SCP, which was of great importance for OAPI. The Representative appreciated the quality of the documents and the richness of the debate. He also welcomed the spirit of conviviality and wished a long life for international cooperation.

224. The Chair expressed her gratitude for the participation and intervention of every delegation and for its fantastic contributions to the work of the Committee. She also commended all delegations for their commitment and willingness to pursue constructive dialogue. In her view, the maturity within the Committee was demonstrated by the fact that the future work program contained many activities in the field of patents, which were of utmost importance for every economy and for every country. The Chair expressed her satisfaction that she would end her mandate with success. Noting that she had come to the Committee with hope, the Chair stated that she had chaired the SCP with pleasure and with her belief in intellectual property and in patents. She also expressed her gratitude to the Secretariat, with which she was able to work together as a great team. She then thanked the Regional Coordinators for their support and for the delegations who had participated in the informal sessions. She further extended her gratitude to the interpreters for their hard work. She wished a successful completion of the future work, and future endeavor of the Committee. The Chair closed the session.

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

[Annex follows]

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