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Standing Committee on the Law of Patents

Twenty-Fifth Session
Geneva, December 12 to 15, 2016

REPORT

adopted by the Standing Committee

INTRODUCTION

1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its twenty-fifth session in Geneva from December 12 to 15, 2016.

2. The following Member States of WIPO and/or the Paris Union were represented: Algeria, Angola, Argentina, Australia, Bahamas, Belarus, Belgium, Bolivia, Brazil, Bulgaria, Cambodia, Cameroon, Canada, Chile, China, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cyprus, Czech Republic, Denmark, Dominican Republic, El Salvador, Ecuador, Estonia, Finland, France, Gabon, Georgia, Germany, Ghana, Greece, Guatemala, Holy See, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Malawi, Malta, Mexico, Monaco, Morocco, Nigeria, Norway, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Senegal, Serbia, Singapore, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Thailand, Trinidad and Tobago, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uzbekistan, Yemen, and Zambia (85).

3. Palestine was represented in an observer capacity. Representatives of the following intergovernmental organizations took part in the meeting in an observer capacity: African Intellectual Property Organization (OAPI), 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), World Health Organization (WHO), and World Trade Organization (WTO) (9).

4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), Association of Spanish Attorneys before International Industrial and Intellectual Property Organizations (AGESORPI), Centre for International Intellectual Property Studies (CEIPI), Centre for Internet and Society (CIS), Chartered Institute of Patent Attorneys (CIPA), Civil Society Coalition (CSC), CropLife International (CROPLIFE), International Association for the Protection of Intellectual Property (AIPPI), European Law Students' Association (ELSA International), International Chamber of Commerce (ICC), International Federation of Pharmaceutical Manufacturers Associations (IFPMA), Innovation Insights, Institute of Professional Representatives Before the European Patent Office (EPI), Intellectual Property Owners Association (IPO), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Knowledge Ecology International, Inc. (KEI), Médecins Sans Frontières (MSF), Medicines Patent Pool Foundation (MPP), and Third World Network Berhad (TWN) (20).

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/24/6 Prov.2); "Draft Agenda" (SCP/25/1 Prov.); "Report on The International Patent System: Certain Aspects of National/Regional Patent Laws" (SCP/25/2); "Practical Experiences on the Effectiveness of, and Challenges Associated to, Exceptions and Limitations" (SCP/25/3 and SCP/25/3 Add.); and "Compilation of Court Cases With Respect to Client-Patent Advisor Privilege" (SCP/25/4).

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); "Feasibility Study on the Disclosure of International Nonproprietary Names (INN) in Patent Applications and/or Patents" (SCP/21/9); "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 that were 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-fifth session of the Standing Committee on the Law of Patents (SCP) was opened by Mr. Marco Aleman (WIPO), who acted as Secretary.

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

10. The SCP unanimously elected, for one year, Mrs. Bucura Ionescu (Romania) as Chair and Mrs. Diana Hasbun (El Salvador) and Mr. Nafaa Boutiti (Tunisia), as Vice-Chairs.

AGENDA ITEM 3: ADOPTION OF THE AGENDA

11. The SCP adopted the draft agenda (document SCP/25/1 Prov.).

AGENDA ITEM 4: ADOPTION OF THE DRAFT REPORT OF THE TWENTY-FOURTH SESSION

12. The Committee adopted the draft report of its twenty-fourth session (document SCP/24/6 Prov.2), as proposed.

GENERAL DECLARATIONS

13. The Delegation of Chile, speaking on behalf of GRULAC, congratulated the Chair on her election, and thanked the Secretariat for the preparation of the session. The Delegation stated that the work carried out by the Committee was of vital importance for its region, as it allowed for the sharing of ideas and experiences in areas crucial to development. The Delegation further stated that the agenda item on exceptions and limitation to patent rights, which had had the constant support of its Group, focused on carrying out work that allowed to approach, from different perspectives, the importance of the exceptions and limitations in patent law. The Delegation expressed its hope that the sharing session on exceptions and limitations would become an important reference for the Member States, allowing them to learn from the first source concrete examples of their use, as well as the challenges associated with them. The Delegation also expressed its hope that the SCP would continue with those types of exercises, which would provide an analytical view on exceptions and limitations to patent rights as an integral part of the intellectual property system. In addition, the Delegation expressed its support to the proposal by the Delegation of Brazil, contained in document SCP/14/7, discussions on which had provided the SCP with relevant inputs for consideration by the members of the SCP. Taking into account the available inputs, both in the prepared documents and during the subsequent discussions, the Group proposed to develop a non-exhaustive manual on the subject, to serve as a reference to the Members of the Organization. With regards to the agenda item on patents and health, the Delegation stated that the relationship between patents and health was a key aspect that illustrated the delicate balance required for the patent system. The Delegation noted that recent discussions on the subject in international fora demonstrated the renewed interest of Member States, particularly as the difficulties of countries in ensuring the availability of medicines in a sustainable manner remained. The Delegation expressed the hope of its Group for the advancement of the discussion on that topic. With regards to the agenda item on transfer of technology, the Delegation stated that GRULAC considered that the sharing session on the relationship between patent systems and transfer of technology, in particular, the information exchange on the impact of sufficiency of disclosure on transfer of technology, would enable the SCP to highlight one of the core elements for the dissemination of knowledge in developing countries. The Delegation wished to make progress on the study of examples and cases in which the disclosure allowed and facilitated the transfer of

technology, as well as in a way of making such information accessible to the public. Further noting that GRULAC's proposal on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5, had had different reactions from members of the Committee, the Delegation stated that it valued the debate that had taken place on a central issue: the technical assistance provided by WIPO, and the legal materials and models used in training exercises. The Delegation stressed that, being a group of developing countries that issue was of high interest and essential because technical assistance was a central element in the modeling of their systems. Taking the exchange of views held in the sessions of the Committee into account, the Delegation proposed that the review process be not carried out based on the negotiation of terms of reference nor modalities to be approved by the Committee, but that the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, be made in a request directly addressed to the Secretariat. In conclusion, the Delegation stated that for GRULAC, it was essential to continue the work of the Committee. Part of that commitment, the Delegation stated, was reflected in the various proposals it had tabled for consideration. The Delegation reaffirmed the commitment of its Group to advance discussions during the session.

14. The Delegation of Nigeria, speaking on behalf of the African Group, congratulated the Chair and Vice-Chairs on their election. The Delegation stated that the African Group looked forward to a fruitful session. In particular, the Delegation noted that it expected to hold frank discussions during that session on the constraints of the patent system to growth priorities of developing countries and least developed countries (LDCs). The Delegation expressed its hope that the sharing sessions would contribute significantly to the discourse and shed further light on the instrumental role of the patent system in facilitating knowledge and in fostering innovation and technology transfer in a manner that did not depart from the *quid pro quo* nature of the patent system and the international IP structure: enjoyment of exclusive rights in exchange for fostering knowledge, innovation and creativity. The Delegation further stated that, concerning the five but non-exhaustive list of issues on the agenda of the SCP, it looked forward to reaching an agreement on a more ambitious future work program that would be: (i) transparent, balanced and progressive; (ii) aligned with the Development Agenda recommendations; (iii) taking into account the different levels of development of WIPO Member States; and (iv) aimed at fostering a more accessible patent system. The Delegation noted that, as in the past, it placed particular emphasis on the vital subject of patents and health, for which the African Group had submitted an updated proposal (document SCP/24/4) and looked forward to discussing it further. In the same context, the Delegation looked forward to discussing the findings and recommendations of the United Nations High-Level Panel on Access to Medicines, amongst others. Similarly, it looked forward to discussing the subjects of innovation and technology transfer, and exceptions and limitations to patent rights, just as it would engage constructively on the issues of quality of patents, including opposition systems, and confidentiality of communications between clients and their patent advisors. The Delegation stated that the African Group continued to view favorably the proposal by GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions. The Delegation concluded by thanking the Secretariat for the preparation of documents SCP/25/2, SCP/25/3 and SCP/25/4.

15. The Delegation of Indonesia, speaking on behalf of the Asia and Pacific Group, congratulated the Chair on her election and expressed its confidence in her experience and leadership skills. The Delegation also expressed its appreciation for the hard work done by the WIPO Secretariat towards the preparation for the meeting. The Delegation further stated that, even if the Paris Convention and the TRIPS Agreement set minimum international standards of patent protection, the patent laws remained essentially territorial. As a result, 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 of countries with limited resources, the necessary policy space to meet their health needs, and, at the same time, 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 to development, during the twenty-fifth session of the SCP, would provide guidance for improving and further enhancing the efficiency of the current patent system in a manner sensitive to the diverse needs. More specifically, the Delegation stated that document SCP/25/3 provided valuable information on exceptions and limitations which were not being utilized to their fullest extent, despite their presence in most developing countries and LDCs, and the constraints that prevented their optimum use. The Delegation was of the view that the submissions in the aforementioned document clearly indicated the need to ensure that WIPO's technical assistance in designing national patent laws, or national IP strategies, took those constraints into consideration, and WIPO would provide assistance on how developing countries could 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. The Delegation noted that that 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, must involve the United Nations Development Program (UNDP) which had facilitated the preparation of the High-Level Panel Report. Further, the Delegation requested that the Secretariat revise the feasibility study on the disclosure of International Nonproprietary Names (INN) in patent applications and/or patents, and address the question about the feasibility of disclosure of INN in patent applications where the INN was known to the applicant. As regard the opposition systems, noting that the Asia and Pacific Group supported the idea that the SCP should have discussions on that topic, the Delegation 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 system that could comprise a questionnaire or a survey on different kinds of opposition mechanisms available in various countries, the procedures and modalities for their use and constraints in their use, and how much such systems could be strengthened and constrains 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. 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 was implemented in different countries, and how its broader use might promote quality. Turning

to the proposal regarding the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, contained in document SCP/22/5, the Delegation noted that a thorough revision of the Model Law should emphasize legislative and policy options for Member States. The Delegation was of the view that that agenda item by no means was at a lower level of priority and should be given equal importance as the other substantive agenda items within the Committee, even if labelled as "other issues" on the agenda.

16. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, congratulated the Chair and Vice-Chairs on their election. The Delegation also thanked the WIPO Secretariat for its extensive work in preparing for the meeting. The Delegation was pleased with the progress made and positive conclusions reached during the previous session of the SCP to continue discussions on the topics of quality of patents, including opposition systems, confidentiality of communications between clients and their patent advisors, exceptions and limitations to patent rights, transfer of technology and patents and health. The Delegation stated that the program for the coming days reflected the balance between different priorities and that it would provide opportunities for all delegations to make steps forward. Noting that there were four sharing sessions on the agenda of the SCP, the Delegation emphasized the importance of such sessions in general, and expressed its hope that those sessions would provide useful information in relation to challenges and opportunities faced. Further, the Delegation highlighted its areas of interest. In particular, the Delegation stressed that it attached considerable importance to advancing work on the topic of "quality of patents" along the lines proposed by the Delegations of Canada, the United Kingdom, Denmark, the United States of America, and Spain, as endorsed by all other Member States of the European Union, as it believed that work on that topic would be of interest to Member States across the spectrum of development. In addition, the Delegation was keen to continue discussions on the topic of "confidentiality of communications between clients and their patent advisors", as, in its opinion, 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. In that regard, the Delegation stated that the sharing session on that particular topic at the following session of the SCP could help, because it could provide valuable input in view of taking that work forward. Further, the Delegation stated that it also remained committed to discussing key aspects of substantive patent law. In conclusion, the Delegation informed the Committee that the European Union, under its enhanced cooperation procedure, had made significant advances on the European patents with unitary effect. The Delegation noted that the unitary patent would help to attract and retain innovation, talent and investment. In that context, the Delegation continued, the significant advances had also been made on the creation of the Unified Patent Court. The Delegation stated that the unitary patent system would come into effect once the necessary ratifications of the Agreement on a Unified Patent Court had taken place.

17. The Delegation of Turkey, speaking on behalf of Group B, congratulated the Chair on her election. The Delegation stated that its Group supported the work of the SCP and attached great importance to its mandate. The Delegation expressed its hope that discussions on the five agenda items at that session would lead to great success for all participants. In relation to agenda item 11 on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, the Delegation noted that that topic was not part of the five subjects that form the body of the agenda, and underlined that continued discussion on that topic would create a significant and unacceptable imbalance in the SCP discussions. The Delegation expressed its belief that the SCP, a multilateral forum in the field of patents, had a responsibility to provide a venue for technical discussions on issues of substantive patent law, in a manner responding to the evolving real world. Further, the Delegation stressed that the topic of "quality of patents, including opposition systems" was an important aspect of the patent system. The Delegation underlined that international work sharing and substantive patentability requirements, such as inventive step, were important issues to

consider. Recalling that, at the previous sessions of the SCP, national experts from various countries and regions had shared their experiences on the evaluation of the inventive step, which was one of the core patentability requirements, the Delegation observed that Member States had showed great interest in the discussions on that topic. 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 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 the communication between patent advisors and their clients had been extensively discussed in the Committee and those 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. 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.

18. The Delegation of Latvia, speaking on behalf of the Group of Central European and Baltic States (CEBS Group), congratulated the Chair and Vice-Chairs on their election and expressed its confidence in the experienced leadership of the Chair in the work of the Committee. The Delegation also praised the Secretariat for all the efforts invested in the preparation of the session. The Delegation stated that the areas of interest of the CEBS Group lied on the topics of the quality of patents and confidentiality of communications between clients and their patent advisors. As regards the former, the Delegation expressed its belief that it was crucial to continue work on improving the quality of patents. With regard to the latter, the Delegation supported work towards a soft law. The Delegation welcomed four sharing sessions that were foreseen during the week of the SCP, under the topics of exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health, and transfer of technology. The CEBS Group was of the view that all the Member States would benefit from the exchanges of the experiences of the different countries from various regions. Further, the Delegation reiterated its view that the proposal to review the 1979 Model Law for Developing Countries on Inventions might shift the achieved balance of the current agenda. Moreover, in its opinion, that work would lead to the harmonization of the substantive patent law, which was not, for the time being, the objective of the Committee. The Delegation further welcomed the agreement reached during the previous session of the Committee regarding the future work and stated that it was based on five agenda items which accommodated the interests of all Member States and, at the same time, represented a delicate balance. Noting that as 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 future work during the current session. Finally, the Delegation stated that the CEBS Group believed that the SCP should focus its efforts on more substantive discussions in order to enable the experts, who had come to the SCP from capitals, to fully benefit from the exchanges in the framework of that session. Therefore, the Delegation did not support dedication of an excessive amount of time to the discussions on the future work of the Committee.

19. The Delegation of China congratulated the Chair and Vice-Chairs on their election and expressed its belief that under the leadership of the Chair, the SCP would make satisfactory progress. The Delegation also thanked the Secretariat for the good preparation of the session. The Delegation wished to reiterate that it always attached great importance to the work of the SCP as an important platform for discussing the international patent system. The Delegation expressed its hope that the joint efforts of the Member States would give full play to the role of the patent system in encouraging innovation and promoting economic,

social and technological development. The Delegation was also pleased to see the efforts made by countries to maintain the smooth and sustainable progress of the SCP. The Delegation stated that it would continue to participate constructively in discussions and sharing sessions on issues such as exceptions and limitations to patent rights, patents and health, transfer of technology and other issues. The Delegation noted that those issues were important for balancing the interests of patent holders with the public interest, for effective use of the patent flexibilities, and better realization of the social effects of the patent system. The Delegation stated that extensive and in-depth exchange of information on those issues and experience sharing would assist Member States to further deepen their understanding, to learn from one another, and to improve domestic legislation and practices. At the same time, the Delegation was of the view that effective measures could be taken to improve the quality of patents, including enhancing capacity-building among national patent offices, carrying out effective work sharing, improving applicants' understanding and knowledge of other countries' patent systems. The Delegation recognized that, because of different national conditions and differing stages of development, the focus of attention and interests of the various Member States were not the same. Therefore, the Delegation called for greater flexibility and cooperation from the Member States in order to take account of the interests of all parties involved in advancing the work of the SCP. The Delegation looked forward to the fruitful outcome of the meeting.

20. The Delegation of India expressed its confidence in the experience and leadership of the Chair, and complimented the Secretariat for the preparation of that session. The Delegation reiterated that patent monopoly rights were being granted to the applicants under the principle of *quid pro quo* for the disclosure of their inventions to the public to foster the industrial development and the national economy. The Delegation stated that the fundamental objective of the patent offices should be rightful grants by filtering frivolous patents and improvement of the quality of patent system as a whole to protect public interests. The Delegation reaffirmed that harmonizing patent laws across countries having vast differences in economic, industrial and scientific developments would only create a concentration of intellectual property (IP) assets within certain regions which would not help developing countries and least developed countries (LDCs). The Delegation stated that it attached great importance to the work of the SCP and reaffirmed its views expressed at the previous sessions of the SCP with respect to the topics of exceptions and limitations to patent rights, quality of patents, including opposition systems, patents and health and transfer of technology. The Delegation stated that its mandate was to ensure the global intellectual property regimes with the TRIPS flexibilities. The Delegation expressed its hope that the sharing session under the agenda item "exceptions and limitations to patent rights" would be very useful for the Member States to properly analyze the patent systems in their respective countries. On the issue of quality of patents, including opposition systems, the Delegation expressed its belief that work sharing had nothing to do 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 the high social cost of granting patents to insignificant improvements could be eliminated to a greater extent. However, the Delegation was of the view that the sharing session on quality of patents, particularly with respect to paragraph 8 of document SCP/24/3, would definitely enhance the understanding of the issue. The Delegation further stated that experience sharing might improve the quality of patents and technical expertise of patent offices. On the issue of patents and health, the Delegations 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". The Delegation expressed its hope that the sharing session on the use of health-related patent flexibilities would enhance Member States' understanding, particularly in developing countries and LDCs. In that regard, the Delegation expressed its gratitude to the Delegation of Nigeria for preparing a work program on patents and health. 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 balance of rights and obligations, and that the protection of rights should be based on technological content disclosed in patent applications. Furthermore, the Delegation expressed its support to the proposal from GRULAC on the revision of the 1979 WIPO Model Law for Developing Countries on Inventions, and stated that any revision should present the needs of developing countries and LDCs to fully utilize the TRIPS flexibilities.

21. The Delegation of Iran (Islamic Republic of) aligned itself with the statement made by the Delegation of Indonesia on behalf of Asia and Pacific Group. The Delegation stated that the SCP, as a multilateral forum which provided a platform for discussing the patent-related issues, should set out a balanced work program which would provide the opportunity for fruitful exchanges of views on the wide range of topics related to patents. The Delegation was of the view that the discussions on the topics of exceptions and limitations to patent rights, patent and health and technology transfer were significant to balance the interests of patent holders with the public interest of making effective use of flexibilities of patent systems and 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 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 was of the opinion that strengthening the balance between private interests of right holders and public interest in the patent system was necessary. The Delegation continued that, accordingly, 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. 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. The Delegation expected that all Member States would join efforts to allow the patent system to play a more prominent role with regard to promoting social, economic and technological development.

22. The Delegation of Brazil aligned itself with the statement made by the Delegation of Chile on behalf of GRULAC. The Delegation stated that the SCP was an important platform for discussing the international patent system, its underlying assumptions, and the level of attainment of its goal vis-à-vis the concrete effects in the economy of countries. The Delegation expressed its hope that the discussions in the Committee would focus on the role of the patent system in fostering innovation and promoting social, economic and technological development. The Delegation continued that such a focus necessarily had to take into account the different levels of national conditions, as well as the priorities and goals of each country. The Delegation stated that, in that sense, a “one-size-fits-all” approach would lack the flexibility that was necessary for the adaptation of each country’s legal framework and practices, in light of their individual socio-economic goals. The Delegation observed that the agenda of the session contained very interesting topics. In particular, the Delegation stated, under agenda item 6 on exceptions and limitations to patent rights, a sharing session would take place, offering an opportunity for Member States to bring their views and experiences on the matter. The Delegation stated that the discussions on exceptions and limitations had provided many important elements and documents for the consideration of the Member States, shedding light on the tools necessary for adapting

patent systems to the demands of contemporary society. The Delegation looked forward to progressing on the third phase of its proposal: the elaboration of a non-exhaustive manual regarding exceptions and limitations to patent rights. In that regard, the Delegation noted that progress on the subject would benefit all countries, particularly developing countries. The Delegation continued that another relevant item in that session was “patents and health”. The Delegation stated that discussions on the relationship between patents and health had a long and rich history at WIPO and other organizations of the United Nations. The Delegation stressed that providing access to health and medicines at affordable prices was part of the 2030 Agenda for Sustainable Development, agreed by consensus by the Member States of the United Nations. The Delegation noted that, more recently, the High-Level Panel commissioned by the United Nations Secretary-General had raised additional aspects to be considered during the discussion on that item. The Delegation thanked the African Group for their proposal on the matter, and stated that a work program on patents and health had great merit and deserved consideration by Member States, as it contained a balanced set of activities that were divided into three elements with a clear link with the relevant Development Agenda recommendations. The Delegation expressed its hope that the exchange of views during the SCP session would advance the discussions on that fundamental subject. In conclusion, the Delegation reiterated its willingness to contribute to the discussions of the week. The Delegation stated that it remained committed to the agreement of a balanced work program for the SCP, which would carefully analyze matters of interest to all Member States.

23. The Delegation of the Republic of Korea congratulated the Chair and Vice-Chairs on their election. The Delegation also conveyed its appreciation of the work done by the Secretariat in view of preparing the session of the SCP. The Delegation aligned itself with the statement made by the Delegation of Indonesia on behalf of the Asia and Pacific Group. The Delegation further emphasized the importance of the SCP as the only global forum in the field of patents. The Delegation recalled that the SCP, over the last few years, had provided Member States with an opportunity to share their experiences on important issues, such as exceptions and limitations to patent rights, quality of patents, patents and health and transfer of technology. The Delegation stated that the Committee should play a greater role by providing substantive and technical discussions to improve the patent system, and that an agreement reached on future work at the previous session was a good and meaningful starting point for the SCP. The Delegation expressed its strong belief that enhancing the quality of patents should be a core topic of the SCP, since it was an important matter in improving the patent system. The Delegation stressed that a high quality of patents was essential in order to avoid unnecessary social and economic costs, and to achieve innovation and economic development, i.e., the goal of the patent system. Further, the Delegation informed the Committee that, in order to improve the quality of patents, its national patent law had recently been revised to introduce the opposition system and *ex officio* re-examination, on which the Delegation was intending to make a presentation during the sharing session under agenda item 7. The Delegation wished to reiterate that, from the perspective of the quality of patents, the Committee should study and exchange views on work sharing. The Delegation considered that work sharing was the most effective solution in enhancing the quality of patents. In addition, the Delegation expressed its hope to progress, during that session, on the issues of confidentiality of communications between clients and their patent advisors, patent and health, transfer of technology.

24. The Delegation of Belarus considered the work of the Committee to be vital as it provided a forum for discussions on any patent-related issues. For the Delegation, all of the issues on the agenda were timely and important. Noting that the work on the modernization of patent law had been undertaken in its country, the Delegation emphasized that the topics of particular interest for its country were exceptions and limitations to patent rights and

patents and health. The Delegation was convinced that the sharing sessions to be held on those topics during the session of the SCP would be very useful. In conclusion, the Delegation expressed its support of the work program proposed by the Delegation of Brazil regarding exceptions and limitations to patent rights.

25. The Delegation of Chile associated itself with the statement made by itself on behalf of GRULAC. Noting that the agenda of that session contained sharing sessions on different topics, the Delegation stated that, undoubtedly, they would be very enriching for all Member States of WIPO. Further, the Delegation stated that the different challenges faced by countries had an impact on the way they approached each one of those issues. It was for that reason that the Delegation expressed its hope that when incorporating the shared information in the work, a balanced approach, where the interests of all Member States could be reflected, be maintained. The Delegation underlined that the issue of particular interest to its Delegation was exceptions and limitations to patent rights. On that matter, the Delegation specifically supported the way forward suggested by itself in the statement made of behalf of GRULAC. With regards to the topic on patents and health, the Delegation noted the growing interest, expressed in various fora, with respect to the relationship between intellectual property and health. As an example, the Delegation referred to the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines in which a concrete call had been made to take new approaches with respect to innovation in health technologies. The Delegation expressed its hope that the exchange of opinions on the topic would consider such developments. As regards the topic of transfer of technology, the Delegation stressed the need to study the relationship between sufficiency of disclosure and transfer of technology, and in particular the way in which such information was made available to third parties, since that was one of the main sources of access to knowledge. Finally, the Delegation expressed its hope to participate in the discussions that would arise with the objective of continuing a balanced work that would take into consideration the interests of all Member States.

26. The Representative of KEI, with regard to the government rights in patented inventions when the government funded or partly funded research, stated that the United States of America, like many other countries, retained certain rights in patents for inventions for which it had funded the research. That included worldwide royalty free rights to practice, or to practice on its behalf, an invention. The Representative continued that, recently, a generic drug manufacturer in Canada had requested the government of the United States of America to use those rights in order to export a generic version of a prostate cancer drug called "enzalutamide", which had been sold under the brand name of "Xtandi", to countries with a per capita income of less than one third of that of the United States of America, including South Africa and Chile. The Representative stated that while the government of the United States of America had rejected the request, it had also indicated that it had wanted to consider such requests within a broader policy framework. In that regard, the Representative proposed to WIPO to make an instrument that would create reciprocal rights in government-funded inventions so that countries that were members of such an agreement would agree to the terms and modalities under which they could share access to government-funded inventions. With regards to the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines that several delegations had referred to, he encouraged the SCP to consider it, with particular attention to the recommendations made on transparency and the delinkage of R&D costs from product prices. With regard to the latter, the Representative stressed that it was an important topic that had implications for the practical implementation of patent protection for medical inventions, as well as norms concerning patents.

27. The Representative of TWN stated that the SCP discussions should be conducted in accordance with the Development Agenda recommendations, and 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 Representative further noted that, although minimum international standards of patent protection had been set by the TRIPS Agreement, patent law remained territorial. The Representative continued that governments had flexibilities in the design of their domestic patent laws. The Representative underlined that maintaining that flexibility was critical for policy makers in designing, amending or delaying domestic patent laws in accordance with national development priorities and social and economic realities. The Representative continued that, however, developing countries often faced political pressure against the use of the TRIPS flexibilities. The Representative stated that those undue political and economic pressures had been used to dissuade governments from using the flexibilities that could protect public health, which had been reported in the United Nations High-Level Panel Report on Access to Medicines. The Representative further stated that the Report recommended that governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that would undermine the right of countries to use TRIPS flexibilities. Furthermore, the Representative emphasized that although patent monopoly had often been justified as a tool for promoting innovation, more and more evidence had suggested that patents have negative effects on innovation. The Representative further noted that, according to the said Report, public health-sensitive intellectual property rules and mechanisms could help address the misalignment between pro-active innovation models and public health priorities. In addition, the Representative reported that a Nobel Laureate, Professor Joseph Stiglitz, had recently stated that the patent system, the TRIPS Agreement, was not about innovation but that it was about monopoly profit. The Representative therefore stressed the importance for the SCP to initiate discussions based on the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, specifically based on its recommendations that WIPO, in collaboration with stakeholders, would develop an international, easily searchable database which would include: (i) standard international common names for biological products; (ii) international non-proprietary names for products, either as known at the time of application, or after the granting of a patent; and (iii) dates of the granting and expiry of patents. The Representative concluded that it looked forward to seeing those recommendations taken on board by WIPO and its timely implementation.

28. The Representative of MSF welcomed the continuing discussions by the SCP on the issues of patents and health and exceptions and limitations to patent rights. The Representative urged the Committee to deepen those discussions to allow Member States to explore the policies that would facilitate access to affordable medicines and implement public health safeguards in their patent laws. The Representative stated that the Committee meeting was being held at a critical time as it came in the wake of the United Nations' Secretary-General having welcomed the final report that had been delivered in September by the High-Level Panel on Access to Medicines. Noting that WIPO had contributed to the formulation of that Report through the Expert Advisory Group of the High-Level Panel, the Representative urged WIPO Member States to take the analysis and recommendations stated in the report into full consideration when discussing the future work of the Committee. The Representative continued that in its day-to-day work, MSF continued to face challenges in securing access to more affordable sources of medicines and diagnostic tools, and noted that the issue of access to medicines was particularly difficult in middle-income countries. The Representative reported that a third-line treatment regimen for HIV was priced over 17 times more than the lowest price for first-line treatment, because patent and regulatory barriers blocked generic competition and the wide availability of more affordable generic sources. The Representative further noted that countries that legitimately used compulsory licenses remained under tremendous political pressure, as it had been demonstrated in Colombia in early 2016, where Colombia had faced the threat of withdrawing international

support for the peace process used as a political bargaining chip against the Colombian government's attempts to curb the high price of medicines. Facing that reality, the Representative urged three improvements in the Committee's work, in light of the recommendations provided by the United Nations High-Level Panel Report. First, the Representative stated, WIPO Member States should take concrete steps towards assessing the health impact of trade agreements and rejecting the proposals of TRIPS-plus provisions on intellectual property. The Representative observed that, despite numerous studies showing the detrimental impact on access to medicines, TRIPS-plus provisions, such as data exclusivity and patent term extensions on medicines, continued to be pushed by the pharmaceutical industry, backed by the governments of certain Member States. The Representative noted that those proposals were pushed through trade agreement negotiations, such as the ongoing Regional Comprehensive Economic Partnership agreement, which involved 16 countries in the Asia-Pacific region. In that regard, the Representative referred to the United Nations High-Level Panel Report which recommended countries to consider rejecting TRIPS-plus intellectual property provisions, and to conduct thorough health impact assessments in trade agreement negotiations. The Representative expressed its hope that Member States would integrate those recommendations in the discussions under the agenda item on patents and health. Second, the Representative stated that Member States should address the lack of transparency in patent information concerning medicines, vaccines and diagnostics, and establish disclosure requirements for INN in patent applications. In that regard, the Representative pointed out that the United Nations High-Level Panel Report had explicitly recommended WIPO to "establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines" and that such information should be periodically updated and consolidated by WIPO, in collaboration with stakeholders, to develop an international, easily searchable database which should include: (i) standard international common names for biological products; (ii) INN for product, either as known at the time of application or after the granting of a patent; and (iii) dates of granting and expiry. The Representative further noted the steps taken by WIPO in providing new chemical search functionality in the PATENTSCOPE database. However, in the view of the Representative, further steps were needed in implementing the full recommendations set out by the United Nations High-Level Panel Report. In addition, the Representative noted that the disclosure of INN should also be made as a normative requirement in patent applications. The Representative continued that WIPO should provide public health-oriented technical assistance, with concrete follow up on public health safeguards in the patent laws of Member States. The Representative observed that many of the challenges facing access to medicines and overcoming patent barriers had been repeatedly shared by Member States and observers. She noted that patent evergreening on medical technologies in particular remained a critical hurdle. The Representative further stressed that the United Nations High-Level Panel Report clearly recommended WIPO to cooperate with other multilateral organizations and United Nations bodies to "support governments to apply public health-sensitive patentability criteria", and to "strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability, taking into account public health needs." In conclusion, the Representative urged WIPO to implement those recommendations in its future work, and to review and improve its technical assistance to Member States with a better aligned approach of facilitating access to medicines and innovation, as explicitly recommended by the United Nations High-Level Panel Report.

AGENDA ITEM 5: REPORT ON THE INTERNATIONAL PATENT SYSTEM: CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS

29. Discussions were based on document SCP/25/2.

30. The Delegation of Portugal stated that in response to the invitation of the Secretariat, Portugal took the opportunity to inform about small amendments to the text concerning the grace period, exclusions from the patentable subject matter, as well as exceptions and limitations to the rights, in accordance with the English translation of the Portuguese Industrial Property Code.

31. The Delegation of Belarus stated that in its country, the Office had been actively working on changing the national patent law. Specifically, the Delegation stated that in order for the Republic of Belarus to join the Patent Law Treaty in 2016, the consequential amendments to the law had been introduced. In addition, the discussions on other aspects of the laws, in particular the provisions on exceptions to the methods of treatment of human beings as well as the examination criteria of the utility model protection in the framework of the invalidation proceeding, had been carried out by the working group, consisting of various related ministries and organizations. The Delegation further noted that the most disputed question of the working group was the issue of exceptions and limitations to the rights, and how to ensure the right balance between the interests of the rights holders and the society. In particular, the Delegation informed the Committee that those discussions were related to the provision on the regulatory review exception. Further, the Delegation stated that another amendment to the law related to the provision on compulsory licensing in case of non-working or insufficient working of the patent. Specifically, according to the amendment, such license could be issued upon the expiration of three years from the date of the grant of the patent. The Delegation noted that, to that date, no compulsory license had been issued in the Republic of Belarus. In addition, other changes introduced to the law concerned the dependent patents and utility models. Further, the Delegation stated that another amendment that had been proposed, but had not been supported by the majority of the working group and, therefore, was ultimately not reflected in the law, was the possibility to issue a compulsory license in the case of national security.

32. The Delegation of India informed the SCP on the latest development that had taken place in its country. In particular, the Delegation stated that the Indian national office had been making continuous efforts for infrastructural improvements as well as on the topic of human resources. As regards the latter, the Delegation stated that its Office had recruited 400 new examiners. The Delegation stated that those examiners had been thoroughly trained in the Rajiv Gandhi National Institute of Intellectual Property Management at Nagpur, before inducting them into the examination system. The Delegation noted that those efforts had resulted in the speedy processing of patent applications to meet international obligations, and that its country, as an International Searching Authority (ISA), was issuing international search reports and written opinions of comparable international quality and standard.

AGENDA ITEM 6: EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

33. Discussions were based on documents SCP/25/3 and 3 Add., SCP/14/7 and SCP/19/6.

34. The Secretariat presented document SCP/25/3 and 3 Add.

35. The Delegation of Latvia, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing the document SCP/25/3, and noted that only two Member States, and several international and non-governmental organizations, had been included in that

document. The Delegation believed that document SCP/25/3 and the document presented during the 23rd session of the SCP would be a useful source of information, and was looking forward to the sharing session among the Member States on case studies, including court cases, and those exceptions and limitations that had proven effective to address development issues and/or economic strengthening. The Delegation further expressed its view that the exceptions and limitations to patent rights represented a balance between the rights of patent owners and those of the larger public, and therefore the question of the exceptions and limitations should be discussed at the same time as the issue of the criteria used in order to determine whether an invention is patentable or not. The Delegation concluded that discussions on the novelty, inventive step and industrial applicability were necessary for a holistic approach.

36. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, thanked the Secretariat for preparing documents SCP/25/3and 3 Add., and also noted that it contained information from only two Member States and some observers. Nevertheless, it believed that documents SCP/25/3 and 3 Add. would serve as a useful reference. The Delegation was pleased to see the sharing session planned on that topic, and was confident that it would provide useful insights, as well as a valuable basis for achieving further progress in that area. The Delegation stated that the exchange of practical experiences on the effectiveness and challenges of exceptions and limitations in addressing development issues was the main prerequisite for meaningful outcomes. As regards exceptions and limitations in general, the Delegation stressed that exceptions and limitations to patent rights maintained an appropriate balance between the interests of right holders and the general public. Taking that balance into account, in the view of the Delegation, it was important to address both sides at the same time: on the one hand, exclusions from patentability or exceptions and limitations to patent rights, and on the other hand, the corresponding legal standards used to determine whether an invention was patentable, such as the novelty, inventive step, and industrial applicability.

37. The Delegation of Turkey, speaking on behalf of Group B, also thanked the Secretariat for preparing documents SCP/25/3 and 3 Add., and noted that they contained only the responses from the Delegations of Guatemala, the Dominican Republic and Canada, as well as from several international and non-governmental organizations. The Delegation encouraged additional Member States to provide information. While the Delegation recognized that the use of exceptions and limitations was at times appropriate in specific circumstances, it was worried that exceptions and limitations were at times regarded as a tool for development. In the view of the Delegation, development was strongly related to the presence of innovation, and innovation was fostered by an effective patent system, where the delicate balance between the interests of the right holders and the general public was maintained. Regarding the instrumentation of the exceptions and limitations, the Delegation noted that an enormous amount of work in that area had been done already by WIPO, including in the SCP, and that a great number of valuable references, which could be used by any country when considering its domestic arrangements in a manner fitting to its specific circumstances, had been already produced. The Delegation, therefore, believed that those discussions had given the Committee sufficient information for reflection.

38. The Delegation of Brazil expressed its view that exceptions and limitations were intrinsic elements of every law, and vital for striking a balance between rights granted and the interests of the society at large. The Delegation explained that they served a number of purposes by conferring the necessary flexibilities that guaranteed national security and public health, among other goals, whilst they also shaped public policies to meet, *inter alia*, development, competition and health surveillance goals. The Delegation was of the opinion, that a flexible policy space was necessary in order to allow Member States to develop and adapt more adequately the set of exceptions and limitations to their own realities. It stressed that exceptions and limitations were relevant to an adequate and balanced patent system

and shared its observation that members had developed different approaches for implementation. In the view of the Delegation, the compilation of responses to the questionnaire available in document SCP/17/3 clearly showed the widespread availability of exceptions and limitations in the laws of countries with very different levels of development in every region of the world, which reflected a shared understanding that exceptions and limitations were integral to patent laws. The Delegation further noted that exceptions and limitations also had a role in spurring innovation by providing the incentives for competition between stakeholders, and a guarantee that the market power granted by a patent was balanced and did not create anti-competitive externalities: they also ensured that consumers and stakeholders were able to have access to the patented inventions for a multitude of goals, such as research or obtaining regulatory approval, in accordance with the complexity of the contemporary society. Therefore, the Delegation concluded, that exceptions and limitations generated an increase of societal welfare, without violating the legitimate rights of the patent holders. It acknowledged that the continuous development of new inventions by competitors was indeed ensured, while at the same time third parties were able to benefit from the dissemination of knowledge and the technology contained in patent applications. The Delegation recalled document SCP/14/7, where it had highlighted that users of the patent system comprised not only intellectual property title holders, but society as a whole. The Delegation looked forward to progressing on the third phase of its proposal: the deliberations of a non-exhaustive manual regarding exceptions and limitations to patent rights. It stressed that progress on the subject would be to the benefit of all countries, particularly the developing countries, since it would provide guidance to members which could be reflected upon, and further implemented, in national legislation.

39. The Delegation of Nigeria, speaking on behalf of the African Group, underscored the utility of exceptions and limitations in the international intellectual property system. The Delegation explained that the TRIPS Agreement had specifically recognized the relevance of that tool as a means for pursuing certain public interest goals in various fields, including patent rights. However, in its opinion, there remained a significant depth in capacity, knowledge, and use of the various existing exceptions and limitations for implementing development priorities, including in the life and death field of public health. Cognizant of that, the African Group fully supported the proposal made by the Delegation of Brazil on exceptions and limitations. As some of the activities in that proposal had been undertaken, the Delegation strongly supported the call by the Delegation of Brazil for the SCP to turn its attention to the third phase of the proposal which was the deliberation of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference for the Member States. The Delegation thanked the Secretariat for the preparation of document SCP/25/3 and expressed its appreciation to the Member States and observers that had responded or made proposals. The Delegation was looking forward to the sharing session as a time to gain more insight on the difficulties experienced, and the effective uses of exceptions and limitations, in order to enhance the work of the Committee in that regard.

40. The Delegation of India, speaking in its national capacity, reaffirmed its support for the work shown in document SCP/19/6 on exceptions and limitations to patent rights, and expressed its belief that the proposed study should focus on the use of exceptions, such as compulsory licensing, parallel imports, governmental use and other exceptions, which were extremely important from the perspective of accessibility and affordability of medicines and other areas of socio-economic importance, namely environment and technology transfer to developing countries. The Delegation was of the view that, like any rights, patent rights could not be absolute and that they carried the accompanying obligations that had to benefit the public at large – and that those rights and obligations should balance one another. The Delegation reiterated that since scientific and research institutions had been good places to use research exceptions, and also civil societies involved in public policy could be a good source of information regarding the use of exceptions, the Secretariat should also take into account the experiences of such institutions by compiling such information.

41. The Delegation of Iran (Islamic Republic of) supported the statements and the proposal made by the Delegation of Brazil, and was of the view that exceptions and limitations played an important role in supporting the good functioning of a patent system, because they provided a balance between interests of the public and the right holders. The Delegation further stated that the issue of flexibilities in the intellectual property system recognized the need to adopt national legislations on patents, based on each country's economic and social situations. In that regard, while the Delegation believed that exceptions and limitations to patent rights were relevant to an adequate and balanced system, it also believed that a flexible policy speed was necessary to allow Member States to develop and adopt a set of exceptions and limitations that were more adequate for their realities, independent of whether it was a developed or a developing country. The Delegation suggested that after having prepared the studies on exceptions and limitations, based on the inputs received from Member States, it would be important for the SCP to consider undertaking an analysis of how various exceptions and limitations were utilized by different countries in addressing various public policy objectives. In the view of the Delegation, following the work that had been carried out by the SCP, it was time for the Secretariat to prepare an analysis of the exceptions and limitations that had proven to be effective to address the development concerns, while all material that had been produced during the previous years was needed to be taken into account in such studies. The Delegation then took note of document SCP/25/3. It observed that the contents of the received submissions clarified that there were several structural constraints which prevented many Member States from using exceptions and limitations. Therefore, it was essential to ensure that WIPO technical assistance, in the design of national patent laws or national intellectual property strategies, should take such constraints into consideration and provide assistance on how developing countries could overcome such constraints and make full use of available flexibilities. The Delegation invited submissions from other stakeholders such as scholars, research institutions, civil society organizations and local industries with practical experiences, which would enlighten the SCP of the actual view of the exceptions and limitations, and help the Member States improve their patent laws as appropriate, taking into account the lessons learned from the experience of actual users.

42. The Delegation of Indonesia expressed its support for the proposal made by the Delegation of Brazil contained in document SCP/19/6 regarding exceptions and limitations to patent rights. The Delegation attached great importance to exceptions and limitations. It commended the Secretariat for its efforts in collecting and compiling information on exceptions and limitations to patent rights, and reminded the SCP that the discussion on that issue had been going on since the 14th session of the SCP, which had resulted in the availability of rich information. However, the Delegation was of the view that there had been limited qualitative analyses regarding exceptions and limitations, and therefore, studies on exceptions and limitations should not be limited only to inputs and information sharing, but needed to be extended to cover an evaluation of the effectiveness, and challenges faced in the implementation of exceptions and limitations. The Delegation further continued that in that context, it would be important for the SCP to consider undertaking the work as proposed by the Delegation of Brazil, as well as undertaking further analysis on how various exceptions and limitations were utilized by different countries in addressing various public policy objectives. The Delegation also noted that taking steps forward on that issue would contribute towards ensuring the ultimate goal of promoting socio-economic development, in the broader context of the United Nations 2030 Sustainable Development Goals, and ensuring that the application of flexibilities was consistent with and contributed to the achievement of the Sustainable Development Goals.

43. The Delegation of Belarus thanked the Secretariat for preparing document SCP/25/3, which, in the view of the Delegation, showed some of the approaches to exceptions and limitations. The Delegation further noted that although it was not a member of the WTO, it followed the principles established by the TRIPS Agreement, and took into account the

provisions of the Doha Declaration on the TRIPS Agreement and Public Health. Furthermore, the Delegation stated that within the framework of the accession to the WTO, it had been examining the provisions of the Protocol Amending the TRIPS Agreement, adopted on December 6, 2005. The Delegation believed that the information received from the Delegation of Canada, on the practical experiences of issuing a compulsory license for the export of medical preparations to countries which had not been able to produce such medical preparations on their own, had been very useful. The Delegation would be very grateful if delegations of other countries, which had had experience on issuing compulsory licenses for exports of medical preparations, would share their experiences.

44. The Delegation of Chile, speaking in its national capacity, recognized the need of exceptions and limitations to patent rights as a tool which was part of the patent system, and which allowed calibrating national intellectual property systems according to the realities of each country. According to the Delegation, public policy decisions relating to the patent systems led to introduction of some exceptions and limitations in the legislation. In the view of the Delegation, the clarity of the information concerning the exceptions and limitations was another factor relevant to that topic, and both patent holders as well as any interested parties should have legal certainty regarding the limitations to which their right might be subject. The Delegation explained that at that stage, the legislative techniques were of prime importance, and the complexity of the subject addressed was linked to the complex task of regulating abstract ideas. In response to those challenges, the Delegation supported the proposal made by the Delegation of Brazil and supported by GRULAC, to develop a non-exhaustive manual on exceptions and limitations. The Delegation believed that the exchange of experiences would allow for collecting a variety of information on those challenges.

45. The Delegation of China thanked the countries and non-governmental organizations for sharing their experiences, challenges and cases with respect to exceptions and limitations to patent rights, and also thanked the Secretariat for collecting and summarizing the information based on national inputs. The Delegation further noted that such information was vital for countries to refer to in learning and in improving the patent legislation and the institutional implementation. In the view of the Delegation, it also provided a good foundation for in-depth discussions on exceptions and limitations. Further to what many other Delegations had pointed out, the Delegation was of the view that exceptions and limitations were contained in key provisions of patent laws of many countries, and that such provisions reflected a balance between the interests of the right holders and the public, and also provided support for the well-balanced functioning of a patent system. The Delegation also supported the proposal made by the Delegation of Brazil contained in document SCP/19/6 and was looking forward to the continued discussion on that subject. The Delegation expressed hope that Member States would continue to share experiences, and proposed that the Secretariat continue to compile and update the information submitted by countries.

46. The Delegation of Greece congratulated the Chair and the Vice-Chairs on their election. It associated itself with the statements made by the Delegation of Turkey on behalf of Group B, as well as by the delegation of Slovakia on behalf of the European Union and its Member States. The Delegation explained that the intellectual property system was an enabling environment for innovation, and that exceptions and limitations were provided to allow for the use of patented technology under certain circumstances. While the Delegation acknowledged that intersections between intellectual property, public health, and trade existed, in its opinion, the intellectual property system should neither be isolated from, nor considered independently within, the whole range of parameters affecting trade and public health worldwide. The Delegation further noted that the information compiled in document SCP/25/3 showed a limited use of exceptions and limitations in developing countries, either due to unawareness of patent issues or due to limited production capacities, which

confirmed that patents had by no means impeded on the access to the use of technology. The Delegation concluded that the role of patents in stimulating innovation and economic growth should not be undermined.

47. The Delegation of the Russian Federation congratulated the Chair on her election, and expressed its interest in the practical aspects of exceptions and limitations to patent rights, highlighting the particular importance of achieving a balance of interests between right holders and society. The Delegation believed that it would be a good idea to create a consolidated document on exceptions and limitations to systematize the information available. In addition, the Delegation stated that such document could consider models of application of laws in the field of exceptions and limitations based on the information gathered from the Member States. It added that such kind of information was useful for improving the regulation mechanisms and legal practices of Member States, and would facilitate the overcoming of barriers in the implementation of exceptions and limitations. In particular, the Delegation expressed interest in the application of laws on exceptions and limitations related to compulsory licensing and government use for national security purposes.

- Sharing session among Member States on case studies, including court cases, on those exceptions and limitations that have proven effective to address development issues and/or economic strengthening

48. The Delegation of Brazil noted that the exceptions and limitations were an integral and necessary part for a strong and healthy patent system – they were a basic tenant of the patent system. The Delegation further stated that the legislation should provide incentives that would lead to new discoveries and inventions and assure that those incentives were not overly restrictive and led to the dissemination of knowledge. The Delegation continued that under that framework, the role of exceptions and limitations should be addressed. It noted that in previous years, interesting decisions regarding the scope and use of exceptions and limitations had been published. According to the Delegation, those court decisions were found both in developed and developing countries and they showed that exceptions and limitations were not a subject limited to specific countries. As an initial example, the Delegation mentioned the topic of compulsory licenses and elaborated on that example: in 2007, Brazil had issued its first and only compulsory license regarding the anti-retroviral medicine efavirenz, with the underlying intention to agree that HIV patients in Brazil would receive the appropriate treatment by the Brazilian health system. The Delegation recounted that in spite of those legal provisions in the international and national frameworks, the patent owners had filed legal disputes in the courts. However they had been unsuccessful and the Brazilian government had been able to continue with the issuance of the compulsory license. The Delegation noted that in conjunction with the procedures necessary for the compulsory license, the Brazilian government had initiated the preparation of efavirenz itself. The Delegation recalled that the discussions of the paragraph 6 system in the WTO had shown that issuing a compulsory license had often been insufficient on its own to ensure access to the product, and members had in some cases the need to develop the technological capability for manufacturing the medical product. In light of that, the Delegation continued, two public laboratories responsible for the production of efavirenz had undertaken massive efforts to ensure the production of the medicine: the first step was to comprehensively analyze the invention, as disclosed in the patent, clarifying aspects of the phases of production, and the second step for the laboratories had been to take advantage of a limitation contained in the Brazilian law. The Delegation specified that that limitation had been in Article 43, Subsection 2 of the Brazilian Industrial Property Law, which stated that patent rights had not been extended to acts carried out by unauthorized third parties for experimental purpose in connection with scientific or technological studies or research. It explained that the goal of that limitation had been to maintain incentives for research and studies by third parties and thus allowing for the progress of science and technology. The

Delegation further recounted that the owner of the patent had initiated legal proceedings in order to challenge the public laboratories, and the Brazilian courts had again held that the limitation had been fully compliant with the relevant legislation. The Delegation explained that further to those actions, the last step required to initiate the production of the medicine under the compulsory license had been to obtain regulatory approval by the Brazilian authority known as ANVISA. The Delegation further explained that in order to fulfill that requirement, the Brazilian government used another aspect of intellectual property rights related to clinical test data. As a result of such efforts and having taken full advantage of legally permissible exceptions and limitations, the Delegation stated that its government had been able to substantially reduce the price of the drug from $1.59 to $0.45 per tablet. The Delegation concluded that that had helped ensure the adequate supply of the medicine to HIV patients who had needed it on a daily basis to keep the disease under control. The Delegation further stressed that document SCP/14/7 had been there precisely for the purpose of discussing such obstacles, specifically but not exclusively, in developing countries. The Delegation also pointed to the fact that exceptions and limitations were inherent to the patent system, regardless of the level of development of the country. In that context, it further provided another example relayed by the media, stating that earlier in August, the German Federal Patent Court had issued a compulsory license covering an anti-retroviral drug called Isentress. The Delegation explained that according to the reports, the compulsory license had been granted through a preliminary measure to ensure the supply of the medicine, since patients, including newborns and pregnant mothers, could not have taken the safe treatment without that medicine. The Delegation suggested that other members share their views regarding the exceptions and limitations, ensuing in a rich discussion which would be helpful to all countries and which would add input to the SCP.

49. The Delegation of Chile informed the SCP about an amendment to its industrial property law which was undergoing a parliamentary procedure in order to be adopted, where, along with maintaining the flexibilities related to the non-voluntary licenses and exhaustion of rights, the legislation had been updated in a manner to incorporate new flexibilities, including the ones implemented by paragraph 6 of the Doha Declaration in relation to Article 31 of the TRIPS Agreement concerning the granting of compulsory licenses, to manufacture and export pharmaceuticals in the cases where a WTO Member had no or insufficient manufacturing capacity to address its public health problems. The Delegation also recalled that at the previous CDIP meeting, the national intellectual property office of Chile, INAPI, had presented a document in which it had been possible to visualize the patent flexibility as recognized by Member States of WIPO in an easy and interactive manner. The Delegation announced that that tool was available on the INAPI website. With regard to document SCP/25/3, the Delegation drew attention to the title of the document in Spanish, where the word "challenges" had been translated to mean "problems" in Spanish "problemas". The Delegation believed that a better translation would be "desafios," which was a direct translation of the word "challenges." It believed that that word would allow the SCP to maintain greater clarity on that issue.

50. The Delegation of Nigeria, speaking in its national capacity, thanked the Delegation of Brazil for its presentation and noted the intervention made by the Delegation of Chile. It believed that the presentation made by the Delegation of Brazil shed more light on the utility of exceptions and limitations in the patent system. The Delegation expressed its astonishment with regard to the statement made by the Delegation of Brazil regarding the fact that issuing a compulsory license in itself had not been sufficient, that it had needed to be accompanied by the adequate technological capacity, and that the Brazilian government had faced the constraints and legal suits when it had tried to use the available mechanisms in the system to protect its public interest. Therefore, the Delegation believed that that had added impetus to the proposal made by the Delegation of Brazil, and stated that it was necessary to move to the implementation of the third part of its proposal, the provision of a manual. In the view of the Delegation, that would enable Member States to know when to

use them, how to use them, in what time, and under which conditions they should be used. The Delegation, thus, strongly supported the proposal made by the Delegation of Brazil and the insight provided in their presentation.

51. The Delegation of South Africa aligned itself with the statement made by Nigeria on behalf of the Africa Group. After having listened to the Member States' experiences, it was clear to the Delegation that there were some bottlenecks in the implementation of exceptions and limitations. In that connection, the Delegation supported the proposal made by the Delegation of Brazil with regard to creating a manual on exceptions and limitations to serve as a reference for the Member States.

52. The Representative of KEI provided information about a variety of compulsory licensing cases, and suggested to discuss some pertinent issues in that regard. He stated that there had been a case, more than ten years earlier, which had involved an HIV drug in Zambia. In that case, a compulsory license application had been filed and granted, while at that time, there were no patents on the drugs in the country where the compulsory license had been requested. In the view of the Representative, that had been an interesting case, where the manufacturer seeking the compulsory license had explained to him that there had been sufficient uncertainty over whether patents had or had not existed, or would be granted in the future, and that the manufacturer had wished to have the assurance of a compulsory license, both for patents that might have been filed at the time or later, or for patent claims that the manufacturer might not have been sure about. The Representative explained that the challenges people faced in such cases were the lack of transparency. The Representative also mentioned a case in Mozambique during the same period, where a compulsory license had been issued on an HIV drug, while there had been no patent protection on that drug. He specified that people had been looking at the originator's patents which had covered different drugs, where the originators themselves had filed patents in Mozambique. The Representative explained that one generic drug company had obtained patent protection in Mozambique for a combination of three drugs together, similar to the patents that had been acquired in the United States of America for the combination of Gilead's hepatitis C drugs used together. The Representative specified that in Mozambique, the generic drug company had obtained patent protection for the use of someone else's drug used in combination, that the compulsory license had been something that had been effective at that time, and had ensured that other generic drug manufacturers could operate in Mozambique. The Representative then stated that there had been some interest in Brazil in issuing compulsory licenses as a possible option for drugs on hepatitis C. He also shared his observation that many countries had looked at compulsory licenses on hepatitis C drugs, explaining that the extraordinary cost of the hepatitis C medicines had been causing budget crises in a lot of countries. The Representative named France, which had made a call on that at one point, and Brazil, where an issue had appeared in connection to the fact that the relevant patents had been applied for, but had not been granted by the Brazilian government, and therefore the question had appeared as to whether it had been possible to grant a compulsory license on a patent in that limbo stage. The Representative explained that under the Brazilian law, once a patent application was filed and eventually published, there existed retroactive liability for infringement. That had been a problem, because the Brazilian government had wanted to consider the grant of the compulsory license, but had not believed it to be possible due to the fact that the patent had not been granted. In his view, such things had to come down to national law, and not purely relied on precedent. According to the Representative, in Europe and the United States of America, there had been cases where compulsory licenses had been issued and applied to patent applications on which patents had not been granted yet. The Representative observed that one case involved hepatitis C patents in Germany, and there had been several cases in the United States of America, which could fit into that category. He also stated that there had been a fair amount of competition cases in the United States of America. The Representative then turned to a case in Romania involving hepatitis patents, where there had been some

concern, in the European Commission and in Romania itself, as to whether Romania could issue a compulsory license on a hepatitis C drug, which could lead to those goods being circulated within the European Union, since Romania was part of Europe, even though other countries had not issued compulsory licenses for the same product. On the one hand, the compulsory license could be a good outcome for Romania, if the goods would not have been allowed to circulate in other countries, and as opposed to a voluntary license, which would have had a different status in the European Union, a non-voluntary license gave additional assurances that there would not be diversion of the drugs into other countries that had followed a different policy. The Representative explained that some countries had been looking at compulsory licenses to address evergreening problems where the patents had been extended for a long period. He named South Africa, where patients had been concerned about access to a cancer drug sold under the brand name "Herceptin" by Roche, and explained that the product had been under patent protection for several years in South Africa, a country that had a registration system but not an examination system, whereas in other countries around the world, such patents had essentially expired. The Representative stated that the patient groups had addressed the differences in the periods of time when patents had existed in South Africa versus other countries, and South Africa would have been disadvantaged, because patent protection there would have lasted for a longer time. The Representative recounted that he had met one of the patients who had been involved in that process. She had been a mother, had had children, was fairly young, but she had died. He said that she had never been able to secure access to the important breast cancer drug. The Representative noted that in some countries, compulsory licenses had been used as a limitation to the remedy of infringement, as opposed to a license to use the right, which was the case, for example, in the United States of America. He recounted that the government used a general purpose government use license under 28 U.S.C. §1498, and not a license on the patent, i.e., it would be a limitation on the infringement in case the government would use the patent without getting permission from the patent owner. The Representative stated that that particular approach in the United States of America had come up in several cases involving patents and drugs. The Representative named a first case which had involved the drug named "Cipro" against anthrax poisoning, and another case which had appeared in a crisis at the Department of Veterans Affairs over the access to hepatitis C drugs. The Representative stressed the fact that in such cases, one of the deterrents the government had in using the legal mechanism had been the uncertainty over the amount of compensation that would have been involved under the standard for compensation of the United States of America. In the view of the Representative, that had happened because the mechanism had not been designed for such a purpose, therefore, even though it had been a fairly easy mechanism to use, there had been too much uncertainty over the compensation for them to use that particular method. The Representative further explained that in the case of the Department of Veterans Affairs, it had been necessary to take funds from a program that had been set up to provide private insurance for veterans who had not been able to get care from a traditional Department program in order to pay for the additional cost of the hepatitis C drugs, which had been extraordinary for veterans. The Representative provided a further example of a case which had concerned the Biologics Price Competition and Innovation Act in the United States of America. He explained that under that law that regulated a regulatory pathway for bio-similar drugs in the United States of America, there was a procedure under which the incumbent had to provide constructive disclosure of the patent landscape to a bio-similar competitor. The motivation for that was that since it was expensive for the bio-similar competitor to manufacture a bio-similar drug as it could cost millions of dollars, they would not opt to do so if they were to be sued for infringement. According to the Representative, under that system, the incumbent patent owner had to either show the patents that same day to the competitor, or they would not have been able to come at a later date and get an injunction, and depending on the nature of the disclosure, the patentee's right to royalty could be limited, for example, no royalty payment could be required if the patentee had not done so. The Representative concluded that that had been another area where limitations had been used on the remedies to

infringement and not a compulsory license on the patent *per se*. Furthermore, the Representative recalled the Colombia case which had been mentioned by the Representative of MSF. He also mentioned that there had been a lot of reports over the summer regarding communications involving the Congress of the United States of America and, supposedly, the United States Trade Representative, suggesting that the funding for the peace process in Colombia might have been at risk if the government had issued a compulsory license for a patent on a drug for leukemia. The Representative observed that many stories of the like had come up. He drew attention to the fact that if countries had had legal mechanisms, where the government itself could not be pressured, then the pressure would be less effective. He referred to India, which had a mandatory compulsory licensing statute under Section 92A of the Patents Act for exporting drugs, where if one fitted the requirements, the compulsory license had to be granted. The Representative further stated that there were a large number of compulsory licenses that had been issued in the United States of America, which had benefited companies, such as Microsoft, DIRECTV, Toyota or other companies as the recipients, and in such cases, a judge had been involved and had been able to make the decision. The Representative stressed that in such cases, no amount of political pressure on a government could interfere to that extent, as the judge had some discretion. He continued explaining that people at the time were asking themselves questions such as: "Who is the person that grants the compulsory license?", "Is that person going to be subject to a lot of political pressure, including from foreign governments?", "Can they do things that are achieving the purpose of the statute in terms of the protection of the public or the correction of an abuse?". The Representative further mentioned several cases in Germany: one had involved an HIV product and had been an important case where the originator had sought the compulsory license because he had been facing suits from a patent holder in another country who had been claiming that the product of the originator, i.e. the company that had done most of the development work, the clinical trials, and had put the drug on the market, had infringed their patent – and that had been the basis of that compulsory license. He further stated that Germany had also been involved in cases involving the hepatitis C diagnostic patents where Roche had been the requester of the compulsory license. In addition, the Representative noted that there had been cases with patents involving the Fabry's disease - a drug that had cost four hundred thousand dollars a year – and that there had been a shortage of the drug. During that case, an American patent owner, which was a university, had been trying to prevent Shire from selling a treatment for Fabry's disease in Germany, at a time when the competitor, owned by Sorofy, had not been able to supply its own customers and that some patients, particularly in the United States of America, had been rationed. The Representative explained that the compulsory license request had been made by Shire in Germany, and that had been resolved in Shire getting a license to use the drug, which had protected the patients in Germany, and had turned out in other European countries from having a shortage of that important treatment.

53. The Representative of TWN acknowledged that the subject of exceptions and limitations was essential in providing countries with a policy space to address patent barriers to further development and public interest objectives such as access to affordable medicines. She provided several examples: first, a government use license had been issued in Malaysia in 2003 in order to import generic HIV/AIDS medicines from India for use in public hospitals, and as a result of that, the average cost of the treatment of the Ministry of Health per patient had dropped by 60% to 80%. According to the Representative, as a result of that, the Ministry of Health had been able to treat 4,000 patients, compared to 1,500 HIV patients, therefore one could conclude that there had been significant implications in terms of positive public health impact. The Representative provided a second example, the case of Zimbabwe, where a compulsory license had been issued to a local company to manufacture and import generic medicines for HIV/AIDS. In that case, according to the Representative, the average price of HIV drugs had dropped by $30 to $50 per month to $15, thus by almost 50%. The third example from the Representative concerned a case in

Ghana, were a government use license had been issued in 2005 to import generic HIV/AIDS medicine, and the average cost had dropped substantially, by almost 50%. The Representative pointed to the fact that it had had a publication which documented several such cases and their impact on public health. She stressed that that showed the significant importance of exceptions and limitations, and the difference they could make in the lives of people. However, she also stated that one needed to be aware that there had been a number of challenges in the use of exceptions and limitations, several of which had been highlighted in its submission in document SCP/25/3. The Representative pointed to several points which had been made in that submission, for instance, in the submission by UNCTAD: "It may be stated that patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational." Furthermore, the Representative highlighted the fact that there had been a number of structural impediments which had prevented many members from using exceptions and limitations, for example, the lack of technological capacity, especially the manufacturing capability. She noted that, for example, a vast majority of developing countries and least developed countries, except for Bangladesh, would lack manufacturing capacity in the pharmaceutical sector, and in the absence of such capabilities, developing countries would not be able to rely effectively on the use of flexibilities without depending on another country. The Representative pointed to the fact that it had been even more worrying that some countries wishing to use exceptions and limitations had faced significant pressure from developed countries and the pharmaceutical industry, which had deterred them from using such flexibilities, especially compulsory licenses. The Representative explained that that had been specifically mentioned during the United Nations High-Level Panel Report on Access to Medicines. According to the Representative, as a result of that pressure, many people would not have access to important medicines, and that would come at the cost of their lives. She reiterated that that was not a problem only in developing countries but also in developed countries. The Representative further stated that there had also been a number of institutional and administrative barriers, such as flawed technical assistance from developed countries and international organizations, which meant that at times, the incorporation of exceptions and limitations into national law had not been done in an optimal manner, and when it had been necessary to use flexibilities, it had become a significant challenge. She further outlined several other threats such as TRIPS Plus obligations and agreements, as well as bilateral investment treaties, which had given investors certain rights to take action against the country if exceptions and limitations were used – all of those challenges had been problematic, significant challenges in using exceptions and limitations. As two final points, the Representative mentioned that: (i) there was a need to have more clarity and transparency on WIPO's technical substance in national IP strategies and laws, and how such technical assistance could take those constraints into consideration and what kind of assistance they could give in terms of overcoming such barriers; (ii) it was necessary to consider the role of WIPO in addressing some of the political pressures that countries faced when they wanted to use exceptions and limitations.

54. The Delegation of Colombia was delighted to see the Chair having been reelected. The Delegation stressed the fact that it did not share the view presented by the Representative of TWN regarding Colombia, and considered it important to describe the process which had been going on that year in Colombia, through a statement that had been made on compulsory licensing before the Ministry of Health. The Delegation quoted the Executive Report for the "Process for the declaration of public interest of imatinib in Colombia". The Delegation noted that that had been the official statement of the Ministry of Health, and that the compulsory license had been declared through the established process for reasons of public interest in order to control prices, since it had not been possible to reach an agreement with the manufacturer. The Delegation explained that that was what had been achieved during the preceding quarter in Colombia. It further specified that it had been an administrative act, and as to the legal issues which had been called into question by non-governmental organizations in Colombia, as to how the decision regarding compulsory

licensing had been made, the Delegation believed that the effects were clear and that the documentation could be consulted on the website (see https://www.minsalud.gov.co/salud/MT/Paginas/medicamentos-propiedad-intelectual.aspx). It concluded that the hypotheses put forward by the Representative of TWN were not provable, and stated that it was clear that there had been a proper administrative procedure which had been followed and which could be consulted on the website as indicated.

55. The Delegation of Brazil thanked the members and observers who participated in the sharing session and provided their comments and views which were consolidated in the document SCP/25/3, in particular Guatemala, Dominican Republic, Canada, WTO, UNCTAD, and TWN, for their contributions which contained useful information on the uses of exceptions and limitations. The Delegation pointed to the fact that the submission made by UNCTAD in document SCP/25/3 contained an important aspect for consideration by members, namely: "patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational". Furthermore, the Delegation stressed that the contribution made by UNCTAD also highlighted the issue of lack of awareness regarding exceptions and limitations, especially in developing countries. In the view of the Delegation, that reinforced the necessity of advancing the agenda item in order to produce a non-exhaustive document compiling exceptions and limitations to patent rights. The Delegation stressed that all those issues would benefit from the production of a manual compiling exceptions and limitations that were used in the different jurisdictions. It explained that the manual could serve as a valuable tool for the promotion of awareness by WIPO and other organizations. From the perspective of the Delegation, it should contain: (i) the description of the exceptions and limitations in question; (ii) its stated goal; (iii) options that countries had used to implement it internally; (iv) obstacles that members had reported to have faced; (v) the eventual results of the implementation. The Delegation explained that many sources of information could be used for the elaboration of such a manual, such as: (i) studies circulated during the SCP, in particular the expert study contained in document SCP/15/3 and its annexes, as well as the five studies produced by the Secretariat for the 20th session of the SCP; (ii) the answers provided by members to the questionnaire, as available in document SCP/17/3 and addenda; (iii) the seminars held during the 20th and the 21st sessions of the SCP; (iv) Member States' experience in case studies, as available in documents SCP/23/3 and SCP/25/3; (v) the discussions held during the SCP, including sharing sessions. The Delegation further explained that that had been a non-exhaustive list and the Secretariat could also rely on documents produced by international organizations, such as the WTO or UNCTAD, which also addressed the use and existence of exceptions and limitations. The Delegation hoped that members would be able to agree on that matter as that was in the interest of each and every Member State. The Delegation further expressed its appreciation for the support received for its proposal from the regional groups, the African Group, GRULAC, and China, as well as from the individual Delegations of Chile, Iran (Islamic Republic of), India, Indonesia and South Africa.

56. The Delegation of China thanked the Member States for sharing the information with regard to document SCP/25/3. The Delegation further noted that it had received an addendum, SCP/25/3 Add., containing the experience and practice of the Dominican Republic, which mentioned that the Ministry of Health had been exploring the use of a drug for HIV countrywide, but had failed. The Delegation asked to provide more specific information as to whether there had been any clarification to explain why it had failed, and why the experience had not succeeded. The Delegation explained that it was very interested in that particular information, as information from different countries and their experiences was very useful for all the Member States to design their own legislation and practice.

57. The Secretariat explained that the document reflected the text that had been received from the Delegation of the Dominican Republic.

58. The Delegation of Indonesia reiterated its support of the statement and proposal delivered by the Delegation of Brazil. In its view, the elaboration of an exceptions and limitations manual in a non-exhaustive manner to serve the Member States was important to face the challenges in the implementation of exceptions and limitations, such as the lack of clarity and scope that made the implementation difficult, as well as other structural impediments, such as the lack of technological capabilities that had been highlighted in the document SCP/25/3.

59. The Delegation of Nigeria, in its national capacity, expressed support for the proposal made by the Delegation of Brazil.

60. The Representative of TWN explained, with regards to the statement made by the Delegation of Colombia, that it had not been TWN who referred to the experience of Colombia in its intervention, but it had been a reference made by other non-governmental organizations.

61. The Delegation of Iran (Islamic Republic of) reiterated its support for the proposal made by the Delegation of Brazil and believed that that proposal could be a very good basis for the future work on exceptions and limitations.

62. The Delegation of India expressed its full support for the proposal made by the Delegation of Brazil. It was looking forward to working on it as a good basis on which further work could be done on exceptions and limitations, and was hopeful that the SCP would be able to produce a concrete document, which could be used by various patent offices all over the world, to further the exceptions which had been important for patent offices, especially those in developing countries.

63. The Delegation of the Dominican Republic expressed its appreciation to the Chair for her work and guidance and thanked the Secretariat for preparing the documents for the 25th session of the SCP. The Delegation aligned itself with the statement made by the Delegation of Brazil. Referring to the question raised by the Delegation of China concerning document SCP/25/3 Add., the Delegation stated that the industrial property office of the Dominican Republic had been approached by the HIV/AIDS Council of the Dominican Republic to issue a compulsory license for an anti-retroviral drug. However, the industrial property office had concluded that the requirements for issuing a compulsory license under the law of the Dominican Republic on industrial property had not been met, and informed that fact to the Council.

AGENDA ITEM 7: QUALITY OF PATENTS, INCLUDING OPPOSITION SYSTEMS

64. The discussion was based on documents SCP/17/7, 8, 10, SCP/18/9, SCP/19/4, SCP/20/11 Rev., SCP/23/4 and SCP/24/3.

65. The Delegation of Latvia, speaking on behalf of the CEBS Group, stated that it was pleased to see that a sharing session under agenda item 7 would take place, and was looking forward to fruitful discussions. The Delegation further noted that the quality of patents was at the core of the patent system. It stated that a high quality of patents allowed the intellectual property system to fulfill its functions and that work sharing was one of the instruments facilitating the patent offices to deliver high quality patents and, at the same time, it helped them to avoid the duplication of work. The Delegation was of the view that more in-depth discussions on the quality of patents, and on various aspects that ensured the high quality of patents, would benefit all Member States and all patent offices. Finally, the

Delegation reiterated its support for the proposal to launch a questionnaire on the quality of patents, as it had been outlined in the proposals of the Delegations of Denmark, Canada, the United Kingdom and the United States of America, as well as for the proposal made by the Delegation of Spain contained in document SCP/24/3.

66. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, noted that it was convinced that the cornerstone of efficiency and effectiveness of patent offices' daily work was international cooperation, including work sharing. The Delegation explained that such work sharing played an important role as a powerful tool for the granting of high quality patents. It further noted that patent offices took advantage of work sharing in order to reduce backlogs, to avoid the duplication of work and to improve the overall efficiency of the patent granting process. The Delegation was aware of the complexity of the assessment of the inventive step, and wished to see further studies on the assessment of the most difficult patentability requirement within the SCP. The Delegation recalled that at the previous session of the SCP, the Committee had had presentations not only by the Secretariat on the web page for work sharing and WIPO CASE, but also by some Member States on how to facilitate examination and administration of patent applications. The Delegation believed that having more examples on quality of patents could help Member States collect information on existing work sharing programs and to educate themselves. In that respect, the Delegation was looking forward to discussing the questionnaire, which covered cooperation and collaboration between patent offices, in search and examination of patent applications, as well as quality of patents. In the view of the Delegation, that sharing session and the proposed study on the assessment of the inventive step could provide an additional source of useful information. The Delegation reiterated its full support for the proposals submitted by the Delegation of the United States of America (documents SCP/19/4 and SCP/23/4), by the Delegation of the Republic of Korea, the United Kingdom and the United States of America (document SCP/20/11), by the Delegation of Spain and endorsed by all other Member States of the European Union (documents SCP/19/5/rev.) and by the Delegation of Spain (document SCP/24/3), as well as earlier proposals concerning quality of patents made by the Delegations of Denmark, Canada, the United Kingdom and the United States of America (documents SCP/17/7,8, 10 and SCP/18/9). The Delegation expressed its belief that the presentations that some Member States of the European Union were going to deliver on that item would contribute to the ongoing discussions. The Delegation was looking forward to constructive discussions and was ready to commence work to the benefit of all Member States.

67. The Delegation of India, speaking on behalf of the Asia and Pacific Group, was of the view that the SCP should arrive at a common understanding on what was meant by "quality of patents": whether it meant efficiency of patent offices in granting patent applications, or the quality of patents granted, in particular, how to ensure that patent offices did not grant patents of questionable validity. The Delegation expected that the Secretariat provided regular information to Member States on the outcome of patent applications in different jurisdictions, as well as outcomes of opposition procedures. The Delegation highlighted that Article 29.2 of the TRIPS Agreement stated that a party to the TRIPS Agreement might require patent applicants to provide information about applicants' corresponding foreign applications and grants. In that regard, the Delegation stated that the Secretariat should conduct a study on the extent to which Article 29.2 of the TRIPS Agreement was implemented in different countries, and how it's broader use might be promoted to improve patent quality.

68. The Delegation of Turkey, speaking on behalf of Group B, thanked the Secretariat for the presentation to be made on the website regarding the opposition systems. The Delegation hoped that it would be a good resource on the matter for the stakeholders. Moreover, the Delegation thanked those Delegations who were going to deliver the presentations. The Delegation was glad to see that there had been continuing interest in the

topic of inventive step/obviousness. It was looking forward to further work on that substantive issue, and would like 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 SCP/24/3. With respect to work sharing and collaboration, the Delegation continued to stress that further discussions and exchange of views on those topics in the SCP would be valuable, given their importance to many Member States. The Delegation considered unfounded concerns that work sharing was intended to lead to the harmonization of substantive patent law. It explained that work sharing had been simply a means for intellectual property offices to share information relating to a particular patent application, which had allowed for a broader scope of prior art to be considered as part of the patent examination process, while reducing duplicative work by the intellectual property offices. In the view of the Delegation, the result was that patent examination had been both faster and more thorough, which had ultimately lead to higher quality patents and a more efficient patent system. The Delegation hoped that all could agree that such a result had been beneficial to all Member States, and intellectual property offices, and had not constituted a step in the direction towards the harmonization of substantive patent laws. The Delegation stressed that work sharing and collaboration were not the only a means to ensure high quality patents. Nevertheless, it believed that such mechanisms were important tools that Member States could use to complement other efforts to ensure that the national patent systems fulfilled the objectives and granted high quality patents.

69. The Delegation of Nigeria, speaking on behalf of the African Group, stated that beyond the work sharing aspects of the quality of patents, it had a different view on that subject. It approached the subject from the basis of acknowledging that disclosure had been the bedrock of the patent system and, like the questions posed by the Delegation of India in its statement on behalf of the Asia and Pacific Group, there needed to be a certain level of understanding, or a shared view of what “quality of patents” actually meant. For the Delegation, it continued to be a concern that certain practices within the patent system had enabled the avoidance of full disclosure of all necessary information required to ensure high quality of patents, which stifled innovation and allowed for excessive protection of exclusive rights. The Delegation was looking forward to engaging constructively on that agenda item, and was hoping that the sharing session would provide an opportunity to discuss more in depth and gain more insight.

70. The Delegation of China thanked the Secretariat for its efforts on the questionnaires, information updates and exchanges on court cases. Regarding the questionnaires on the quality of patents and work sharing, the Delegation stated that those were vital for future discussions and they would help to further consider the definition and the scope of quality of patents; they would also help facilitate the collection of information on work undertaken by Member States on work sharing. The Delegation was looking forward to hearing more national experiences during the coming session. In the view of the Delegation, improving the quality of patents had a catalytic role for the effective operation of the patent system, therefore the quality of patent issues on the exchange of information would have a certain positive significance - Member States could learn from each other’s experiences. The Delegation also hoped that that agenda item could lead to prioritizing capacity building for the patent offices through information exchange and discussions relating to the use of IT facilities, such as patent databases and patent search and examination tools, technical assistance to developing countries and enhanced training on conducting prior art search and examination for patent examiners.

71. The Delegation of Iran (Islamic Republic of) associated itself with the statement made by the Delegation of India on behalf of the Asia and Pacific Group on the issue of quality of patents, including opposition systems. The Delegation was of the view that the first and the most important stage in considering and discussing the quality of patents was that the SCP arrived at a common understanding on the meaning of the term “quality of patents”, since the

terminology might have different meanings. The Delegation reiterated that a precise definition of the concept of patent quality was necessary for further discussions on that issue during the SCP. In the view of the Delegation, a lack of common understanding of the meaning of the concept had made it difficult to fully comprehend the topic. With regard to work sharing, the Delegation was of the view that work sharing had nothing to do with the quality of patents. In its view, the quality of examination needed to be improved substantially, in conformity with the national policy objectives of a country, so that the high social cost of granting patents to insignificant improvements, which would only create barriers for the dissemination of knowledge and transfer of technology, could be avoided. Instead, the Delegation stated, experience sharing, for example, sharing of technical skills and experiences of patent offices through bilateral cooperation, might improve the quality of patents. The Delegation was of the view that work sharing in general, and the PPH in particular, would lead national laws to harmonization in practice. In its opinion, work sharing was a matter of procedure which fell outside the mandate of the SCP as a substantive committee, the Delegation reiterated that that should not be construed as a pool of norm-setting in the future. Lastly, the Delegation expressed its dissatisfaction that while the topic of opposition systems continued to be maintained in the agenda along with quality of patents, the focus of the discussions under that agenda item had been exclusively on patent quality during the four previous sessions of the SCP. The Delegation therefore urged that the Committee would give equal prominence to patent quality and opposition systems in its future sessions.

72. The Delegation of Brazil stated that the discussion on quality of patents was a debate with merit considering that patents of high quality were key to reaching the objectives of patent protection. The Delegation noted that the debate within the SCP had confirmed the vision that a one-size-fits-all approach was inadequate for the efficient implementation of the patent system, as different countries had high level goals which in turn were affected by many factors, including policies and individual country's capacities to absorb technology. In the view of the Delegation that also implied that a common definition for substantive patent criteria would reduce policy space and, thus, affect the capacity of Member States to fine-tune their patent systems according to their specific challenges and goals. The Delegation pointed out that the definition of the term “quality of patents” had a range of perceptions, as had been demonstrated by the discussions among members of the SCP. It mentioned the revised proposal made by the Delegations of Canada and the United Kingdom contained in document SCP/17/8, where the understanding of “quality of patents” was defined as encompassing the quality of the totality of the features and characteristics of the work that national and regional patent offices and judicial systems pursued in satisfying their legal, social and economic requirements. Additionally, the Delegation referred to the comments contained in document SCP/17/INF/2, which had also indicated different perceptions on the matter, for instance, some countries had framed the issue as something related to the quality of the internal procedures of the patent office, while others had seen it as mostly related to the quality accorded to the applicants and third parties. The Delegation further highlighted another very important element related to the information technology tools that were necessary to meet the needs of a modern patent office. As an example of activities related to the topic, the Delegation noted the role of quality management systems that would improve the internal control, risk management and governance within patent offices, which had also been raised by the Delegations of Canada and the United Kingdom in document SCP/17/8. The Delegation further referred to document SCP/17/INF/2 where the Delegations of Denmark, Germany, Portugal and Spain had underlined the importance of quality management systems. The Delegation agreed with that vision, namely that it was necessary to consider matters related to the structure of the information technology tools used by patent offices. The Delegation explained that the information technology tools included access to patent databases and specialized scientific publications, which are fundamental for the deliberation of a comprehensive report of prior art among other activities of the patent offices. In the view of the Delegation, that was especially relevant for

developing countries, and should form an integral part of the discussion. Lastly, the Delegation stressed the importance of opposition procedures for patents of quality. It explained that the possibility of opposition by third parties and other stakeholders was a fundamental mechanism of the patent system, since it offered the opportunity for the submission of technical information relating to the patentability, which was of great assistance during the substantive examination of patent applications. The Delegation added that through opposition procedures, the patent system increased the legal certainty and the quality of the examination of patent applications. The experience of the Delegation had shown that the participation of competitors and other interested third parties through the opposition procedures had provided valuable information for consideration during substantive patent examination, and enhanced the quality of the work done by the office. In the view of the Delegation, that matter should be addressed during the discussion under the topic to further explore the role of opposition systems for the provision of high quality patents.

73. The Delegation of Indonesia aligned itself with the statement delivered by the Delegation of India on behalf of the Asia and Pacific Group. It also thanked the Delegation of Brazil for laying out the different views and perceptions regarding the quality of patents. The Delegation stressed the importance of a precise definition and common understanding of the concept of "quality of patents" to further discussion in the SCP. Furthermore, in the view of the Delegation, the problem of patent quality could not be resolved by simply adopting the practice of other intellectual property offices or by simply collaborating with other offices through work sharing arrangements. It noted that the concept of work sharing had little to do with patent quality. Further, the Delegation stressed that the examination should be improved in conformity with the policy objectives of a country. It reiterated its position that one size did not fit all and there was diversity, including implementation of the flexibilities related to the scope of patentability criteria in view of public policy objectives, as well as diversity in the scope of patent protection. In the view of the Delegation, work sharing would indirectly interfere with that diversity, leading to substantial harmonization of patent laws which it could not support. Furthermore, the Delegation was of the view that discussions on the quality of patents should include discussions on opposition systems, because opposition systems had strengthened the quality of patents. It concluded that equal prominence should be given to the opposition system under that agenda item.

74. The Delegation of Argentina congratulated the Chair on her reelection and extended the congratulations to the Vice-Chairs. It also thanked the Secretariat for the organization of the meeting and the preparation of the documents. The Delegation stated that for the patent system to work correctly and promote innovation, for the economic interests and well-being of the public, there was a need of a high quality patent system. In other words, it explained, it was essential to improve the understanding of the requirement of inventive step, because it was closely connected with the quality of patents. The Delegation acknowledged that the examples and cases that had been shared during the sharing session should have been of interest to all members of the SCP. The Delegation further noted another matter of interest to all Member States regardless of their level of development, namely, an improvement in the quality of search, because that would benefit not only the patent holders, but society as a whole. In the opinion of the Delegation, the examiners' work would be facilitated by the searches carried out by other offices on the same invention. The Delegation also observed that the use of other routine work that had been done by other offices did not mean that the criteria for patentability had less diversity. The Delegation concluded that it was open to make progress on all of the different topics under consideration.

75. The Delegation of Colombia referred to the draft questionnaire that had been under consultation within the SCP, and was of the opinion that the quality of patents was connected to the compliance with the patentability requirements in specific jurisdictions. In its view, if an application had met the requirements and procedures laid down in the applicable law (preferably including prior art examination and access of third parties in the

administrative stage to exercise their right of filing an opposition), a patent should be granted. The Delegation observed that that would be the best way of guaranteeing the due process, respecting the interests of researchers and technological progress, the rights to exclusivity and the expectations of society with regard to new inventions and progress in technology.

76. The Representative of OAPI associated himself with those delegations who had spoken before him to congratulate the Chair on her election. He noted that the previous speakers had taken the words out of his mouth to some extent, because he had wished to have discussions on the meaning of "quality of patents". The Representative stressed the importance of reaching an understanding on the term "quality of patents". He acknowledged that when the SCP had received the questionnaire on quality of patents, it had been rather divided: all the questions had referred to the procedure for the granting of patents, the prior art search and examination system, whereas in the world, there were several different patent systems, such as those that conducted substantive examination and those that conducted formality examination only. The Representative noted that each system had a number of instruments enabling the inventor or right holder to defend their rights. He described the system of OAPI, which was soon to be changed, where no substantive examination had been carried out until the point when there was a legal challenge during which the compliance with the patentability criteria would be examined. The Representative concluded that an agreement had to be reached on the concept of "quality of patents" taking into account such different systems. Furthermore, the Representative considered that the issue of opposition systems was very tricky, and that there was a need to reach an agreement. He observed that there had been several different systems throughout the world, regarding the timing of oppositions and the grounds for opposition. In his opinion, it was important to discuss the term "opposition systems" to reach an agreement on what exactly was being discussed.

77. The Delegation of Singapore congratulated the Chair and the Vice Chairs on their election. The Delegation stated that the topic on the quality of patents, like some of the other topics within the main agenda including patents and health, were broad issues. The Delegation further stated that the quality of patents depended on a myriad of factors. The Delegation suggested that a more practical approach to advance discussions could be for the Member States to first agree on the effectiveness affecting the quality of patents, and subsequently, to examine quality issues that related to the work carried out by patent offices. For example, in the area of search and examinations, steps could be taken to analyze ways of increasing the quality of examination. While acknowledging the fact that the examination practices might differ across various jurisdictions due to policy objectives, the Delegation noted that the sharing of search results among offices would be a pragmatic and effective way to increase efficiency and reduce the duplication of work by examiners. The Delegation expressed its hope that the SCP would advance discussions on the quality of patents.

78. The Delegation of India congratulated the Chair on her election, and thanked the Delegation of Spain for its proposal contained in document SCP/24/3. The Delegation of India stated that the quality of patents was not finally determined by instrumental efficiencies but rather by the appropriate application of formal and substantive issues of the respective Member States, in conformity with their national laws. The Delegation was of the view that the problem with the deterioration of the quality of patents was not mainly due to an inadequate infrastructure but as a result of lowering standards of patentability and examination practices. The Delegation further stated that the SCP first needed to advance on the common understanding of what was meant by quality of patents since this terminology might have different meanings for each Member State. The Delegation referred to paragraph eight of document SCP/24/3 and expressed its hope that the proposed study would improve the understanding of the inventive step for examiners in the national patent offices. The Delegation expressed its interest in discussing the following topics: (i) common general knowledge; (ii) combination with state of the art; (iii) combination/juxtaposition

versus synergic effects; (iv) dangers of hindsight analyses; (v) secondary indicators; (vi) selection inventions; and (v) the assessment of inventive step in the chemical sector with a special reference to Marrakech claims and further topics. Furthermore, the Delegation stated that it was not in favor of any attempt of harmonization of patent laws, in the name of work sharing under the pretext of quality of patents, and expressed its concerns for the norm setting in the future. The Delegation affirmed the proposal for further studies on different thresholds in national patent legislations for sufficiency of disclosure. According to the Delegation, such studies might further be enhanced to probe the role of sufficiency of disclosure in the context of transfer of technology, since transfer of technology was also linked to the quality of patents. The Delegation pointed out that it was concerned by the traditional knowledge related databases and stated that the opening of databases like the Indian Traditional Knowledge Library might risk rampant bio piracy. The Delegation noted that India had shared its Traditional Knowledge Digital Library with some patent offices for search and examination, but that was not made available to the public. The Delegation was of the opinion that the possible acceptance of patentability decisions reached by another office under the PPH was unwarranted. The Delegation explained that the Indian Patent Office utilized reports from foreign patent offices, but the Indian Patent Act required Indian patent examiners to carry out the search and examination themselves. The Delegation of India stated that as long as the work remained within the confines of the study, and as long as there was no attempt for any harmonization, the Delegation had no major concern and was very happy to participate in the discussions on the agenda item on quality of patents.

79. The Delegation of the United States of America stated that work sharing programs were simply a tool which could be used by patent offices to streamline their work and to increase the efficiency and quality of their work. The final product would be the eventually issued patent. Further, the Delegation pointed out that work sharing made the work product by an examiner who had conducted an initial examination of the corresponding application available to a subsequent examiner who later conducted examination of corresponding applications. The Delegation continued that the patent prosecution highway (PPH) was a formalized process, imposing various requirements on applicants in order for them to participate. The Delegation noted that the basis of the program was still to let a later examiner have access to the results of an earlier examination, whereby the second examiner was still expected to carry out an independent prior art search. The Delegation pointed out that since the second examiner had access to the prior art found during the earlier examination, he or she could carry out the prior art search in a more efficient manner leading to a more complete and thoroughly searched examination. The Delegation concluded that that resulted in a better examination of the application and in higher quality of patents. The Delegation noted that in the PPH and in other work sharing arrangements, every examiner was expected to carry out a search and was expected to examine the application according to the applicable national laws. The Delegation stated that the determination as to whether a patent should be granted or not was still made by the national offices using their national laws, and therefore, there was no loss of independence by the offices when taking part in work sharing programs such as the PPH or the PCT system. The Delegation indicated that just because an examiner was given the opportunity to see the work which was carried out earlier by an examiner did not mean that the national laws under which the second examiner carries out the patentability determination were changed. The Delegation pointed out that there was no harmonization of those national laws, since there was nothing in work sharing programs that affects how the national legislature wrote and courts interpreted those national laws.

80. The Delegation of Australia congratulated the Chair on her election and aligned itself with the statement made by the Delegation of the United States of America. In its opinion, work sharing would assist in the removal of unnecessary duplication and to make an important contribution to patent quality.

81. The Delegation of Ireland thanked the Delegation of the United States of America for its statement. The Delegation pointed out that search reports played an important part in the patent application process, since insufficient search might result in granting of a patent where it should not have occurred. The Delegation stated that, in its country, applicants could submit the search reports of the UK Patent Office, the German Patent Office and the European Patent Office before the Irish Patent Office, and that the Irish Patent Office would consider those search reports during its examination procedure. The Delegation considered that that was the only way a very small office, such as the Irish Patent Office, could work.

82. The Delegation of Japan congratulated the Chair on her election and thanked the Secretariat for preparing the meeting. The Delegation aligned itself with the statement made by the Delegation of the United States of America, and stated that work sharing programs such as the PCT and the PPH had been developed in order to provide useful information to patent examiners but not to restrict the examination practice of any patent office. Therefore, in its opinion, work sharing did not lead to restriction of the examination practice of patent offices. The Delegation pointed out that some delegations expressed concerns on how to define quality of patents. The Delegation believed that instead of defining what quality of patents meant, the aim should be to consider the best possible ways to improve the quality of patents. According to the Delegation, quality of patents included various quality elements, such as the quality of granted patents themselves, and the quality of patent examination. The Delegation concluded that it was important to consider how to improve the quality of those elements in order to improve the intellectual property system.

83. The Delegation of Portugal stated that it continued to support all proposals to increase the quality management system of each national office, and the work sharing experience programs that could avoid the duplication of work. The Delegation aligned itself with the statement made by the Delegation of the United States of America.

84. The Delegation of Colombia expressed its support to the statement made by the Delegation of the United States of America. It stated that the work sharing mechanisms had been supportive during the past few years to speed up work and to obtain information in a way that had previously not been possible.

85. The Delegation of Canada congratulated the Chair on her re-election and aligned itself with the statement made by the Delegation of the United States of America. The Delegation affirmed that it was a firm believer in the value and efficiencies that could be derived from work sharing agreements.

86. The Delegation of the United Kingdom congratulated the Chair and Vice Chairs on their election and aligned itself with the statement made by the Delegation of the United States of America. The Delegation stated that work sharing among patent offices could help improve quality by giving examiners a head start, considering the additional prior art found by another office and improving efficiency of examination. Further, the Delegation pointed out that although the IP Office of the United Kingdom (UKIPO) was a member of the PPH and other bilateral PPH agreements, Sections 17 and 18 of the UK Patent Act obliged examiners to conduct their own search and patent examination. The Delegation concluded that those Sections of the UK Patent Act did not prevent the UKIPO from taking part and seeing the value in the work sharing efforts, such as the PPH. The Delegation affirmed that it continued to support all work sharing efforts and efforts within the SCP to recognize the value of such efforts or initiatives, in particular the proposal outlined in document SCP/20/11 Rev.

87. The Delegation of South Africa aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation recognized work sharing as an important tool in patent quality, but noted that that could also be dangerous to

some extent. The Delegation stated that other factors needed to be discussed in order to improve the quality of patents, such as sufficiency of disclosure, defining the concept of inventive step and analyzing the impact of opposition proceedings on the quality of patents.

88. The Delegation of Tunisia congratulated the Chair on her re-election. The Delegation wished to highlight that the topic on quality of patents was an important one, especially for the patent holders, as they could be sure to have a technically solid and legally valid patent. The Delegation noted that the quality of patents also depended on the material and human resources that the national patent offices had available.

89. The Representative of Innovation Insight referred to the statement made by the Delegation of Tunisia. She stressed that the quality of patents was important to patent applicants and society as a whole, as poor quality patents created uncertainty in the market and were a problem for the competitors of the applicants. Further, she stated that the topic of quality of patents should receive considerable attention.

90. The Representative of MSF aligned herself with the statement made by the Delegation of India and stated that the discussions on the quality of patents should not undermine the discussion of any patentability criteria, especially with regard to public health issues. The Representative noted that WIPO should have better public health-oriented technical capacity building activities in order for the national IP offices to adapt strict and public health-sensitive patentability criteria.

91. The Representative of KEI pointed out that the debate on the quality of patents had a long history which was connected to the question of what should be patented and what should not be patented. The Representative indicated that it would be interesting to have more evidence on the areas where patent quality problems appeared to loom the most. Further, the Representative stated that clearer guidelines on what could be patented, and on what could not be patented, might be a pragmatic solution to the problems on the quality of patents.

92. The Representative of TWN expressed her belief that there was no evidence that work sharing improved the quality of patents as there were a large number of weak patents being granted. The Representative stated that other measures than work sharing had proven successful in a number of different countries, like raising the threshold of patentability or implementing opposition systems.

93. The Representative of Innovation Insight referred to a study carried out by the KIPO, EPO and USPTO, where it was found that in 92 percent of all analyzed cases that involved collaborative search and examination , additional prior art had been found by other offices. The Representative concluded that the SCP should take such studies into account.

94. The Secretariat made a presentation on the new WIPO website on opposition and administrative revocation mechanisms.

95. The Delegation of the Republic of Korea made a presentation on the recent revision of its Patent Act to improve the quality of patents. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_quality_of_patents_republic_of_korea.pdf.

96. The Delegation of India reported that there were two opposition proceedings in India, the pre-grant and the post-grant oppositions. The Delegation informed that the pre-grant opposition could be launched by any third party and that no fees were charged for filing such a pre-grant opposition. In comparison, the post-grant opposition could only be filed after publication of the patent application. Further, the Delegation reported that India was in the

process of introducing a further post-grant opposition which could be filed up to one year after the grant of a patent.

97. The Delegation of the United Kingdom made a presentation on inventive step. The Delegation explained how the requirement of inventive step was applied in the United Kingdom. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_inventive_step_united_kingdom.pdf.

98. The Delegation of Romania made a presentation on inventive step and the quality of patents. The Delegate explained the concept of inventive step and its application under the patent law of Romania and its impact on the quality of patents. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_inventive_step_romania.pdf.

99. The Representative of the EPO made a presentation on the requirement of inventive step and its application in the EPO. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_inventive_step_epo.pdf.

100. The Delegation of Ireland thanked the Representative of the EPO for her presentation, and asked the Representative about her experience with the PPH in the EPO and if such programs improved the quality of patents.

101. The Representative of the EPO replied that the number of applications received under the PPH was limited, and therefore the EPO had had only limited experience with the PPH.

102. The Delegation of Spain made a presentation on the assessment of inventive step in biotechnology patent examination. The presentation is available on the WIPO website at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_inventive_step_biotechnology_spain.pdf.

103. The Delegation of Côte d'Ivoire thanked the Delegation of Spain for its presentation. The Delegation believed that the inventive step posed many problems and that it represented the patentability criteria on which it was necessary to insist the most. The Delegation further asked the Delegation of Spain how it assessed industrial applicability in patent examination concerning antibodies.

104. The Delegation of Spain replied to the Delegation of Côte d'Ivoire and specified that industrial applicability of antibodies was determined as any other protein. The Delegation clarified that, in patent applications, the industrial application usually indicated for proteins was a clinical application. The Delegation observed that, if such application had not been indicated, antibodies could in any case be used as testing devices or diagnostic testing devices. The Delegation therefore considered that antibodies *per se* had a diagnostics use, since they always had to be synthesized to interact with a protein. The Delegation added that antibodies had the implicit use to join the protein for diagnostics purposes, to find it in a sample.

105. The Delegation of Spain made a presentation on the common general knowledge of a person skilled in the art as it was evaluated before the Spanish Patent and Trademark Office. The presentation is available on the WIPO website at: http://www.wipo.int/edocs/mdocs/scp/es/scp_25/scp_25_inventive_step_knowledge_person_skilled_in_the_art_spain.pdf. The Delegation further considered that it would be interesting to hear the experiences and practices of countries other than Group B countries on the topic under discussion.

106. The Delegation of Ireland observed that most of the presentations made by Delegations within the SCP had been about the problem-solution approach to evaluating inventive step. The Delegation was of the opinion that, although the Delegation of the United Kingdom had referred to a different test, the Pozzoli test, it would be interesting in the future if the Committee could hear other presentations from offices that used alternative methods. The Delegation believed that even if many patent offices, because of the EPO influence, used the problem-solution approach, some of them, such as the UK Patent Office and possibly the German office, used a different approach.

107. The Delegation of Japan made a presentation on the Examination Guidelines for Patentability - Inventive Step - of the Japan Patent Office. The presentation is available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_inventive_step_japan.pdf. The Delegation further supported the proposal made by the Delegation of Spain, contained in document SCP/24/3.

108. The Delegation of the United States of America thanked the Representative of the European Patent Office and the Delegations of the United Kingdom, Romania, Spain and Japan for their presentations on the assessment of inventive step. The Delegation reminded that in the previous session of the SCP, they had already given a general presentation on the assessment of inventive step in the USPTO. The Delegation expressed its wish to briefly add to such a presentation an explanation on how the non-obviousness requirement was applied in the United States of America in the context of chemical compounds. The Delegation noted that in the United States of America, a large body of jurisprudence guided the patent examination process at the USPTO. The Delegation pointed out that the law, and some significant cases in that area, were summarized in the Manual of Patent Examination Procedure (The MPEP), which provided guidance to the USPTO on how to do the examination. The Delegation specified that Chapter 2100 of the MPEP clarified the topic of patentability, and encouraged people interested in finding out more about examination of inventive step in the USPTO to consult the Manual which was freely available on the USPTO's website. The Delegation stated that in the context of examining obviousness of inventions relating to chemical compounds, it was generally expected that compounds that were similar in structure would also have similar properties. Thus, the Delegation noted that a *prima facie* case of obviousness could be made when chemical compounds claimed to have very close structural similarities, similar properties and similar utilities to compounds described in prior art. The Delegation observed that, for instance, compounds which were positioned isomers, or true homologs, were considered to be of sufficiently close structural similarity, and therefore there was an expectation that such compounds also possessed similar properties. However, the Delegation pointed out that other types of isomers, such as stereoisomer, that had the same empirical formula, but a different spatial relationship of atoms within their molecule, were not necessarily considered as equivalent by those skilled in the art. Therefore, the Delegation stressed that those isomers were not suggestive of each other, and if they were found in the prior art, they did not necessarily render a claimed isomer obvious. Similarly, the Delegation stated that homologs which were far removed from adjacent homologs were not generally expected to have similar properties. The Delegation specified that in any case, close structural similarity between the prior art and the claimed compound was only one element and must be considered with all the other relevant facts in determining the issue of obviousness. The Delegation considered that a finding of obviousness, based on the structural similarity of compounds, could be overcome by the applicant by presenting evidence showing that there was no reasonable expectation of similar properties in structurally similar compounds. For example, evidence that would negate a conclusion of obviousness could include a showing that there was a substantial degree of unpredictability in the pertinent art area. In another example, an obviousness objection based on structural similarity between the claimed compound and prior art compounds could be rebutted by showing that the claimed compounds possessed unexpectedly advantageous or superior properties. The Delegation observed that another

issue that could come up during the examination of chemical patent application claims was whether a claimed compound or species was obvious over a genius disclosed in prior art, which encompassed but didn't specifically disclose the claimed compound or species. The Delegation stressed that, once again, the determination of obviousness or non-obviousness should be made based on the facts of the particular case, in light of the totality of the circumstances. The Delegation stated that the fact that the claimed species were encompassed by the prior art genius was not sufficient by itself to establish a *prima facie* case of obviousness. The Delegation considered that the examiner had to consider a number of factors, including similarities and differences between the closest disclosed prior art genius and the claimed species with respect to structure, properties and utilities. The Delegation noted that the level of ordinary skill in the art, the size of the genius disclosed in the prior art, any motivation provided by the prior art to select the claimed compound or species, the predictability of the technology, and other factors, all had to be considered by the examiner. The Delegation observed that those were just a few examples of issues that could come up in the patent examination of chemical compounds, but that there were many other issues that were pertinent to the determination of non-obviousness, or also called inventive step, that could not be covered by their presentation. In view of the complexity of the topic of inventive step and obviousness, the Delegation supported additional work on that topic to be carried out within the SCP. For example, as previously proposed during the twenty-second session of the SCP, the Delegation suggested that the SCP study additional elements of the obviousness and inventive step evaluation, such as how various offices determine the conditions under which it was proper to combine prior art references, to decide whether claims were non-obvious, and the manner in which secondary considerations, such as commercial success and supplemental data, could be considered and applied during examination in different jurisdictions. In addition, the Delegation noted that work on inventive step would also include studying whether offices considered the content of previously filed applications in evaluating both novelty and non-obviousness, or only the novelty of claims in subsequently filed applications. The Delegation also supported studying the practices of various offices with respect to the selection of the relevant prior art which would be used in the evaluation of non-obviousness.

109. The Delegation of Portugal made a presentation on the Portuguese office experience on quality management systems within its organizational model. The presentation is available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=361136

110. The Secretariat informed the Committee on the status of the draft questionnaire on quality of patents.

111. The Delegation of Brazil stated that patents of high quality were essential for the attainment of the goals of the patent system. The Delegation believed that the topic touched upon the fundamental basis of the patent system in aspects such as sufficiency of disclosure and the behavior of a patent in a market economy. The Delegation considered that since the TRIPS Agreement did not define inventive step or the person skilled in the art, sufficient flexibility was provided in the TRIPS Agreement for members to define the level of a skilled person, depending on the technical development of the country. The Delegation was of the opinion that reaching a common definition would infringe on the ability of Members to attain their national policy objectives of the intellectual property system. The Delegation believed that the protection of IP was not an end in itself, but an instrument to further economic and social development, including the promotion of innovation, economic growth, public health, food safety and education, amongst others. Thus, the Delegation deemed that it should be looked at within the framework of trade and development for each country and should preserve the policy space necessary for the continuous adaptation of the patent system. The Delegation noted that in Brazil, natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and the natural biological processes, were excluded from patentability. The

Delegation specified that during the last four years, an international trend to that direction could be observed, especially when related to claims involving human genes isolated from nature. The Delegation observed that Court decisions in different jurisdictions had found that laws of nature, natural phenomena and abstract ideas were not patentable. The Delegation stressed that the rationale was that they were the basic tools for scientific and technological work and accordingly, without that exclusion, there would be considerable danger that the granting of patents would tie up the use of such tools and thereby inhibit future innovation premised upon them. In its opinion, that was yet another form of illustrating the necessity of effectively creating incentives that led to creation, invention, and discovery while making sure that nothing impeded the flow of information that might permit, or indeed spur, invention. The Delegation considered that one related topic was the patentability of the biological characteristics of plants. The Delegation noticed that in some jurisdictions, applicants had successfully received patents on essential biological processes used for breeding plants. The Delegation observed that the conventional selection and crossing of plants, however, was a widespread technique and was commonly used by breeders. Therefore, the Delegation believed that patents covering conventional breeding methods would fail to comply with the inventive step requirement in other jurisdictions. In the Delegation's view, excluding the genome of natural living beings and natural biological processes from patentability would enhance the overall quality of patents. Their exclusion would provide increased legal certainty to stakeholders and patent applicants regarding the scope of protection and patentable subject matter. Furthermore, the Delegation believed that it would reduce the workload of patent examiners by avoiding excessively broad claims, and by allowing them to focus on matters that were not mere discoveries. The Delegation was of the opinion that the purpose of patent laws would not be served by granting a patent to a class of claims which, by their very nature, lacked well-defined boundaries or had negative or chilling effects on innovation. The Delegation considered that such a result would be at odds with the purposes of the patent system, would effectively defeat its goals, or at the very least create unwarranted obstacles to their attainment.

AGENDA ITEM 8: PATENTS AND HEALTH

112. The Delegation of Nigeria, speaking on behalf of the African Group, recognized the importance of the patent system in incentivizing research and development, as well as inventions that provided solutions for health challenges. The Delegation recognized also its relevance as a mechanism for promoting innovation and facilitating access to knowledge and information for the public good, including public health. The Delegation was of the opinion that the international intellectual property system precluded the mutual supportiveness of its foundational tenant. Therefore, the Delegation stated that the African Group had been investing in seeing the SCP undertake a work program that would promote a patent system able to benefit the rights holders and the public stakeholders in an informed and predictable manner. The Delegation believed that obstacles of the patent system were largely manmade, whether they were capacity of LDCs to make use of the flexibilities in the patent system, inherent difficulties in the patent system, or difficulties directly linked to agreements and contracts among the parties. The Delegation stated that a number of activities undertaken by the SCP had been aimed at shedding light on that topic, including the half day seminar on patents and health which had been held during the twenty-third session of the SCP. The Delegation considered that such a half day seminar had been particularly instructive concerning the barriers posed by the patent system to facilitating access to knowledge, fostering innovation and transfer of technology, for solving public health challenges predominantly experienced by LDCs. The Delegation pointed out that that event had also provided some resourceful ideas on the way forward, and in that regard, the Delegation requested that the Secretariat consult the records of the half day seminar for the preparation of the study to be submitted to the 26th session of the Committee, which would examine constraints to the use of patent flexibilities and their impact on access to sustainable, safe and affordable medicines. The Delegation advocated for a bold,

purposeful and actionable WIPO program on patents and health. It hoped to have the opportunity to discuss further, under that agenda item, the updated proposal of the African Group on patents and health contained in document SCP/24/4. In its opinion, it was crucial that the work of the SCP balanced the needs and interests of the various stakeholders in the international patent landscape, in accordance with WIPO's Development Agenda. Referring to its updated proposal, the Delegation explained that the African Group proposed three interlinked work programs to be pursued simultaneously through studies, information exchanges and technical assistance. The Delegation specified that the proposal aimed to facilitate the use of the patent system and its flexibilities to meet public health needs and priorities of the developing countries and LDCs, including the increasing public health threat of antimicrobial resistance. The Delegation further underscored the recommendations of the United Nation's Secretary-General High-Level Panel on Access to Medicines which had highlighted the multiple barriers to accessing medicine and healthcare technologies, policy incoherence, and had shared ideas on ways forward, including specific recommendations to WIPO. Taking into account a study containing information on the constraints experienced in the use of flexibilities in the patent system to be presented at the 26th session of the SCP, the updated African Group proposal and the Report of the United Nations Secretary General's High-Level Panel on Access to Medicines, the Delegation proposed some future activities. The Delegation suggested that the Committee undertake a half day information exchange with the United Nations Special Rapporteur on the Rights to Health, during which he would present his report to the Human Rights Council on Intellectual Property Rights and Access to Medicines. The Delegation further asked the Committee to request the WHO to present the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) and Global Action Plan on Anti-Microbial Resistance (GAP) reports, and to invite the Co-Chairs of the High-Level Panel on Access to Medicines to share their views on the Panel's objectives, findings and recommendations. The Delegation further suggested establishment of a balanced working group or task force at the end of the session, in order to synthesize the reports and recommendations, and consider how the SCP could contribute to implementing the recommendations contained in the mentioned documents, including the health related Sustainable Development Goals. Following up on the information exchange during the twenty-sixth session of the SCP, the Delegation proposed that the Committee commission a study, for its twenty-seventh session, by leading independent experts to examine the challenges faced by the developing countries and LDCs, in incentivizing innovation in healthcare technologies, where patents were proven to be an insufficient motivator. The Delegation stressed that that study should include an examination of regulatory and other incentives that could spur innovation, without promoting the overuse of antibiotics, including non-patent incentives, to drive drug committees to invest in Anti-Microbial Resistance (AMR) research. The Delegation was of the opinion that the study should include the consideration of a 'pay or play' levy on the pharmaceutical sector, which would require companies to either pay the levy, or invest in R&D that would be deemed useful for AMR. The Delegation further requested a feasibility study, or feasibility exercise, for a globally-accessible patent database that would contain information on health-related licenses that had been issued, including those for essential medicines. Furthermore, in line with the recommendations of the High-Level Panel, the Delegation was of the view that WIPO should accelerate its technical assistance efforts in working with other relevant agencies to assist Member States in the use of Article 27 of the TRIPS Agreement, through the adoption and the application of rigorous definitions of the invention and patentability criteria, in order to curtail evergreening of patents. The Delegation believed that assistance would insure that patents would only be awarded for genuine innovations. The Delegation further requested WIPO to support Member States with the required expertise to apply public health-sensitive patentability criteria. The Delegation pointed out that the access to health, as well as safe and affordable medicine, had long been a United Nations recognized human right which had been encapsulated in the Sustainable Development Goals (SDG), the TRIPS Agreement, the Doha Declaration on TRIPS and Public Health, and in the spirit of the Development Agenda recommendations. The Delegation specified that

the SDGs, a universal commitment by all members of the United Nations organizations, sought to: (i) promote and ensure access to quality healthcare for all, leaving no one behind; (ii) accelerate progress made on preventable deaths; (iii) fighting malaria, HIV/AIDS, and other orphan diseases including Ebola, which had ravaged the West African Sub Saharan region and caused thousands of deaths. The Delegation further expressed its wish to pay attention to other communicable diseases, including antimicrobial resistance and unattended diseases that predominantly affected developing countries. The Delegation was of the opinion that, as a specialized UN agency, WIPO's role in facilitating the implementation of the SDG was obvious. The Delegation encouraged the Committee to take a bold step in reaching an agreement on a work program that would address the critical interface of patent rights *vis à vis* life and dignity. The Delegation urged WIPO Member States to engage in discussions on that subject, showing their integrity and moral responsibility that it deserved. The Delegation expressed its wish to make further comments on its proposals, in response to real life situations as they occurred. The Delegation hoped that the Committee could support the proposals put forward by the African Group.

113. The Delegation of Chile, speaking on behalf of GRULAC, believed that the relationship between patents and health was a fundamental aspect which illustrated the delicate balance of the patent system. The Delegation observed that recent debates on that topic in international fora had demonstrated a renewed interest from members, particularly due to the fact that difficulties persisted in some countries to insure the availability of medicine in a sustainable manner. The Delegation hoped that the Committee would make progress on the discussion on patents and health.

114. The Delegation of Latvia, speaking on behalf of CEBS Group, highlighted the importance of that agenda item for the countries of their Group. The Delegation believed that the question of public health and patent systems was a complex one, and that there was a need for a holistic approach in order to facilitate access to medicines. The Delegation was of the opinion that a multitude of factors, and not just a single one, explained the existence of the lack of access to medicines. The Delegation recalled the importance of the ongoing work of other international organizations on that topic, such as the WHO, WTO, and the trilateral cooperation on public health, IP and trade. The Delegation stressed that in the context of WIPO, the SCP should focus discussion within the WIPO mandate. However, the Delegation believed that problems and solutions concerning that topic were beyond one international organization. The Delegation welcomed the sharing session on national experiences on the use of patent-related flexibilities to promote public health objectives and the challenges thereof. The Delegation concluded by observing that the proposal elaborated by the Delegation of the United States of America, contained in document SCP/17/11, would be a way forward under that agenda item.

115. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, took note of the contribution provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and the subsequent message by the Secretary-General, which had encouraged all stakeholders to chart a way forward within appropriate fora, to ensure access to medicines and health technologies for all who needed them, wherever they were. The Delegation observed that the work conducted by the Panel started with the assumption that there were some policy incoherencies between the justifiable rights of inventors, international human rights laws, trade rules and public health. As the European Commission had already indicated in its written contribution to the Panel, the Delegation, did not share that assumption. The Delegation shared the view acknowledged in the Report that there were many reasons why people did not get the healthcare they needed, ranging from under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights. The Delegation noted that another important problem was the global medicines shortages and

stock-outs. That was why, in its written contribution to the Panel, the European Commission had encouraged adopting a holistic approach to the problem of accessing medicines which could result in a valuable contribution to the wider debate. The Delegation believed that, due to its limited mandate, the High-Level Panel had focused its proposals exclusively on addressing an alleged conflict between a research and development model that (partially) relied on intellectual property rights, and the possibility of providing affordable medicines. The Delegation was of the opinion that, in doing so, the High-Level Panel had missed an opportunity to advance more balanced, comprehensive and workable solutions addressing the problem of access to health. The Delegation expressed the wish to highlight that no conclusion could be reached without the support from all the Members of the Panel, as demonstrated by the dissenting opinions reflected in that report. The Delegation stated that the European Union and its Member States were committed to increasing access to affordable medicines and to finding solutions to the world's pressing public health challenges and inequities. The Delegation specified that, in line with the 2010 Communication and Council Conclusions on 'the EU role in Global Health', the European Union pursued a rights-based approach to health. The Delegation pointed out that strengthening all areas of a health system, including the availability of qualified health workers, provisions for affordable medicines and adequate financing of the sector, were central to moving towards universal health coverage with quality health services accessible and affordable for all. The Delegation considered that quality and integrity of the pharmaceutical distribution chain were essential in improving public health. The Delegation observed that the challenge was to strike the right balance between the need to promote and finance the research of new and better medicines for all, ensuring that medicines were accessible and affordable to those in need, while guaranteeing the sustainability of the health systems. The Delegation believed that those goals were not contradictory and must be pursued jointly. The Delegation noted that the current innovation model, including the role of trade related to IP, had delivered consistent progress in global public health, leading to key, new and improved treatments as well as extended life expectancy, both in developed and least developed countries. The Delegation considered that such a model already integrated a variety of tools, such as incentives for innovation based on intellectual property, on public and private financing and awards for public research. In the Delegation’s view, that variety was necessary to address situations where there was a functioning market, and those where there could be market failures. The Delegation believed that the Report underplayed the fact that the development of new drugs required significant investment and long-term research, coupled with clinical trials and regulatory approval procedures. The Delegation observed that the exclusive rights conferred by a patent represented an important incentive for innovating pharmaceutical companies to make the necessary investments towards that research and development. The Delegation noted that without incentivizing the innovator pharmaceutical companies to invest in research, the sustainable development goal of ensuring healthy lives and promoting well-being for all, including achieving universal health coverage, would be severely undermined. The Delegation pointed out that several of the issues covered in the Report's recommendations were addressed in the European Union legislation, and European Union & Commission policies and actions, including at multilateral levels. The Delegation quoted a few examples: the Commission was a major funder of research and innovation for poverty-related and neglected diseases and for new antibiotics. At the WHO, the European Union and its Member States supported the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, including the development of the Global Observatory on Health Research and Development. In the area of trade, the European Union ensured that its free trade agreements were consistent with the Doha Declaration and it supported the extension of the drug patent exemption for the least-developed countries. Finally, the Delegation stated that as part of its health policy, the European Union had adopted new legislation to ensure that all clinical trials to be conducted within the European Union would be registered in a publicly accessible European Union database (Regulation EU No 536/2014). However, the Delegation stressed that several other recommendations were not in line with the European Union rules and practices, and

thus could not be supported. The Delegation specified that, in particular, that was the case for the proposal to revise the paragraph 6 of the TRIPS Agreement on those matters, the recommendations in relation to INN and standard international common names for biological products, and the proposal to create additional structures at a United Nations level on the issue of health technology innovation and access. The Delegation stated that any future activities at the United Nations level in that area should be conducted on the basis of a much broader understanding of the complex issues involved.

116. The Delegation of Turkey, speaking on behalf of Group B, expressed its wish to reiterate that both innovation and access to medicines were equally important in the relationship between patents and health. The Delegation, keeping in mind that innovation was fostered by the patent system, considered that IP protection was crucial for the development of new medicines, including lifesaving ones. The Delegation was of the opinion that, when looking at the whole picture of research and development in the field of pharmaceuticals, it was obvious that incentives for patent protection were critical for that sector. The Delegation stated that it was in the interest of the broader public to have further research and development on safe and effective medicines. In its opinion, it was important to focus not only on specific elements of the patents, but to keep in mind the broader context. 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 healthcare, shortage or lack of access to trained healthcare personnel and adequate medical facilities, fragmented and unreliable procurement systems and processes, lack of infrastructure, conflicting policies that discouraged market entry and competition on innovative drugs, supply chain management, full visibility of demand, retail markups, taxes and tariffs. The Delegation recalled that the lack of access to medical technologies was rarely due to a single isolated factor, according to the WIPO-WTO-WHO Trilateral Study "Promoting Access to Medical Technologies and Innovations". The Delegation further noted that they continued to follow the recently launched a PATENTSCOPE search tool that had improved the searchability of chemical structures, for example, searching pharmaceutical compounds in published patent applications. The Delegation further believed that investment in those technologies was the most efficient way forward. The Delegation noted that, as clearly indicated in document SCP/21/9, INN was assigned only years after the filing of a patent application and even sometimes after the patent grant, and therefore could not form part of the original disclosure. The Delegation specified that even if in the few cases the INN had become available before the filing date, its inclusion in a patent database would be an extra burden for the patent applicant and the patent office. The Delegation did not believe that the current international framework gave countries the sufficient policy space to propose new patentability criteria or to require information beyond the current requirements to provide an adequate description, i.e. a description that was sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The Delegation deemed that work sharing could be useful in that technical field because of the different levels of information available to the various patent offices. In that context, the Delegation believed that a study prepared by the Secretariat focusing on the differences of information available to IP offices and on how to overcome those differences through work sharing, would also be a good way forward under that agenda item.

117. The Delegation of India, speaking on behalf of the Asia and Pacific Group, stated that the United Nations Secretary-General's High-Level Panel on Access to Medicines had specifically explored the policy incoherence between IP, trade and human rights, and had made a number of recommendations in that regard. The Delegation specified that some of those recommendations were specifically addressed to WIPO and were directly relevant to the SCP agenda item on patents and health. The Delegation therefore requested that the SCP begin an exploratory discussion based on that report. Secondly, the Delegation believed that the Committee should insure that the study on the constraints faced by developing countries and LDCs in making full use of patent flexibilities and their impact on

access to affordable essential medicines in developing countries and LDCs must have involved the UNDP which facilitated the UN High-Level Panel Report. Furthermore, the Delegation requested the Secretariat revise the feasibility study and address the question on the feasibility of disclosure of INN in patent applications, specifically where the INN was known to the applicant.

118. The Delegation of China believed that in stimulating innovation, the patent system should also safeguard the public interest. Taking that into account, the Delegation expressed the wish to support the African Group's proposal. The Delegation suggested that the SCP discuss the content and the recommendations Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines. The Delegation further proposed that the Committee make a detailed work plan for the future work and carry out sharing sessions and studies. In its view, such a proposal would be useful in effectively advancing on that agenda item, helping all parties understand the flexibilities provided by different international treaties, and promoting countries' legislation and practices that would safeguard public health and access to medicines.

119. The Delegation of Iran (Islamic Republic of) supported the statement made by the Delegation of India on behalf of the Asia and Pacific Group. The Delegation believed that access to essential and lifesaving medicines at affordable prices was the goal of all countries and a necessary step towards the achievement of the SDGs. The Delegation mentioned that SDG Goal 3 referred to the goal of universal health, including access to safe, effective, quality and affordable essential medicines and vaccines for all. The Delegation was of the opinion that the availability, at an affordable price, for all in need, depended largely on patent law and on decisions taken by regulatory and procurement authorities. The Delegation observed that new diseases and epidemics had caused global health threats, challenging both developed and developing countries. The Delegation stated that many countries faced serious challenges in access to available, affordable and safe medicines and the relevant technologies. In its opinion, the high prices of medicines, particularly those under patent protection, could present major barriers for the access to medicines, treatment, medical products and related health technologies. The Delegation considered that having access to essential medicines with affordable prices was a specific and important component for the right to access to health as a fundamental Human Right. Those facts constituted the rationales behind the decision to discuss that issue in the framework of the Human Rights Council. The Delegation noted that in order to meet the public health requirements with respect to patented drugs, and to provide them at an affordable price, it was essential for the Committee to work on the effective utilization of compulsory licensing provisions under the patent laws and the consequential impact of grant of compulsory license on the availability and prices of patented drugs. The Delegation observed that, as there were no other international fora where countries were sharing experiences on the use of health-related patent flexibilities, the work of the SCP in that direction was vital. The Delegation supported the proposal made by the African Group and the Development Agenda Group contained in documents SCP/16/7, SCP/16/7 CORR. and SCP/24/4. The Delegation hoped to see those proposals operationalized within the Committee, in order to get a better understanding of the challenges and constraints in making full use of public health-related patent flexibilities. The Delegation highlighted that any work program on health and patents should be balanced and based on a long term approach. In the Delegation's view, the work program of the SCP should provide the possibility of analyzing the potential impediments and obstacles created by the system in accessing medicines, such as the legal and structural impediments and capacity constraints in making full use of flexibilities and how those constraints could be overcome. The Delegation emphasized on the importance of the Report of the United Nations Secretary General's High-Level Panel on Access to Medicines which was published in September 2016. The Delegation firmly believed that it was an urgent need not only to support, but also to undertake follow-up activities and seriously consider the panel's recommendations to transform them into an action so that access to medicines would

become a reality. Accordingly, the Delegation considered that the report should form the basis for future discussions and study in the SCP in the field of IP and health, and WIPO should support countries to address intellectual property-related barriers impacting availability, affordability and accessibility of medicines, treatments and related technologies in low and middle income countries.

120. The Delegation of South Africa aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation recalled that, through the adoption of the United Nations 2030 Agenda for Sustainable Development, countries had committed to achieving universal healthcare where everybody was to receive the required health services, regardless of their financial status. The Delegations stated that in that regard, SDG Goal 3 concerned ensuring healthy lives and promoting the well-being for all, at all ages, while SDG Target 3.8 required that the international community strive to achieve universal health coverage, including financial risk protection, access to quality essential healthcare services, and access to safe, effective, quality and affordable essential medicines and vaccines for all. The Delegation observed that a paper on Universal Health Coverage, published in May 2016 by Elders, a group of independent international leaders convened by former South African President Nelson Mandela in 2007, to use their collective experience and influence for peace, justice and human rights worldwide, painted a very dire picture. The Delegation specified that the report noted that, although universal health coverage was the commitment of every United Nations Member State, the realities on the ground did not reflect that commitment. The Delegation further quoted the report, according to which, across the world, hundreds of millions of people were denied lifesaving health services or were plunged into poverty, because they had to pay unaffordable prices for their care. The Delegation also noted that the report stressed that the burden was particularly felt by women, children and adolescents who often had high health needs, but a low access to financial resources: in some instances, women and babies were even imprisoned in health units because they could not finance their own medical bills. The report considered that that represented a violation of their basic human rights. The Delegation noted, on one side, that the report prepared by Elders had identified political commitment at the national level as an essential element for the implementation of universal health coverage as mandated by SDG Goal 8, as well as a remedy to the problems articulated by the same report. On the other side, the Delegation observed that the United Nations Secretary General's High-Level Panel on Access to Medicines, which was convened by the UN Secretary General and mandated to review and assess proposals and recommend solutions for remedy the policy incoherencies between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies, pointed to serious impediments to achieving the noble goal of health for all, impediments which were brought about in one way or another by factors related to intellectual property, and patents in particular. The Delegation mentioned that, for example, the report of the United Nations Secretary General's High-Level Panel on Access to Medicines noted that many governments had not used the flexibilities available under the TRIPS Agreement for various reasons, ranging from capacity constraints to undue political and economic pressure from other states and corporations, both express and implied. The Delegation stated that the Panel concluded that political and economic pressure placed on governments to forego the use of the TRIPS flexibilities violated the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement and reaffirmed by the Doha Declaration. The Delegation expressed its wish to elaborate further on the experience of their country in undergoing external pressure in the sharing session. Among several recommendations of the High-Level Panel, the Delegation referred to the one that recommended that countries make use of the flexibilities enshrined in the TRIPS Agreement, and use the policy space available in Article 27 of TRIPS by adopting and applying rigorous definitions of invention and patentability that were in the best interest of the public health of the country. The Delegation further specified that amending laws to curtail evergreening of patents and granting patents only to genuine inventions should be included in such flexibilities. The Delegation concluded

on that topic by considering that the report constituted a reference document. The Delegation believed that the implementation of the recommendations of the mentioned report, and other intellectual property and health-related recommendations, as articulated in the African Group's proposal contained in document SCP/24/4, had the potential to minimize the unfortunate situations where women and babies were imprisoned in health units in the world because they could not finance their medical bills. The Delegation welcomed further dialogue and contributions from all the Member States on that agenda item.

121. The Secretariat made a presentation on Chemical Compound Search in PATENTSCOPE. The presentation is available on the WIPO website at: http://www.wipo.int/edocs/mdocs/scp/en/scp_25/scp_25_patentscope_chemsearch_wipo.pdf

122. The Delegation of Brazil supported the statement made by the Delegation of Chile on behalf of GRULAC. The Delegation considered the topic of patents and health very important for its country. The Delegation understood that policies that had a bearing on access to health technologies were associated with different policy objectives related to trade, intellectual property, health and human rights goals: each was governed by its own legal and regulatory framework, and each imposed obligations that might not be aligned with the others. The Delegation stated that intellectual property regimes sought to balance the rights of inventors with the wider interests and needs of society, and observed that policy incoherence might arise when economic, social and political interests and priorities were misaligned or in conflict with the right to health. The Delegation recalled that State obligations included duties to not only respect but to protect and fulfill the right to health. As affirmed by a resolution of the Human Rights Council, the Delegation believed that ensuring access to medicines, and particularly to essential medicines, was a fundamental element of those State obligations. The Delegation considered the role of public funding of health technology R&D could be a matter to be considered by Member States. The Delegation pointed out that it was especially the case when insufficient investment was being made for R&D for diseases that predominantly affected the poor, or when publicly-funded research was translated into patented medicines that were priced out of the reach of both public and private sector consumers. The Delegation acknowledged that access to medicines was a challenge for most countries, whether least developed, developing or developed. The Delegation specified that it was presenting those views with a spirit of dialogue, convinced that they were in everyone’s interest, and encouraged the whole membership to work constructively towards achieving the goal of universal access to medicines through a balanced patent system. The Delegation concluded by expressing its support for the proposal contained in document SCP/24/4 and presented by the African Group, as a good way forward for debates within the Committee.

123. The Delegation of Indonesia endorsed the statement made by the Delegation of India on behalf of the Asia and Pacific Group. The Delegation expressed its wish to echo other Member States’ statements that patents and health was a topic of great importance to all Member States. The Delegation believed that providing access to essential and lifesaving medicines at affordable prices was in the interest of all countries. The Delegation noted that the Sustainable Development Goals recognized and affirmed the importance of public health, and the SDGs are a set of development goals that stem from member-driven processes and were agreed upon and endorsed by all the United Nations Member States. The Delegation recalled 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 to Member States in the understanding and the use of TRIPS flexibilities for health, recalling the fact that there was a cooperation agreement for technical assistance between WIPO and WTO which clearly gave WIPO the mandate to offer assistance on intellectual property-related matters that were also covered by the WTO agreements. The Delegation drew the Committee’s attention to the report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines. The Delegation noted that the said report had the same focus of the exercise on patents and health in the

Committee. The Delegation, in particular, deemed critical the recommendation made by the High-Level Panel to consider further discussions on patents and health in the SCP, as well as the recommendation that governments should draft national laws in a way that facilitated the prompt and expedient use of a compulsory license, or government use of a patent for non-commercial purposes, including the criteria to determine the remuneration for right holders. The Delegation was aware that the issue of public health could not be addressed by WIPO alone, but considered that as a member of the United Nations system, WIPO should do its best to play its role in ensuring the attainment of universal access to medicines, through a balanced patent system. The Delegation supported the proposal made by the African Group contained in document SCP/24/4, including the work program that had already been outlined by the Delegation of Nigeria on behalf of the African Group in its statement. The Delegation hoped to have a meaningful discussion and make progress in that agenda item, and stood ready to make further comments and interventions.

124. The Delegation of Côte d'Ivoire endorsed the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation declared that the patents and health was an issue of great concern to its country. The Delegation specified that Côte d'Ivoire had adopted, during the Council of Ministers of September 14, 2016, a communication with regard to the accession to the protocol amending the agreement on intellectual property rights related to trade and health.

125. The Delegation of Uganda aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation acknowledged the role of the patent system in promoting scientific and technological innovation, which had contributed significantly to the improvement in health conditions and health crises such as HIV, malaria and tuberculosis. However, the Delegation believed that new challenges to public health, including pandemics which had the potential to affect all parts of the world, needed global responses. The Delegation further considered that it was necessary to consider a notion of global health, and observed that local actions could add up to create a global health movement. The Delegation urged to look at examples of global health crises that had affected not only developing countries, but had spread all over the world, such as the Zika virus, which was affecting parts of the Americas and the Caribbean. The Delegation believed that if collective responses had been achieved earlier, that scourge would have probably been contained. The Delegation was of the opinion that the emergence of global challenges demanded a shared, coordinated and cooperative international response, not only to counter local and global threats to human health, but also to address interlinked issues such as trade, security, human rights and climate change, which were basic determinants of health. The Delegation believed that WIPO could contribute to resolving those challenges by finding an optimal balance between the rights of patent owners and the needs of the general public, both in the developing and developed world. The Delegation underlined the importance of the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, which had specifically exploited the policy incoherence between IP, trade and human rights, and had made some WIPO-specific recommendations that the Committee ought to explore. In the Delegation's view, those recommendations and the African Group proposal contained in document SCP/24/4 would provide the Committee a solid basis for the SCP's future work program, as well as a guide for a proposed joint study by the WIPO Secretariat, in conjunction with independent experts, the WHO and WTO, on the constraints met by developing countries in making full use of patent flexibilities, as well as their impact on the access to affordable medicines. The Delegation looked forward to further fruitful discussions on that agenda item.

126. The Delegation of India reaffirmed that the patent system should strike a balance between the interests of innovators and public health. The Delegation was of the opinion that it was one of the foremost responsibilities of the patent system to ensure the accessibility of medicines at affordable prices to the public. The Delegation recalled the objective of the

TRIPS Agreement in Article 8, and the Doha Declaration on the TRIPS Agreement and their calls for empowering states to take appropriate measures to protect public health using the TRIPS flexibilities effectively. The Delegation requested a study on the ways and means for limiting broad Markush claims, and for reducing timelines for INN publications which were very important for patents and public health. The Delegation fully supported the proposal submitted by the Delegation of Nigeria on behalf of the African Group on patents and health to work out the balance between patent rights and caring for public health by means of restricting a patentees' rights so that their pharmaceutical products would be sold at an affordable price. The Delegation reiterated its stand on the inclusion of INN in a patent specification, which in its view, would facilitate the granting of quality patents. The Delegation supported the proposal made by the Delegation of Nigeria on behalf of the African Group, composed of three broad interlinked items, namely studies, information exchange and technical assistance taken under WIPO's work program on patents and health. The Delegation aligned itself with the Asia and Pacific Group's statement, especially with regard to the United Nations High-Level Panel on Access to Medicines.

127. The Delegation of Tunisia supported the statement made by the Delegation of Nigeria on behalf of the African Group on patents and health. The Delegation then underlined the importance of public health and patents, particularly for developing countries. The Delegation believed that WIPO and its Members States could work on the Development Agenda recommendations and the Sustainable Development Goals, and could particularly contribute towards giving people the possibility to live healthily. The Delegation stated that the work plan proposed by the African Group included important items on that topic, and expressed its willingness to find a fair balance between intellectual property and health.

128. The Delegation of Ethiopia congratulated the Chair and Vice-Chairs on their election, and expressed appreciation on their guidance and leadership in the work of the Committee. The Delegation recalled the United Nations 2030 Agenda for Sustainable Development, and highlighted that the SDG Goal 3 promoted the well-being of people of all ages. The Delegation further recalled that the SDG Goal 3 referred to the goals of universal health coverage, including access to safe, effective, quality and affordable medicines and vaccines. The Delegation stated that it would guide the Member States perfectly, and would support the updated proposal by the African Group contained in document SCP/24/4. The Delegation considered that the Standing Committee's work in accordance WIPO's Development Agenda was vital for the balance of the interests of the diverse stakeholders in the international patent landscape. The Delegation further considered that the SCP should examine the study on the constraints faced by developing countries and LDCs on the use of patent flexibilities and their impact on access to affordable essential medicines in accordance with the recommendations of the United Nations High-Level Panel.

129. The Delegation of Nigeria stated that with the realities of the dynamic global health challenges, the work of the SCP should be focused on how to sustainably address the difficulties experienced by the lesser developed countries, when addressing their public health needs. The Delegation further stated that the patent system had been focused on the principle of protecting the rights of the patent owners as well as promoting the public interest. In that regard, the Delegation expressed its support to the opening statement and the statement on patents and health made by the African Group. The Delegation further expressed its support to a work program that balanced the needs of patent owners while ensuring that the patent system served its facilitative function in the fields of education and innovation. The Delegation pointed out that the proposal of the African Group detailed in document SCP/24/4 sought to address certain policy incoherencies, capacity gaps, and to institute a continuous review mechanism for patent activities related to health care technologies. The Delegation further pointed out that the proposal of the African Group was aligned with some findings and recommendations of the United Nations High-Level Panel on Access to Medicine. In that regard, the Delegation explained that the proposal outlined

concrete steps that all relevant stakeholders, including WIPO, might take to ensure a system that would facilitate the use of patent-related flexibilities, including measures to accelerate access to safe and affordable medicines, to developing countries such as Nigeria. The Delegation remarked that the SDGs required a revitalized global partnership to ensure its implementation, and encouraged all Member States and stakeholders to act in a collaborative partnership to implement the SDGs. The Delegation pointed out that according to SDG Target 3b, The United Nations Member States were committed to supporting the research and development of medicines for the non-communicable diseases that primarily affect developing countries, and provide access to affordable essential medicines and vaccines in accordance with the Doha Declaration on the TRIPS Agreement on public health. The Delegation remarked that Member States should acknowledge that the Doha Declaration affirmed the right of developing countries to use the full range of provisions of the TRIPS Agreement regarding flexibilities, and in particular provided access to medicines for all. In that regard, the Delegation stated that it was a matter of concern that several years later, the international community was still discussing the TRIPS flexibilities: how to use them and the difficulties thereof. The Delegation expressed its belief that it was incumbent upon the SCP, and WIPO as a United Nations agency, to accelerate the work on facilitating the implementation of the SDGs in a coordinated and sustainable manner. The Delegation therefore considered that, as contained in the United Nations High-Level Panel report, that should include an efficient and effective level of policy coordination with other relevant stakeholders within the United Nations system and beyond. The Delegation expressed its support for the SCP work program on patents and health as detailed in the African Group statement under the current agenda item. In that regard, the Delegation expressed its wish to have work programs that included technical assistance workshops, and a more vigorous interpretation and application of the patentability criteria by patent examiners with regard to patent applications covering health technologies in developing countries and LDCs. Furthermore, the Delegation suggested two workshops on negotiating and drafting license agreements for generic manufacturers based on the flexibilities available in the patent system, and three workshops on development-oriented successful practices for the issuance of compulsory licenses on medical patents.

130. The Delegation of Egypt congratulated the Chair on her appointment, and expressed its support to the proposal made by the Delegation of Nigeria on behalf of the African Group. The Delegation stated that with regard to improving public health in developing and least developed countries, everyone knew the deteriorating health situation in many countries, specifically on the African continent. The Delegation explained that when people got sick due to a simple thing like influenza, one might need to travel to the closest country in order to obtain medicines, whether that be to Senegal, Egypt or any other nearby country that had an advanced level of providing medicines to its citizens. The Delegation recalled that when that precise question was raised by the Delegation of Nigeria on behalf of the African Group, it thought about the way WIPO would carry out its responsibilities in providing medicines and improving the health system in developing countries and LDCs. The Delegation emphasized that obtaining medicines was a human right, and that it was the right on which the other rights were founded: the right to life. The Delegation further emphasized that all Members States carried common responsibilities in undertaking efforts in favor of developing countries and LDCs in combatting pandemic diseases, like AIDS, hepatitis C and other illnesses. The Delegation finally referred to the statement made by the Delegation of Nigeria regarding access to medicines being a moral obligation, and added that it was also a divine obligation, to which all members could contribute towards finding a solution.

131. The Delegation of Gabon thanked the Chair and congratulated her for her re-election. The Delegation expressed its support to the proposal made by the Delegation of Nigeria on behalf of the African Group. The Delegation stated that there was a real need to use the flexibilities under international agreements in order to provide essential drugs for developing countries and the LDCs. The Delegation further stated that the responsibility of WIPO was

to find a midway to reconcile all of the different interests that came into play in the interest of public health. The Delegation, therefore, expressed its support to the views of those delegations who had said that the SCP had been the best forum to deal with those issues. The Delegation concluded by expressing its support to the proposal made by the African Group contained in document SCP/24/4, and stated that such a document would make significant progress in advancing discussions.

132. The Delegation of Japan expressed its support to the statement made by the Delegation of Turkey on behalf of Group B. The Delegation further expressed its belief that the access to medicines was important. In that regard, the Delegation explained that the Government of Japan had been working on an important project with the United Nations Development Program (UNDP) to develop a joint research. The Delegation further referred to the statement made by the Delegation of the Republic of Korea that the issue had been due to a combination of many factors, including sustainable financing and supply systems. The Delegation remarked that the mandate of the United Nations High-Level Panel seemed to be narrowly focusing only on so-called policy incoherencies. In that regard, the Delegation pointed out that the United Nations High-Level Panel report had not been a Member State-driven process, did not reflect the opinions of the Member States and had not been addressed by the Member States. Therefore, in its opinion, the said report did not constitute a basis for discussions, as its controversial conclusion would bring more divergences into the agenda item. The Delegation believed that such an item could effectively be dealt with through a comprehensive approach. Thus, the Delegation expressed its support to the proposal made by the Delegation of the United States of America contained in the document SCP/17/11.

133. The Delegation of Turkey, speaking on behalf of Group B, delivered a statement referring to the written proposal presented in document SCP/24/4. The Delegation specified that modifications proposed by the African Group the day before had not been included in the document, and pointed out that it contained elements which were out of the scope of the mandate of the Committee, which had not been endorsed by the Member States. The Delegation considered that before getting into a new study in the SCP, there should be an inventory of studies and analyses produced by other United Nations and multilateral fora in order to avoid unnecessary duplication with already-existing work. The Delegation believed that the WIPO Secretariat, on the existing collaborative relationship with the WHO and WTO, would be well placed to conduct such studies. The Delegation further believed that given that the access to affordable medicines and health technology was a complex topic, it would be important for Member States to keep an open mind on any study, and not to presume that the solution to addressing access to medicines would be to make changes in national laws or to conduct a study proposed in the United Nations High-Level Panel Report. The Delegation stated that Group B was open to studies as a proposed balanced work program that would advance the common understanding of policies and initiatives that could enhance access to affordable medicines and health care technologies. In that regard, the Delegation pointed out that the work of the WHO, WTO, WIPO collaboration, “Promoting Access to Medical Technologies and Innovation: Intersections between public health, IP and trade”, could serve as the basis for productive discussions. The Delegation remarked that Group B would like to consider that issue in a holistic manner, including other related proposals such as those contained in document SCP/17/11. The Delegation finally concluded that only a balanced approach would bring the Committee forward, and therefore, expressed its willingness to engage constructively on the matter in general.

134. The Delegation of Sweden thanked the Chair and congratulated her on her election. The Delegation expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States.

135. The Delegation of France congratulated the Chair on her election, and thanked the Secretariat for the preparation of the session. The Delegation expressed its support to the statements on patents and health made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation further expressed its support to the statements made by the above Delegations regarding the African proposal. In the Delegation's view, the proposal contained in document SCP/24/4 listed a number of points that were neither in the agenda nor within the SCP's remit. The Delegation stressed once again that the Committee's work in such an area should reflect a balanced approach, taking into account the relevant factors which go beyond patents, as stated in document SCP/17/11. The Delegation stated that while many delegations had referred to the United Nations High-Level Panel, it was not a Member State-driven process. The Delegation reiterated that the Committee should not go beyond the mandate of the SCP or WIPO, and expressed its willingness to engage in a constructive debate.

136. The Delegation of Ireland expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation further stated that the work of the Committee should not go beyond its mandate.

137. The Delegation of the United Kingdom expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation reiterated two key points. Firstly, in its opinion, many proposals contained in document SCP/24/4 duplicated existing studies. In that regard, the Delegation suggested that before embarking on further work in the Committee, members should take stock of relevant existing studies. Secondly, the Delegation observed that some of the proposals contained in document SCP/24/4 appeared to be related to non-patent issues, and therefore, fell outside of the scope of the Committee. The Delegation expressed its willingness to engage in a constructive and balanced debate.

138. The Delegation of Spain thanked and congratulated the Vice-Chair on her election. The Delegation expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. Particularly, the Delegation stated that it was open to studies that would lead to an improved understanding of initiatives, and consequently, to an improved access to medicines at a reasonable cost.

139. The Delegation of Italy congratulated the Vice-Chair on her election. The Delegation expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation further aligned itself with the statements made by the Delegations of France and Ireland.

140. The Delegation of Canada thanked the African Group for the proposed work plan on patents and health. The Delegation underlined the importance of the access to affordable medicines and health technology, and highlighted that it was an essential priority of its foreign aid programs. The Delegation stated that Canada was a major financial contributor to partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Global Drug Facility (GDF) and Gavi, the Vaccine Alliance. The Delegation further stated that all countries should strike a balance between providing incentives to encourage the development of new and innovative medical advancements, while ensuring timely access to those advancements at a cost that individuals and society could afford. In that regard, the Delegation remarked that the IP system was an important factor in striking that balance. The Delegation pointed out that the topic of patents and health had been the subject of extensive research and analysis in recent years: for example, the WIPO-WTO-WHO Trilateral Study

“Promoting Access to Medical Technologies and Innovations”, and the Lancet report “Essential Medicines for Universal Health Coverage” had explored many of those themes in detail and covered the full range of factors that related to the access to medical advancements. The Delegation recalled that earlier that year, the Medicines Patent Pool had launched a database called MedsPal that compiled information on the patent and licensing status of 35 patented medicines and more than 100 formulations for the treatment of HIV, hepatitis C and tuberculosis, included in the WHO guidelines and its Essential Medicines List. In its opinion, that facilitated the competitive manufacturing and supply of those medicines in low and middle income countries. The Delegation highlighted that WIPO had made Patent Landscape Reports on specific medicines that sought to provide a snapshot of the patent status of medicines in many countries. The Delegation pointed out that the mentioned examples illustrated the broad range of work that had been done, but remarked that it was likely not aware of the full range. In order to address such knowledge gap, the Delegation was of the view that a worthwhile approach to addressing the issue of patents and health in the SCP would be to prepare an inventory of existing studies on that topic, namely studies and research prepared by the United Nations agencies and other multilateral bodies. The Delegation therefore considered that the end result would be a factual report that would summarize research on the role of the patent system and other factors in the context of accessing medical advancements and could inform the discussions under the patents and health agenda item. Furthermore, as a result of that work, the Delegation believed that members would be in a better position to engage in the topic of patents and health, based on a comprehensive understanding of the current stock of knowledge. The Delegation stated that that approach would help to ensure the work built on that stock, thus avoiding the duplication of existing work or failing to consider all aspects of the issue. The Delegation proposed that the preparation of the report should be undertaken by the WIPO Secretariat, in consultation with the WHO and WTO, as those three organizations had a pre-existing collaborative relationship and experience researching that topic. The Delegation clarified that it did not envision the mentioned proposal as competing with or replacing any other work under that agenda item, but rather, positioned it as a stand-alone proposal that could be beneficial in its own right. The Delegation expressed its willingness to prepare a formal proposal along those lines for consideration by the SCP, circulating it in advance of SCP/26. The Delegation finally welcomed the views of members on the precise scope of activities that should be captured by the report.

141. The Delegation of Sudan congratulated the Vice-Chair on her election and expressed its support to the statement made by the Delegation of Nigeria on behalf of the African Group.

142. The Delegation of Portugal aligned itself with the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States, and reiterated the need to keep the discussions within the Committee's mandate.

143. The Delegation of the United States of America expressed its support to the statements made by the Delegation of Turkey on behalf of Group B and the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation reiterated its strong support for the Doha Declaration on the TRIPS Agreement and Public Health, and stated that it respected Member States' right to protect public health. In support of the vital role of the patent system in promoting development and the creation of new and innovating life-saving medicines, the Delegation was of the view that a robust patent system did not prevent countries from taking measures to protect public health. With regard to the proposal made by the African Group, the Delegation expressed its concern that the narrow focus of the proposal contained in document SCP/24/4 would lead to an oversimplified view. In that regard, the Delegation considered that making full use of patent flexibilities would not significantly improve the access to medicines in developing countries or LDCs. The

Delegation expressed its disagreement with the view that patent rights are the only obstacles for the availability of medicines. In its opinion, the issue was multifaceted, and many factors that are fundamental in addressing access to medicine were left out. The Delegation stated that the patent protection system provided the incentives to pharmaceutical industries around the world to develop treatments and medicines and to carry out transfer of technology that would ultimately benefit all countries. In its view, without patent protection, there would be fewer new drugs, fewer treatments and diagnostics tools. A WIPO/WHO/WTO joint study "Promoting Access to Medical Technologies and Innovation" (Trilateral Study), published in 2012, supported the view that many factors besides the patent system contributed to the availability, or lack of availability, of medicines. Some of those factors include regulatory regimes, pricing, taxes and tariffs, policy, procurement, mechanisms, increasing the production sale and use of the sub-standards in fake or counterfeit medicines and overly complex supply chains and other factors that were listed in Chapters 3 and 4 of the study. The Delegation considered that an important conclusion of that study was that the mere existence of IP rights on a product was neither a barrier to, nor the absence of IP rights a guarantee of, access to that product. There were multiple factors which were not related to patents that could impact the availability of medicines. The Delegation believed that focusing on patents only, and without an understanding of the many other factors that could affect public health and access to medicines, would not likely result in an effective long-term solution. The Delegation further believed that a holistic approach to that problem would be the effective way forward, and in that vein, recalled the proposals made by the Delegation of the United States of America in document SCP/17/11. The Delegation underlined the importance of avoiding the duplication of work in that field, and expressed its support to the statement made by the Delegation of the United Kingdom with respect to conducting an inventory of work that had already been carried out.

144. The Delegation of Latvia congratulated the Vice-Chair on her election and aligned itself with the statement made by the Delegation of Slovakia on behalf of the European Union and its Member States regarding the African Group's proposal and the United Nations High-Level Panel on Access to Medicines. The Delegation reiterated its commitment to the question of access to medicines. The Delegation, however, believed that the SCP, as a technical Committee, should not undertake activities going beyond its mandate, and should not duplicate activities already taking place in other international organizations.

145. The Delegation of Poland congratulated the Vice-Chair on her election and expressed its support to the statement made by the Delegations of Latvia on behalf the CEBS Group and Slovakia on behalf of the European Union and its Member States. The Delegation further expressed its support to the positions of other European Union's Member States. The Delegation was of the view that the discussion under that agenda item should be kept within the mandate of the Committee.

146. The Delegation of Hungary congratulated the Vice-Chair on her election and aligned itself with the view expressed by the Delegations of Latvia on behalf the CEBS Group and the Slovakia on behalf of the European Union and its Member States.

147. The Delegation of Slovakia aligned itself with the statement made by its Delegation on behalf of the European Union and its Member States, and emphasized that the work of the Committee should not go beyond its mandate.

148. The Delegation of Zambia congratulated the Chair and Vice-Chairs on their election. The Delegation aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group.

149. The Representative of OAPI stated that the patent system aimed, among other things, at capitalizing on knowledge to ensure the continuous progress and well-being of mankind. The Representative further stated that those two objectives were not incompatible, if there was a determination to find a balanced solution. He remarked that if everyone tried to do that, it would be possible to reach a common understanding, which would encourage researchers to make even greater efforts. Otherwise, the Representative pointed out that the door would be open to the risk of imitations and counterfeit medicines. The Representative clarified that he was referring particularly to criminal imitations rather than counterfeit medicines, which would be in the benefit of neither mankind nor pharmaceutical firms. He remarked that it was the Committee's duty to find some grounds for a common understanding, leading to continuous progress in research for better drugs, and the well-being of mankind. He recalled the interventions of some delegations, stating that all members were on the same boat when a pandemic started in one part of the world, as the rest of the world would also be threatened, and therefore, it would be necessary to find common understanding on such an important issue. The Representative expressed its view that the proposal made by the Delegation of Nigeria was fully aligned with the issue if it would be slightly polished according to everyone's views. The Representative finally expressed his full support to that proposal.

150. The Representative of KEI expressed its view on the importance of patents and health. He stated that sometimes, people said that pharmaceutical drugs were the best case for the patent system in the sense that amidst other industries, it was the one sector where one could tie the existence of the patent system to the success or failure of companies in terms of their business. The Representative further stated that there were a lot of sectors in the economy where, if the patent system was eliminated, only the patent lawyers would notice. He remarked however, that it was not true in the area of pharmaceuticals. Although people said it was the worst case for the patent system, he pointed out that such was the case where the success of the patent system could lead to the death of patients. He nonetheless clarified that it would be an extreme case. He therefore stated that it was both the strongest case for granting the monopolies on invention and also the worst case. The Representative remarked that nobody would deny anywhere that the patent system played an important role in the development of new drugs. However, he further remarked that no-one could deny that it also presented huge problems in terms of inequality of access, and in some cases, the death of patients who could have had benefited from access to medicines. He highlighted that people should take that fact into consideration. The Representative noted that the notion that patents were not the only factor affecting access had been made and stated, for example, by the Delegation of the United States of America. In that regard, the Representative believed that there was no single thing, but rather several things, that determined access; the patents was one of them, and the same thing could be said about innovation. The Representative stated that public sector funding of R&D, education, collection of data and many other factors affected drug development. In that regard, he called the attention to the WIPO's Global Innovation Index, which was published every year, and underlined that it only gave minor weight to the patent system when ranking countries on their innovation list. He remarked that WIPO took time to work on patent policy because even though taxes, transparency, investments on education and a million other things were important, patents were important enough to work on, and it was true on the access to medicine issue as well. The Representative expressed his support to the work on the United Nations Secretary-General's High-Level Panel on Access to Medicines. The Representative, however, further expressed that he was dumbfounded by the notion that the Delegations of Slovakia on behalf of the European Union, Turkey on behalf of Group B, Japan, and the United States of America had questioned the idea that there was incoherencies between the policies on intellectual property and the human rights on access to medicines. Expressing his disagreement, the Representative stated that to suggest there was no incoherence was denialism of what was a fundamental concept in the system. The Representative then underlined that cancer was an important topic, which would be included

in the agenda of the WHO in January 2017. Referring to the Study made by IMS in June 2016 on the Global Market for Cancer Treatments, he stressed that 49 new oncology active substances had been launched between 2010 and 2014, and that fewer than half had been made available to patients by the end of 2015 in all but six countries. He further stressed that only in the United States of America, Germany, the United Kingdom, Italy, France and Canada, half of the new drugs had been put on the market and had been made available to patients. The Representative pointed out that in a 2014 study, it was stated that the cost per quality adjusted life year approach was taken into account in order to determine whether to reimburse a drug in Australia, Canada, England, Scotland and Sweden. He further pointed out that in those five countries, patients had lower access to cancer drugs than in other countries. He underlined that the fewer cancer drugs were being reimbursed, that the reimbursement decisions took longer, and that cancer drugs had been historically adopted at a slower rate. The Representative stated that countries that engaged in cost control are threatened by an actual policy of not reimbursing an expensive drug, putting the patient at risk for accessing important drugs. The Representative explained that the difference in access was a life-or-death matter for patients. He believed that the discussions embraced in the United Nations High-Level Panel were an attempt to overcome that, by separating the incentive for drug development from the price of the drug itself. He further believed that if people had a life threatening disease, they would not be in a position to bargain over price. The Representative, therefore, stated that the proposal would be to take the patients out of the loop in order to allow people to invent and develop drugs to monetize their inventions not through the high prices of drugs, but through some other system of financing the research and development. The Representative then questioned why some delegations would somehow not think there was an intellectual property aspect to the debate that had been endorsed not only by the United Nations High-Level Panel, but discussed among the G8 and that had been endorsed in various resolutions by the WHO. In that regard, the Representative highlighted that various proposals referred to studies that had been done in that institution on alternatives to the granting of a monopoly, as the incentive for drug development, and expressed its belief that such an issue was important in that work. Regarding the African Group's proposal, the Representative stated that everything was not subject to another study. For instance, he pointed out that in regard to technical assistance, element 3, sub-paragraph D, not one technical assistance study was made. He remarked that even though that was one of the most important ways to address issues on exceptions to patents rights, and in fact it was the most common system used in the United States of America, there were elements on the mentioned proposal which could point to other areas that had been done, but had not been integrated into the technical assistance programs of WIPO. The Representative finally remarked that there were also some other things that no one had done before.

151. The Representative of TWN stated that there were many barriers to accessing medicines, but it was widely recognized that a major barrier to access affordable medicines was intellectual property, and patents in particular. The Representative further stated that The WTO Doha Declaration on TRIPS and Public Health expressed concerns on the effects of IP on prices, and confirmed that the agreement did not and should not prevent members from taking measures to protect public health. She stressed that high prices as a result of intellectual property was not a concern just of developing countries, but also of developed countries. The Representative emphasized that it was increasingly clear as cancer and hepatitis C treatments were priced beyond what was affordable even to developed countries' governments. She explained that, for instance, a one-time treatment of hepatitis C using the backbone for hepatitis C treatment cost between 48,000 and 96,000 Euros, due to IP-related monopoly held by the pharmaceutical companies, which would not be sustainable for any government. The Representative pointed out that many people died directly as a result of not having access to medicines, and that something should be done about this, given that WIPO's mandate was on intellectual property. The Representative was of the opinion that a discussion on patents and health was critical, and that it was imperative to initiate a concrete

work program on patents and health. In that regard, the Representative pointed out the following. First, she believed that documents SCP/24/4 and SCP/16/17 provided a good basis for developing a work program on patents and health. Second, the Representative stated the importance for the SCP to invite the co-Chairs of the United Nations Secretary-General's High-Level Panel on Access to Medicines for a presentation of the report, as well as for the SCP to discuss the findings and recommendations of the report. She underlined that as WIPO was a specialized agency of the United Nations, the United Nations High-Level Panel report had constituted in furtherance of the SDGs, to which WIPO had been committed to. The Representative recalled that some delegations had mentioned that the report was not a Member States report, and had considered that the report should not be part of the discussion within the Committee. The Representative, however, pointed out that the trilateral study was not a Member States report either, but it had been presented and discussed in the SCP. The Representative noted that, compared to the trilateral process, the process led to the High-Level Panel report involved Member States, civil society, industry, academic as well as international organizations, including WIPO. She emphasized that the report had recognized that there should be certain dissenting views on the matter. Therefore, it would be unacceptable for WIPO, as a United Nations agency, not to recognize the High Level Panel report of the United Nations and its recommendations. In the Representative's view, the report was not beyond the remit of the Committee. Third, the Representative requested the SCP to specifically discuss the United Nations High-Level Panel report's recommendations which stated that governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. She remarked that such information should be updated and consolidated by WIPO, in collaboration with stakeholders, to develop an international easily searchable database which should include: (i) standard international common names for biological products; (ii) international nonproprietary names for products either known at the time of application or after the granting of the patent; and (iii) granting date and expiration date. The Representative pointed out another recommendation contained in the mentioned report, and referred to the fact that United Nations agencies (UNDP, UNCTAD, and WIPO) should support governments. In her view, a number of elements in that report were directly relevant to the Committee. She expressed her belief that those recommendations and the discussion of the United Nations High-Level Panel report should be a priority for the Committee. Finally regarding the study, the Representative stated that the Secretariat was supposed to prepare a study on national experiences using flexibilities and challenges for SCP 26. She expressed her belief that it should be done in consultations with United Nations agencies that had been involved in the United Nations High-Level Panel report, and stated that the contributions of the public would greatly enrich the study.

152. The Representative of MPP referred to the proposal contained in document SCP/24/4, and agreed that transparency in the patent information of essential medicines was fundamental. She stressed that reliable patent information was often hard to come by, but it was essential not only for the work of the MPP who was trying to improve access and innovation for some key medicines in developing countries, but also for governments, procurement agencies and other public health organizations who were engaged in intellectual property and access to medicines. The Representative was pleased to announce that during the previous WIPO Assemblies, MPP had launched MedsPaL, a Medicines Patent and Licenses Database that replaced the MPP's previous patent status database, and included comprehensive information on the patent and licensing status of selected HIV, hepatitis C and tuberculosis medicines. She explained that MedsPaL provided IP status of HIV, hepatitis C and tuberculosis medicines in developing countries, and that it also included information on patents, licenses and data exclusivity protection in well over 100 developing countries. The Representative expressed her gratefulness to the support received by the European Patent Office and national patent offices such of those of Chile and the Dominican Republic with whom there had already been collaboration agreements. She stated that a large number of civil society groups had helped MPP compile the data for

that valuable public resource. The Representative invited other patent offices to contribute to the public patents and licensing status database, in order to allow key new medicines to become available in low and middle income countries, at affordable prices. The Representative was of the view that it was very encouraging to see the report of the United Nations High-Level Panel on Access to Medicines when quoting: "voluntary licenses can be an important enabler of treatment, access and highlighting that the level of transparency in licensing agreements negotiated through the united backed Medicines Patent Pool in which all licenses are publicly available is laudable and rare". The Representative finally expressed her willingness to remain at the Committee's disposal if any clarification was required, and to work with Member States, WIPO and stakeholders to identify local treatments and explore the possibility of supporting national efforts on the scaling up of treatments through its licenses.

153. The Representative of MSF explained that they had been helping civil society correlation named fake patent law to work on nine case studies, and had been documenting the impact of patent practices on access to medicines in South Africa. In that regard, she made reference to two stories. The first story referred to Mrs. Tobic, a mother of two sons, and her battle to access life-saving medicine for her breast cancer. Mrs. Tobic strongly believed that if she could get that treatment, she could live longer, to see her two sons and grandson grow. One month after the report was finished in November, Mrs. Tobic had not managed to get hold of the medicine she needed. The medicine had remained under patent in a country with a single source from Roche which sold it at more than $30,000 U.S. for the treatment. The Representative remarked that at the same time, a similar version of the drug had been available in India and several other countries where primary and second patents had been overturned, allowing more sources and competition within the market and increasing the choice for patients. The Representative referred to a second story that had taken place in the United Kingdom, where Pfizer had attempted to claim second medical use patent over the old treatment that had treated pain. She explained that the case had been heavily debated and was followed by several countries in Europe when the original patent had expired. She further explained that in the United Kingdom, four county court decisions, one appeal court decision and a recent decision in October by the Court of Appeals, had been issued. The Representative pointed out that during the whole process, the Court had not supported Pfizer's claim for that patent, despite the issue of how Swiss form claims should be interpreted, supported or revoked. The Representative emphasized the fact that such an issue had caused a concrete impact on medical practices in those countries. She explained that to pursue such second medical use patent, Pfizer had sent numerous warning letters to the public health authorities of the United Kingdom, urging the suspension of certain medical practices whilst most of the United Kingdom's doctors were relying on it. In that regard, the Representative recalled that in May 2016, the General Assembly stated that legislation was urgently needed to end patent protection for specific indications for pharmaceuticals. The Representative stated that there were more similar stories across different countries nowadays affecting the day-to-day reality of the life and death of patients, regardless of which country they were from. She further stated that all those stories repeatedly illustrated the clear intersection between the public's access to medicines, and how the current patent system was operating, concerning medical treatment and diagnosis and how they had a direct impact on the affordability and accessibility of those tools. The Representative was of the opinion that some of those stories could have been presented, discussed and reflected during the Committee by several countries, not only with regard to how a methodology could be adopted in determining the inventive step for a particular patent claim, but how an alternative methodology patentability criteria and practices could have led to completely different impacts on access to medicines in reality. The Representative recalled the United Nations High-Level Panel recommendation for WIPO to work with relevant agencies and stakeholders in that area and underlined that it was precisely under the mandate of WIPO and the SCP to address intersection of patent health as a specialized United Nations agency. The Representative, therefore, expressed her support to the

proposal made by the African Group which had clearly laid out a roadmap for the Committee to follow when addressing the remaining challenges facing the Member States. Finally, the Representative reiterated that that was a global challenge, no longer a developing country's alone, and suggested that the Committee take full consideration of the recommendation from the United Nations High-Level Panel, including the possibility of inviting a panel representative to present the report before the Committee.

154. The Representative of JIPA noted that his statement was made on behalf of the Japanese Intellectual Property Association comprising 900 major Japanese companies and 72 pharmaceutical companies and that it was supported by IFPMA. The Representative was of the view that the patent system was played an important role in the commercialization of new technologies. He expressed his belief that patent protection of pharmaceutical technology would have allowed pharmaceutical companies to continuously carry out research to develop new drugs for patients in developing countries. The Representative pointed out that those pharmaceutical companies had been seriously working on the issue of access to medicines in developing countries. In that regard, for instance, he recalled Article 18.6 in the intellectual property chapter of the Trans Pacific Partnership (TPP), which referred to certain public health measures and defined that parties shall confirm the TRIPS Agreement and the Doha Declaration on Public Health. In that way, the Representative stated, the TRIPS flexibility in the framework of international treaties should be respected and then, moved forward with business activities. The Representative then mentioned new activities for access to medicines performed by Japanese pharmaceutical companies. He noted that, as reported on the WIPO home page, Takeda would send Professor Koncofe to the Center for Discovery of Infectious Diseases, at the University of California, San Diego. He further noted that on August 26, 2016, Takeda had publicly launched a new strategy for access to medicines. For example, special assistant programs were designed to ensure that patients who were prescribed medicine were able to access the course of treatment through innovative approaches. In addition, the Representative pointed out that the United States of America government had selected Takeda to develop a vaccine for Zika, after the WHO had declared Zika a public health emergency of international concern on February 1, 2016. In that regard, the Representative underlined that a 19.8 million dollar contract had been given to Takeda, which included clinical research and vaccine manufacturing for 2017. The Representative stated that Takeda's work further demonstrated the power of global partnerships and innovation to tackle the most challenging infectious diseases. Furthermore, the Representative remarked that the University of Tokyo had conducted a collaborative development on vaccine for cholera and escherichia coli diseases for the developing countries. He further remarked that other JIPA activities for access to medicine in developing countries were introduced on JPMA's website home page. The Representative was of the opinion that in order to access medicines in developing countries, it would be necessary to promote research and development of medicines centering on patent systems. He expressed his belief that the patent system promoted public health in both developed and developing countries.

155. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated that the subject of patents and health was a priority for the Group. The Delegation expressed its willingness to have a good and frank discussion on the importance of policy incoherencies which had been and would continue to be discussed during different international fora. The Delegation was of the opinion that patents and public health remained an issue of global concern. It stated that if such an issue was doubtful, since the adoption of the TRIPS Agreement, and the consequences of the new post-TRIPS Agreement, for pharmaceutical patents had been quickly seen when the HIV/AIDS pandemic swept across developing and least developed countries. The Delegation believed that the threat of using compulsory licenses by developing countries, and the reaction by developed countries, had caused enough global outrage and had forced the modification of the TRIPS Agreement, with a particular focus on the Doha Declaration on public health that had allowed for exceptions for

public health, had reaffirmed flexibilities and had recognized the right to use compulsory licenses. The Delegation stated that the African Group had made a proposal during SCP/15 in 2010, for the Committee to adopt a work program on the topic of patents and health. That proposal had recognized the particular difficulties that developing and LDCs had faced, of which in Africa's 55 countries, 33 were LDCs. The Delegation further stated that the proposals had aimed to enhance the capacity for developing countries and LDCs to adapt their patent regimes and to make full use of flexibilities under the international IP system. The Delegation was of the view that the fundamental policy requisites for the promotion and protection of public health included policy incoherence, policy setting, and coordination. The Delegation specified that the updated proposal made by the African Group contained in document SCP/24/4, which was the subject of the discussion, had been developed in response to the global issues that the world had witnessed since the time when documents SCP/16/7 and SCP/16/7 corr. had been submitted. The Delegation was of the opinion that the capital intensive nature of the system and profit driven incentive of it vis-a-vis capacity gaps and agreement, had continued to keep less developed countries with inadequate access to safe, affordable medicines and indeed had deterred many countries from utilizing or even entertaining the idea of pursuing the flexibilities that existed in the patent system. As a consequence, there remained a persistent lack of access to health care technologies including medicines, diagnostics, medical devices and vaccines and those were exacerbated. The Delegation recalled that in its opening statement, it referred to the Ebola virus that hit Africa in 2014 and 2015, causing mass death, and the Zika virus in the Americas and the Caribbean. The Delegation remarked that facts and information were abundantly available and that it was important to find new ways of addressing those issues with the SCP, and that other United Nations agencies would have a significant role to play in that regard. The Delegation stated that the African Group's proposal which had been supported by a significant number of Member States, had three interlinked work programs including studies, information exchanges, technical assistance that would be pursued simultaneously, and they had linkages to Development Agenda recommendations 1, 7, 9, 14, 31 and 32. The Delegation believed that WIPO and its Member States could not afford to remain silent in the face of such longstanding questions and challenges related to the role of patents on health technologies, especially as they affected life and the right to human dignity, good health and a safe environment. The Delegation noted that the SDGs, particularly the SDG 3, universal commitment, sufficiently encapsulated that objective, and expressed its hope that WIPO and its Member States could rise to fulfill their moral obligation to that global public health. The Delegation stated that after it listened to the statements made by Group B, members of that Group and the European Union and its Member States, it was concerned by going down a route where it believed that the Committee had no role to play, due to a significant number of elements that were contained in the African Group's proposal. The Delegation expressed its intention to formulate several questions, for the sake of clarity, to the members of the Group B and the European Union. The Delegation believed that the Committee was a good place to have full and frank discussions on the proposals of the African Group that were contained in document SCP/24/4. The Delegation expressed its wish to have a discussion based on the responses provided by Group B and European Union on those elements that they found to be outside the purview of the SCP from the proposals and why. The Delegation first requested additional information on the proposal they had put forward on an inventory on studies that had been undertaken, and secondly, asked about the impact that the said studies could have on the agreed work program of the SCP 26, and thirdly, asked about the incompatibility of the provisions and the content of the African Group's proposal with the work of the SCP. The Delegation expressed its wish to have a conversation on the mandate as they saw it, and how incompatible it was with specific elements of the African Group's proposal. The Delegation finally remarked that it would not enter general discussions and expressed its willingness to respond to questions and hold frank discussions in that regard.

156. The Delegation of Indonesia expressed its support to the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation was of the view that patents and health was a topic of great importance to all Member States. The Delegation pointed out that, even though the United Nations High-Level Panel Report was not a Member State-driven report, the Committee had also presented other reports which were not Member State-driven, and that did not stem from a Member State process. The Delegation further pointed out that a Sustainable Development Goals, particularly SDG No. 3, was in the agenda as an important call for revising the right to health and right to share the benefits of scientific advancement, whose information dated back to the chapter of the United Nations, the Constitution of the World Health Organization and also international covenants on economic and cultural rights, and other international treaties which resulted from Member State-driven processes. The Delegation believed that the objective of the exercise on patents and health during the SCP was to develop a work plan for WIPO in order to improve how it assists Member States in their understanding and use of other flexibilities for health, recalling the fact that it was a cooperation agreement for technical assistance between WIPO and the WTO. In its opinion, it gave WIPO the mandate to offer assistance on intellectual property related matters which was also covered by WTO agreements. The Delegation was of the view that the core of the discussion in the Committee was the policy incoherencies between the justifiable rights of inventors, international human rights and trade rules, in the context of health technologies. The Delegation then expressed its concern on the fact that the Committee did not have the mandate, taking into account that such an issue had clear links to patents and needed policy coherence on intellectual property rights and public health objectives. The Delegation expressed its wish to have further discussion on that, to assure there was a public health-sensitive rule and addressed the misalignment between profit-driven innovation and public health priorities. The Delegation finally reiterated its willingness to have a meaningful discussion to make progress on that agenda item.

157. The Delegation of India expressed its support to the statements made by its Delegation on behalf of the Asia Pacific Group, the Delegation of Indonesia, and the Delegation of Nigeria on behalf of the African Group. Referring to the compulsory licensing problems associated with local manufacture raised by the African Group where essential medicines were not properly supplied and made affordable, the Delegation explained that India could issue a compulsory license to manufacture locally in India, and thereafter export the medicine to other countries.

158. The Delegation of Iran (Islamic Republic of) stated that having access to medicines constituted a very basic human right and was related directly to the rights of life. The Delegation stated that the SDGs had agreed, at the United Nations by all Member States, and that the SDG 3 was exclusively formulated to assure healthy lives for all. The Delegation further stated that the United Nations Secretary-General's High-Level Panel had established, in the framework of the SDGs, ways to incentivize health technology, innovation and increasing access to medicines and treatment. The Delegation was of the view that innovation and access to health technology was a multi-dimensioned and global problem that affected all countries. The Delegation believed that public health-sensitive intellectual property rules and mechanisms could help address the misalignment between profit-driven innovation models and public health priorities. The Delegation remarked that WIPO was also a United Nations specialized agency and that some recommendations that were included in the report of the United Nations High-Level Panel were established in the framework of the United Nations and were hence directly related to the work of WIPO. The Delegation was of the opinion that the SCP was a relevant Committee where WIPO addressed patent related aspects of health rights, that it should consider those recommendations, and base its study and future work in that regard.

159. The Delegation of Brazil expressed its support to the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation underlined that the lack of access to medicines, especially in developing and least developed countries during the recent Zika and Ebola virus outbreaks, had shown there was a need to tackle those threats. The Delegation stated that it was clear on the role of patents and patent-related flexibilities that inspired innovation and provided access to medicines. The Delegation recalled that the Sustainable Development Goals included SDG No. 3, related to providing health access for all. The Delegation remarked that the SDG decision was agreed by consensus, and that it had created obligations for Member States to resolve those problems for the international community. The Delegation was of the view that WIPO, as part of the United Nations system, had a particular role to play during those discussions. The Delegation believed that the proposal made by the African Group would be in line with the relevant Development Agenda recommendations. The Delegation, therefore, reiterated its support to document SCP/24/4.

160. The Representative of the European Commission took note of the contribution provided by the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and the subsequent message made by the Secretary General, which encouraged all stakeholders to chart a way forward, in appropriate fora, to ensure access to medicines and health technologies for all who needed them, wherever they were. The Representative stated that the work conducted by the Panel had started from the assumption that there were ”policy incoherencies between the justifiable rights of inventors, international human rights law, trade rules and public health". He further stated that the European Commission did not share that assumption. The Representative pointed out that the report acknowledged that there were many reasons "why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights". The Representative underlined that another important problem was the global medicines shortages and stock-out, and recalled that in their written contribution to the Panel, it was encouraged to adopt a holistic approach to the problem of access to medicines that could result in a valuable contribution to the wider debate. The Representative, however, noted that due to its limited mandate, the United Nations High-Level Panel had focused its proposals exclusively on addressing an alleged conflict between a research and development model that (partially) relied on intellectual property rights, and the possibility of providing affordable medicines, while, it had missed an opportunity to advance more balanced, comprehensive and workable solutions to the problem of the access to health. He highlighted that no conclusion could be reached without the support from all of the members of the Panel, as demonstrated by the dissenting opinions attached to that report. The Representative stated that they were committed to increasing access to affordable medicines and to find solutions to the world's pressing public health challenges and inequities. The Representative further stated that in line with the 2010 Communication and Council Conclusions on 'the EU’s role in Global Health', they pursued a rights-based approach to health. He remarked 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, were central to moving towards universal health coverage with quality health services accessible and affordable for all. He added that the quality and integrity of the pharmaceutical distribution chain was also essential to improving public health. The Representative considered that the challenge was to strike the right balance between the need to promote and finance the research of new and better medicines for all, ensuring that medicines were accessible and affordable to those in need, while guaranteeing the sustainability of health systems. He believed that those goals were not contradictory and should be pursued jointly. The Representative stated that the current innovation model, including the role of trade related to intellectual property, had delivered consistent progress in global public health, leading to key new and improved treatments, extended life

expectancy, both in the developed and least developed countries. He further stated that that model already integrated a variety of tools, such as incentives for innovation based on intellectual property, on public and private financing, and awards for public research. He remarked that such variety was necessary to address situations where there was a functioning market and those where there could be market failures. The Representative noted that the report underplayed the fact that the development of new drugs required significant investments and long-term research, coupled with clinical trials and regulatory approval procedures. He further noted that the exclusive right conferred by a patent was an important incentive for innovative pharmaceutical companies to make the necessary investments for that research and development. He believed that without incentivizing the innovative pharmaceutical companies to invest in research, the sustainable development goal of ensuring healthy lives and promoting the well-being for all, including achieving universal health coverage, would be severely undermined. The Representative highlighted that several issues covered in the report's recommendations were addressed in the European Union legislation, EU & Commission policies and actions, including at a multilateral level. In that regard, he mentioned the following examples: (i) the Commission was a major funder of research and innovation for poverty-related and neglected diseases, and for new antibiotics. At the WHO, the European Union and its Member States supported the implementation of the WHO global strategy and plan of action on public health, innovation and intellectual property, including the development of the Global Observatory on Health Research and Development; (ii) in the area of trade, the European Unions ensured that its free trade agreements were consistent with the Doha Declaration and that it supported the extension of the drug patent exemption for least-developed countries; (iii) as part of its health policy, the European Union adopted new legislation to ensure that all clinical trials to be conducted within the European Union should be registered in a publicly-accessible database (Regulation EU No 536/2014). The Representative, however, stated that several other recommendations were not in line with the European Union rules and practices and hence could not be supported. In particular, he underlined the case for the proposal to revise the paragraph 6 decision of the TRIPS Agreement on those matters, the recommendations in relation to INN and standard international common names for biological products, and the proposal to create additional structures at a United Nations level on the issue of health technology innovation and access. The Representative finally stated that any future activities at the United Nations level in that area should be conducted on the basis of a much broader understanding of the complex issues involved.

161. The Delegation of Turkey thanked the African Group for their proposal. The Delegation noted that the said proposal contained elements which fell outside of the scope of the SCP and even outside of the WIPO's mandate. It expressed its support to the statement made by its Delegation on behalf of Group B regarding the need for making an inventory of the studies and analyses produced in other fora in order to avoid repeated work or ignoring relevant findings. The Delegation remarked that The United Nations High-Level Panel on Access to Medicines was neither a Member State-driven process nor had it been endorsed by the Member States. The Delegation considered that The United Nations High-Level Panel report presented only one point of the view, and that it could not be taken as a reference for the Committee or for the WIPO in general. Therefore, the Delegation stated that it would come with more specific comments in that regard, after further coordination within Group B.

162. The Delegation of Slovakia aligned itself with the statement made by the Representative of the European Commission.

163. The Delegation of South Africa expressed its appreciation of the opportunity to share its journey in the quest to provide access to essential medicines through the patent system. The Delegation recalled that South Africa had a proud history of robustly engaging in issues that concern the intersection between intellectual property rights and public health. The

Delegation emphasized that the South African Government, in the 1998 case between the Pharmaceutical Manufacturers Association versus the President of South Africa, was a key factor leading to a global dialogue on the potential negative impacts of intellectual property rights on public health, culminating in the Doha declaration on TRIPS and Public Health. The Delegation underlined that South Africa had been a key global player in the global recognition that the duty owed by a state to safeguard public health was not inconsistent with its responsibility to honor international treaty obligations. The Delegation stated that in the late nineties, for countries such as South Africa, the affordability of antiretroviral medicines was the main barrier for them being listed as essential medicines, provided to patients. In 1998 the National Essential Medicines Lists Committee recommended to the Minister of Health that antiretroviral therapy (ART) should be approved for provision to persons living with HIV/AIDS, provided that the price of the medicine could be reduced. The Delegation pointed out that to address some of the challenges associated with the patent-related pricing monopoly, South Africa amended its Medicines and Related Substances Control Act, (Act 101 1965) by introducing Section 15C, entitled “Measures to ensure supply of more affordable medicines.” That section was introduced to provide for parallel importations and compulsory licensing. The Delegation further pointed out that the pharmaceutical industry, backed by some governments, vigorously opposed the enactment of Section 15C, arguing that it was tantamount to a complete annulment of patent rights and that it violated the TRIPS agreement. The Delegation confirmed that in spite of vociferous opposition, Section 15C was signed into law by President Mandela on December 12, 1997. The Delegation explained that in an attempt to block the implementation of Section 15C, over 40 of the world’s largest and most powerful pharmaceutical companies initiated a court action, challenging the constitutionality of Section 15C before the High Court of South Africa in February 1998. In addition, Section 15C was also put on the agenda for high-level bilateral trade discussions between South Africa and certain countries, which resulted in South Africa being placed on a special 'watch list' in 1998 and 1999 relating to international trade relations. The Delegation further explained that tensions escalated, and ultimately created significant public awareness and controversy regarding the conflict between the pharmaceutical industry and developing countries. In that regard, the Delegation noted that as the pressure mounted, a narrative emerged in that pharmaceutical companies were putting 'profit before people'. The Delegation underlined that the lawsuit against the South African government was ultimately withdrawn unconditionally in May 2001, and remarked that civil society treatment access activists cited the successful media campaigns as having been central to achieving that victory. The Delegation stated that as the global narrative in favor of access to medicines continued to strengthen, in 2001, developing countries raised concerns on the possible negative impact a narrow/strict interpretation of TRIPS could have on certain policy objectives, particularly on public health outcomes relating to access to medicines. The Delegation further stated those concerns culminated in the Doha Declaration on November 14, 2001, which clarified that the TRIPS Agreement should be interpreted in a way that supports public health objectives, by stimulating the creation of new medicines whilst also promoting access to existing medicines. Thus, the TRIPS Agreement “should not prevent Members from taking measures to protect public health and should be interpreted in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicine for all.” The Delegation considered that the said declaration clarified TRIPS flexibilities, including compulsory and voluntary licensing, the Bolar exception, non-commercial use and the parallel importation of medicines. The Delegation underlined that those mechanisms had been incorporated into its law through the amendment of the Patents Act of 1979, the Medicines and Related Substances Control Act and other relevant legislation, to circumvent limited access to medicines due to market exclusivity. The Delegation, however clarified that providing access to essential medicines still remained a challenge because of the delicate exercise of balancing interests of both innovators, i.e., pharmaceutical companies, and the general public. The Delegation stated that since 2001, many generic manufactures had secured voluntary licenses to produce medicines in South Africa, including over 20 licenses for medicines in the antiretroviral

category. The Delegation explained that the increase in voluntary licensing (VL) agreements for ARV drugs was often a result of civil society pressure, and the use of competition law. The Delegation cited an example dating back to 2002 when activist initiatives of the Anti-Retroviral Therapy (ART) treatment campaign resulted in some multinational companies being found guilty of excessive pricing by the South African Competition Commission. At that time, the prices of patent holders were between 3 and 10 times higher than those for the least expensive generic version of the same medicines. The Delegation pointed out that in 2004, the prices of ARV dropped to a level where the South African Department of Health introduced them as essential medicines. In that regard, the Delegation stressed that prices remained relatively high and there were concerns regarding financial sustainability. Over time, however, the Delegation explained that often as a result of ongoing civil society pressure, increasing numbers of voluntary licenses were issued, resulting in steady price decreases. The Delegation cited an example of 2006 where a license for the drug tenofovir (TDF) was granted to a generic manufacturer and, as a result, the price of the drug decreased by 64%. The Delegation noted that similarly in 2007, activist pressure resulted in complaints to the Competition Commission regarding multinational companies for excessive pricing. It further noted that as a result, those companies issued voluntary licenses, after which competition increased and prices for the medicines decreased in state tendering processes. The Delegation believed that licenses for generic manufacturing of APIs in other parts of the world also contributed to cheaper APIs, and thus cheaper medicine formulation since APIs accounted for approximately 70% of the cost of manufacturing ARVs. The Delegation considered that the current activist initiative 'Fix the Patent Laws' resulted in a number of media battles and ongoing pressure towards multinational pharmaceutical companies regarding pricing and affordability for patented medicines. The Delegation further considered that activist campaigns aimed to strengthen intellectual property laws in South Africa in the interest of stimulating medicine price competition. The Delegation explained that there was an ongoing process with multiple stakeholder involvement, including the Department of Trade and Industry, the Department of Health and the Department of Science and Technology. The Delegation highlighted that South Africa had never issued a compulsory license but those manufacturers who had actively courted multinational pharmaceutical companies had acquired lucrative voluntary license agreements where pressure existed to improve generic manufacturing. Those companies were careful to maintain intellectual property regulations and good relationships with pharmaceutical firms, in favor of potential of local voluntary patent pools for innovation, rather than supporting a compulsory licensing approach. The Delegation drew attention to the fact that as a way forward, in July 2016, the South African cabinet approved a new IP Policy Consultative Framework, which aimed to promote competition and ensure the levelling of the playing field, in the area of public health and intellectual property rights. The Delegation underlined that the new intellectual property policy framework took a consultative approach that sought to include all relevant stakeholders, including the government, the pharmaceutical industry, NGOs and the general public. The Delegation noted that that framework would consider the amendment of current intellectual property laws, to ensure that a balance was struck between IP rights and the rights of every citizen to access medicines. The Delegation further noted that it would also consider simplifying the processes of providing access to medicines by fast-tracking the approval processes required to access such medicines. The Delegation explained that in South Africa, the current process to obtain a compulsory licence required a lengthy and expensive judicial process, as it involved litigation. The Delegation further explained that the policy therefore would consider a more streamlined and accessible administrative process, as opposed to a judicial process, for obtaining a compulsory licence. The Delegation stated that, as highlighted above, the parallel importation of medicines in South Africa was governed by section 15C of the Medicines and Related Substances Act, and that it was also addressed in the South African Patents Act of 1979 as amended, which provided for the exhaustion of rights. The Delegation however explained that there was some uncertainty over whether Section 15C applied not withstanding any rights conferred in terms of the South African patents. The

policy would also clarify matters on the exhaustion of rights, where parallel importation was concerned. The Delegation specified that the policy would also consider amendments to the Patent Act to provide for the substantive examination of patent applications and the introduction of opposition proceedings in the grants of patent rights. It recalled the story of Thobeka, who needed a drug for the treatment of breast cancer. Due to the high price of that drug, it was inaccessible to most breast cancer stricken patients, resulting in the unnecessary death of patients even though a suitable treatment was indeed available. The Delegation remarked that interestingly enough, the patent had expired in most countries where patent protection had been obtained. However, South Africa had a depository system in that the patent continued to remain in force on the patent Register. The Delegation stated that in terms of South African law, it would have required protracted and expensive litigation to challenge the validity of that patent. The Delegation explained that it was a policy position of the South African government to introduce substantive search and examination and opposition proceedings to ensure that only quality patents remained on the registers. The Delegation concluded that South Africa was embarking on a consultative and inclusive process to address issues of intellectual property rights and access to essential medicines. The Delegation recognized the importance of striking a balance between the needs of indigent people who required access to medicines, but who, because of their status, were unable to afford and access essential medicines, and on the other hand, the need to incentivize pharmaceutical companies to continue investing in the research and development of new medicines to address future needs. The Delegation expressed its wish to continue calling on WIPO's support on intellectual property policies based on the objectives of balancing the rights of innovations with the needs of the public.

164. The Delegation of Brazil shared its experience regarding the use of patent relating flexibility to public health. The Delegation stated that as members were aware, the Bolar provision was one of the key tools to ensure an efficient and balanced patent system and to make sure that patent rights were not unduly extended under the term of protection. The Delegation believed it was a promotion of public health objectives. The Delegation pointed out that recently an enterprise initiated a legal proceeding against Envisa, the Brazilian authority responsible for the concession of marketing authorizations to pharmaceutical compounds. It explained that the company had questioned the procedure for authorizing generic producers of an antidepressant medicine through the use of clinical test data for a regional patented compound. Furthermore, the company also argued that the production of test data regarding substantial investments was protected against unfair commercial use by competitors. The Delegation pointed out that the Court's decision held that the company's rights were not violated, as the only entity that had access to the data was Envisa. Additionally, the Court held that the authority protected the confidentiality of the data adequately against disclosure. It stressed that in the course of providing authorization to the generic producers, competitors had had no access to any of the clinical test data. Furthermore, it explained that the investment did not constitute by itself grounds for enjoying the protection granted by intellectual property rights, taking into account that the demand formulated by the company went beyond the spirit of both the Brazilian law and the relevant international treaties, including the TRIPS Agreement. Therefore, the Delegation underlined that the Court decided that Envisa's procedure was in full compliance with the legal requirements, as granting the demand of the company would have arbitrarily extended the term of protection of the drug beyond 20 years that were already granted by a patent. The Delegation emphasized that that would negatively affect the access to the medicine and it would be against the objective of the industrial property laws which aimed at sparing the development of new products and processes. The Delegation drew attention to Article 5 of the Brazilian Constitution which stated that inventors would enjoy a temporary privilege and that such temporary privilege was granted in view of the social, technological and economic development interests of the country. The Delegation stressed that the Article contained both sides of the protection of intellectual property right, that were to provide incentives for innovation and creativity, while balancing those incentives with the general social interest

including the right to health. The Delegation was of the view that the undue extension of such a privilege would encourage upon the very goal that underpins the existence of patent protection, by creating unjustifiable anticompetitive effects. The Delegation finally stated that as the European Commission Pharmaceutical Sector Inquiry had shown, the anticompetitive use of patents and related intellectual property rights, not only reduced the welfare of society by frustrating access to medicines, but also affected innovation activities in the pharmaceutical sector, damaging a generation of new life-saving products.

165. The Delegation of Nigeria expressed its appreciation for contributing to the segment of the sharing session. The Delegation stated that the SCP agenda was designed to promote the exchange of views and the sharing of national experiences in the field of patents and public health. The Delegation stressed that while Nigeria was a country with a population of over 182 million and with equally challenging health issues, it had rarely used flexibilities in the patent system to mitigate a public health challenge, whether related to epidemics such as HIV/AIDS, Ebola or certain non-communicable diseases and diseases prevalent in the developing countries of Africa. The Delegation stated that reliance was usually on the exhaustion regime to allow for access to necessary medicines in Nigeria within members of the Economic Community of West Africa and beyond. The Delegation pointed out that Nigeria's nonuse of flexibilities was observed in its Patent Act in Articles 7, 8, 27, 30, 31, among others, including the Doha Declaration which provided for the safe harbor for the use of flexibilities by developing and least developed countries in the field of public health. It further pointed out that it was for the lack of desire to access those available and useful tools in the Patent Act. Furthermore, the lack of capacity to fully comprehend the full range of the flexibilities that could be i6mplemented raised concerns about costly violations of existing agreements. The Delegation remarked that a fixture of public health policies of any given country whether developed, developing or least developed, was the institution and sustenance of a viable health care system that ensured, among others, adequate access to medicines by a significant percentage of the population, if not all of it. The Delegation stated that Nigeria's Patent Act did provide for compulsory licensing obtainable by court order and could be used by government authorities. It further stated that such exceptions should be used on the specific circumstances to access medicines for public health emergencies and more specifically the HIV virus. The Delegation explained that it allowed the Government to compel a patent holder to license its rights to generic manufacturers, in exchange for monetary compensation. However, the Delegation further explained that a huge percentage of the patents in Nigeria were granted to foreign patent holders, whilst most of the domestic applications were licensed by foreign owners. The Delegation was of the view that the lack of result of flexibilities to mitigate certain public needs in Nigeria, including protection against anticompetitive practices, was one of the driving forces behind the recently reconstituted ongoing review of Nigeria's statutory Acts, including the draft industrial property bill to enable its response to prevailing realities and dynamic situations. The Delegation stressed that the Ebola outbreak in West Africa in 2014 and 2015, including Nigeria, was its biggest test yet. The Delegation stated that a number of indigenous private sector stakeholders approached the government to explore the acquisition of licenses to undertake research and investments into alternative approaches towards solving such epidemics. It further stated that the Ebola outbreak in Nigeria was swiftly contained in an unprecedented manner through technical tracing, sharing of vital information and medication. In the Delegation’s opinion, given the differences in the implementation of flexibilities by Member States, it was vital that the SCP developed a core and practical guide for Member States on the efficient and effective use of flexibilities in the patent system. The Delegation emphasized that it was also clear that the issues were integrated and interconnected, thus required components such as technological capacity and the ability to effectively use flexibilities of interest for the exercise to be productive. The Delegation expressed its belief that building the capacity of critical mass of human resources was also important. The Delegation underlined that those were recognized in the Sustainable Development Goal 3, which called for substantial increases in health financing, recruitment, development training and retention of health workforce in

developing countries, as well as strengthening the capacity of all countries, in particular developing countries, for early warning, risk reduction and management, national and global health risks. Additionally, the Delegation highlighted that it was important to note that the prevalent use of software in the delivery of medical solutions was an area that was not particularly addressed in the Doha Declaration, in its clarification of the TRIPS flexibilities for health, and deserves the attention of the SCP. The Delegation suggested that the study to be presented to the SCP/26, on the constraints faced by developing countries to health care, could include the examination of how Member States could use medical software for public relation solutions or public health solutions. The Delegation expressed its willingness to work with WIPO and other stakeholders to strengthen capacities in that field through informed access and learnings from the development of best practices.

166. The Delegation of China congratulated the Vice-Chair on her election and thanked her for her leadership in the session. The Delegation expressed its wish to introduce China's experience on public health and legal revisions. The Delegation stated that it may have already introduced such legal practices and had submitted the proposals to the Secretariat. The Delegation recalled that in 2008, China implemented the World Trade Organization's legal provisions in its own national legal system. The Delegation explained that in 2012, regarding compulsory licensing, it also made revisions and improved the relevant procedures and approval procedures. The Delegation pointed out that during its legal revision in 2008 and up to now, it had also made significant improvements on strengthening patent protection. Given that, the Delegation drew attention to the fact that China had not yet issued a compulsory license, and therefore underlined that it did not have much experience in that regard. The Delegation however stated that regarding the use of flexibilities and exceptions, it was linked to negotiation on procurement of medicines, and that it had played an important role that no one should ignore. The Delegation finally made a general statement in which it considered that patent systems needed to seek a balance between protecting public interests and the interest of patent holders.

167. The Secretariat presented document SCP/21/9.

168. The Delegation of Argentina stated that the issue of patents and health was of great importance to all countries. In addition, the Delegation stated that the issue of the disclosure of INN in patent applications and/or patents was of particular interest to its country. The Delegation referred to paragraphs 27 to 29 of document SCP/21/9 and noted that, while in many cases it was not possible to indicate the INN at the time of the filing of the patent application, for patent applications filed after the publication of the corresponding INN, disclosure of INNs should be mandatory. In its view, this would be important with regard to the determination of prior art and assessment of inventive step. In addition, the Delegation stated that such disclosure would contribute to technology transfer, as pharmaceutical companies were primarily concerned with the scope and status of patents relating to drugs that had already been successfully marketed. The Delegation stated that, therefore, for those companies. the possibility of visualizing such patents would be very useful.

169. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, wished to reiterate the understanding of the challenges and constraints certain countries might face in handling public health issues. The Delegation stated that the availability of medicines to treat certain illnesses was a major challenge and a key Sustainable Development Goal that all Member States supported. In relation to the feasibility study on the disclosure of INN in patent applications and/or patents contained in document SCP/21/9, the Delegation reiterated its position expressed during previous sessions of the SCP by stating that, on the basis of the information assessed and provided in the document, the case for disclosure requirements of INN had not been made. The Delegation noted that the cost and benefits for such disclosure requirement were unclear, and that there were other limitations highlighted in the study. Specifically, the Delegation

stated that it was impossible to disclose, at the time of filing, the future corresponding and yet to be published INN, in patent applications filed before the publication of the recommended INN. The Delegation continued that in that scenario, the preliminary findings had pointed to the major challenge of how to link the corresponding INN information to such applications without unduly burdening applicants and patent offices. The Delegation further stated that the feasibility study also highlighted limitations in cases where the INN was known. In particular, the Delegation noted that the sole indication of the INN in patent applications was not sufficient to find out with one click what a patent searcher was looking for. The Delegation observed that the study pointed to the fact that patent searchers have developed methodologies to search patents for medicine, primarily by using publicly available databases, and that increasing the sophistication of IT tools might significantly contribute to a simpler and more cost-efficient patent search in the field of chemistry and pharmacology. 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. The Delegation concluded by stating that, at the same time, the Member States still had to bear in mind not to go beyond the mandates of the SCP and of WIPO, and to allow discussions on factors other than patents to other relevant United Nations organizations.

170. The Delegation of the United States of America stated that the timeline for submitting a request to the INN Secretariat was such that the INN could not be available when a large number of patent applications were filed. The Delegation referred to paragraphs 12 and 13 of document SCP/21/9 and noted that, according to the World Health Organization Guidelines on the Use of INN for Pharmaceutical Substances, applicants should not obtain an INN before all patent procedures were completed, and that the request for an INN should not occur before clinical trials had begun. The Delegation stated that, in its view, requirements to provide the INN once it had become available after filing of the patent application would be excessively burdensome to both the patent offices and the applicants. The Delegation stated that patent offices would be forced to develop and implement new procedures for handling the INN disclosed either later in the patent prosecution process or after the patent grant. The Delegation stated that, most likely, those procedures would be resource-intensive and difficult to enforce. The Delegation further stated that the national laws might not provide a mechanism for reopening the prosecution of patents that were already granted, based on an INN disclosure or lack thereof. The accuracy and timeliness of an applicant's disclosure of the INN would have to be verified and patent examiners would have to be trained on the INN system and procedures. In the view of the Delegation, that would place a high burden on the offices, in part due to the significant differences between the patent processes and INN procedures. In its opinion, the time and resources, both financial and human, needed to implement and enforce those procedures would be much better spent by patent offices for other uses, such as increasing the quality of granted patents and reducing the backlog that many offices had. Therefore, the Delegation did not support the requirement to disclose the INN, and noted that the feasibility study did not address whether a country that was a Member of the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT) or other multilateral agreements could impose such type of an additional requirement in patents. The Delegation was of the view that such a requirement would be an additional requirement and would not be permitted under, for example, the Patent Law Treaty. The Delegation stated that in addition to the question of whether a patent office could require the disclosure of an INN where an invention had a complete disclosure, the question to ask was whether they should do so. The Delegation was of the opinion that the resources would be better spent to further facilitate access to information, such as by enhancing the searchability of patent documentation through information technology systems. The Delegation stated that one such example had been demonstrated by the Secretariat. In its view, adding the new function to the PATENTSCOPE would be a very useful adjunction that would facilitate searches of chemical compounds. Therefore, the

Delegation supported the continued development of the additional capability of the PATENTSCOPE. However, the Delegation expressed its concern that in that discussion, a core concern that patent examiners and others had, i.e., unavailability of conducting a search and identifying relevant patent applications, had yet to be addressed. The Delegation stated that document SCP21/9 indicated that some patent offices seeking to search chemical and pharmaceutical inventions might experience certain difficulties due to the complexity and expense involved in finding prior patent documents relative to those inventions, although many patent offices were able to conduct such searches routinely. To the Delegation, that highlighted the value of work sharing where an office would assist another office in conducting a search and examination. The Delegation continued that such assistance could be in the form of training exercises and an expansion of the knowledge and tools available to the examiners, since one examiner might have access to search databases and have a detailed understanding of a technology, whilst another examiner might not. Thus, the Delegation wished to reiterate its proposal that a Committee carry out a study to determine how cooperation between the various patent offices could be used to facilitate the search and examination, particularly of chemical patents, by offices that, under current circumstances, might encounter difficulties in doing so. As part of the study, it was proposed that the SCP would gather information on how the various offices search and examine patent applications, how much work they generated in relation to the type of patent application, and how and under what circumstances that information could be utilized by other offices to simplify their own search and examination of that type of patent application.

171. The Delegation of Brazil stated that it was in favor of continuing the discussion on the disclosure of INN in patent applications. Noting that the provision of the INN had the potential to facilitate the elaboration of search reports in the course of substantial patent examination procedures, the Delegation stated that it was related not only to the topic of patents and health but also to the issue of quality of patents. The Delegation also suggested that the discussion on costs and the possibility of developing an international and easily accessible database by WIPO be included in the Committee. The Delegation explained that such a database could contain INN for pharmaceutical products, and could also contain standard international common names for biological products.

172. The Delegation of Japan expressed its belief that, where INN were included in patent applications, the questions to be clarified were what effect the disclosure would have on the patent system itself, and what would the result be. The Delegation stated that from the perspective of enhancing the efficiency of patent search, the INN had some utility as a supplement to the existing search methods. The Delegation noted that, in particular, the feasibility should be considered not only from the perspective of enhancing accessibility to prior art, but also by taking into account to what extent the workloads of both applicants and IP offices would increase. In addition, the Delegation was of the view that it was necessary to consider its possible impact on the interpretation of the scope of rights. The Delegation concluded that, in other words, the issue should be discussed carefully, by considering its advantages and disadvantages.

173. The Delegation of China thanked the Secretariat for its presentation on Chemical Compound Search in PATENTSCOPE, which the Delegation would share with examiners of its patent office. The Delegation noted, from the presentation of the Secretariat, that currently, there were more than 6,000 INN retrieved from the database, and that those INN should originate from patent application documents. The Delegation wondered whether it would mean that INN was helpful to the patent search function if it had been disclosed in the patent application. The Delegation noted that the document of the Secretariat did not provide information on whether any office made compulsory the requirement of INN disclosure. The Delegation concluded by proposing that the Secretariat undertake a more

in-depth study to examine the need and feasibility of that requirement, in a comprehensive and multidimensional manner, for instance, for the cases where the INN was already available. The Delegation looked forward to a document which would provide a better and clearer understanding of the relevant issues.

174. The Delegation of India noted that the fundamental concept of patent system was *quid pro quo* and that the monopoly right was granted for the disclosure of the invention. The Delegation stated that INN was also essential information that was required for search and examination which was the fundamental work of patent offices. Referring to the feasibility study (document SCP/21/9), the Delegation noted that an average time period, between the filing of an INN request and the publication of a recommended INN, was of approximately 15 months. The Delegation stated that INN could be added as bibliographic data, during prosecution or after grant, which would be useful for future search and quality of patents. The Delegation further stated that the INN disclosure was not a substantive issue but that it could be a formal requirement. In conclusion, the Delegation requested the SCP to continue studying the issue further.

175. The Delegation of Nigeria, speaking on behalf of the African Group, reiterated its view that disclosure was bedrock of the patent system and, therefore, it supported further discussion of the issue during the SCP through a study that would assess the relevance of disclosure of INN in patent applications in promoting transparency and serving the teaching function of the patent system. While the Delegation noted the finding of the feasibility study that an applicant should not attempt to obtain an INN before all patent procedures were completed, and that no attempt should be made by the applicant to obtain an INN before all patent procedures were completed, it nevertheless stressed the role the INN disclosure could serve in guarding against anticompetitive practices and insuring that patents were not granted for undeserving incremental innovation.

176. The Delegation of Turkey, speaking on behalf of Group B, stated that, as clearly indicated in document SCP21/9, an INN was often only assigned after the patent application had been filed, and sometimes granted, and thus, in many instances, it could not be part of the original disclosure. The Delegation continued that, in a few cases where the INN was published before the filing of the patent application, its inclusion could create extra burden to the applicants and the intellectual property offices. The Delegation was not of the opinion that the current international framework provided the required space to impose new patentability criteria, or require information beyond the current requirement to provide an adequate written description of the invention. The Delegation expressed its belief that the recently launched PATENSCOPE chemical search tool assisted the accessibility of the chemical structures, for example, pharmaceutical compounds in published patent applications, and therefore, the investments in those technologies were the most efficient way forward.

177. The Delegation of Spain thanked the Secretariat for its presentation on the Chemsearch tool, and expressed its support to the statement made by the Delegation of Slovakia on behalf of the European Union and its Member States. The Delegation noted, as an initial premise, that it would be interesting, especially for third parties, to indicate the INN of the active ingredient within chemical-pharmaceutical patents, since it would facilitate the access to all documents related to that product. The Delegation further noted that the precision, uniformity and international acceptance of INN made them the ideal medium of communication among doctors from different countries, making them essential in official documents and in medical publications. The Delegation, however, affirmed that in the context of patents, there were difficulties that made it quite complicated, and in some cases, impossible to fulfill the expectations. The Delegation pointed out that the proliferation of pharmaceutical research, coupled with the system established by patent laws that the right to the patent was granted to the first-to-file, led the pharmaceutical laboratories to rush on

the filing of patent applications in a very early stage of research. The Delegation stated that at that stage, they only had a rough outline of the chemical structure, concreted in a structural formula with numerous substituents that encompassed a multitude of products, which were called 'Markush formulae'. The Delegation explained that at that stage of the research, there was no INN, since that denomination was granted by the World Health Organization to a concrete compound that was authorized for marketing after a long period (established by the pharmaceutical company's directives in about 10 to 12 years counted from the date of the patent application). The Delegation continued that the final compound was obtained after a long process consisting of the screening of several thousand compounds. Therefore, the Delegation remarked that when the INN was disclosed, usually the first patent application related to that compound had not only already been published, but had usually been granted. In the Spanish legislation, the Delegation explained, it would be impossible to amend a document whose administrative procedure was over. The Delegation stated that if the patent application was submitted when the INN was already known, it was usually indicated by the applicant, not only within the description but also in the title and abstract, thus, in those cases the problem did not exist. The Delegation was of the view that the difficulty of patent searches when the INN was not available was not an issue either for patent offices, where there were expert examiners who performed complex searches using connections to specialized databases (Medline, Chemical Abstracts, Biological Abstracts, etc.), or for large pharmaceutical corporations. However, the Delegation noted that other less technically advanced users would need to use the technological information services established by the patent offices, or other service companies, to obtain such information, in order to minimize the risk of manufacturing a drug that was covered by some intellectual property right. The Delegation pointed out that certain countries, such as the United States of America, had a Drug Authorization system which linked the INN of the authorized product with the patents related to that drug, the so-called 'Orange book', in which the applicant of a marketing authorization for a drug was obliged to relate patents related to that drug. The Delegation further pointed out that that FDA authorization system was not applicable to European countries where drug authorizations had no link to industrial property rights. However, the Delegation noted that even the said "improvement" established in the United States of America did not resolve the issue, since in the Orange Book, only the patents of the holder of the marketing authorization of the drug would be found, but not the others. The Delegation was of the view that applications for Supplementary Protection Certificates (SPC) would be an important source of information and relationship between patents and INN, since all SPC applications contained the INN of the authorized product. The Delegation stated that, however, only one patent was related, among many patents that usually covered that product, thus the information was greatly limited. The Delegation expressed its belief that in relation to the INN issue, the way forward would be to improve the free access to patent databases, and in that regard, WIPO should be congratulated for improving the PATENSCOPE by including the Chemsearch tool.

178. The Representative of KEI stated that in the United States of America, there existed two different systems to induce the disclosure of the patent information: one system for pharmaceutical drugs (the so-called "Orange Book") and another system for biological drugs. The Representative stated that when using the Orange Book, there was a consequence for non-disclosure of patents relevant to a pharmaceutical drug under consideration for FDA approval. The Representative states that the system had been criticized because the regulatory stay had been abused. Further, the Representative stated that a similar and somewhat different system was available in the area of biological drugs in the United States of America, a procedure where a biosimilar competitor could notify a company that also had a biosimilar product, for which they intended to pursue a biosimilar pathway to register, and that they would rely upon the evidence and data from the original product. He continued that under that system, the biosimilar company had to pay compensation and sign a non-disclosure agreement to get the patent landscape disclosed. What induced the disclosure of the patents to the competitor and the patent landscape was that there was a

limitation on the remedies for the enforcement of the patent, if the originator did not disclose it to the competitor. The Representative noted that the system had several flaws, one of which being that the system that justified the disclosure of the invention required people to sign non-disclosure agreements to find out what the patent landscape was on a biological drug. He further stated that the lesson to be learned from the both U.S. systems was that patent applicants could be induced for subsequent disclosure of the INN, i.e., after it was made available, through a system where certain privileges for the enforcement of rights would be suspended if they did not disclose it. Finally, the Representative expressed his surprise in relation to the statement made by the Delegation of the United States of America that it would be a costly burden to put the requirement on disclosure of the INN on patent owners.

179. The Representative of MSF wished to share with the SCP why a medical organization, such as MSF, was concerned by the issue of the INN disclosure. The Representative noted that the feasibility study did document the needs of health professionals, and other stakeholders, as primary users of the INN. She stated that the health professionals and other stakeholders often found it difficult to identify the surrounding patents on a particular medicinal product, and that was a challenge faced by the providers of that product. She explained that it was due to the current patenting practice by the industry and the lack of transparency of the system. Therefore, she stated, it was hard for health professionals to identify, in a timely and accurate manner, what was the patent landscape around a particular medicine that they were intending to buy. The Representative thus stated that that was a primary motivation for them to follow-up on the issue, and she was of the opinion that the challenges they were facing were also those faced by other public health professionals, decision makers in various countries, and governments. Further, the Representative referred to the chemical compound search function in PATENTSCOPE, and stated that it was fundamentally different from the discussions on INN disclosure, as well as from the recommendations by the United Nations High-Level Panel on Access to Medicines, which recommended WIPO develop a database on patent status of pharmaceutical and biological medicines. Therefore, while she noted, as a first step, the utility of the chemical compound search function in PATENTSCOPE, she nevertheless was of the opinion that more precise practical guide for the easier use of the database was needed for public health professionals. Specifically, she expressed her hope that further work could be explored from both technical and normative sides, making the system a more accessible, understandable, and transparent one for users who were not trained as patent attorneys and did not have a budget for the expensive commercial databases, and who relied on the transparency of the existing patent system. The Representative referred to the Medicines Patent Pool database as a database that was very close to what they were expecting.

180. The Representative of JIPA stated that, regarding discussions on INN, JIPA/JPMA were not sure why such laborious and costly disclosure of INN in the specification would be useful for public health. In particular, as regards the suggestion to require the disclosure of INN in patent applications if it had been known at the time of filing, the Representative noted that such a requirement, imposed on the applicants of pharmaceutical patent applications alone, needed to be carefully examined in terms of the potential violation of Article 27.1 of the TRIPS Agreement. The Representative further stated that since INN was not necessary for the adequate description of the invention and the determination of its patentability, a new obligation to disclose INN in the specification should not be imposed on the applicants, and that applicants should be allowed to disclose chemical names, chemical structures, CAS Registry Numbers, or INN, at their discretion. Finally, the Representative expressed his appreciation to the Secretariat for its efforts on the expansion of the PATENTSCOPE functionality. He stated that the PATENTSCOPE was a very useful and convenient search

tool, as it could convert a known INN, or chemical compound name, into InChiKey and allow the search of relevant patents. Thus, as PATENTSCOPE could effectively search relevant patents based on INN information, he believed that it was unnecessary to describe INN in the specification.

181. The Delegation of Ireland, referring to the idea of establishing a global legal status database raised by some representatives, stated that while it sounded relatively straight forward, it might, in reality, be difficult to implement. The Delegation explained that in the European Patent Organization, it attempted, a few years ago, to put together a European Patent Register allowing users to find the legal status of the European patents in the national phase. The Delegation stated that up-to-date legal status information was provided by the National Patent Registers and that, at that time, only half of the EPO's Member States were communicating the information to the European Patent Register.

182. The Delegation of India stated that the disclosure of prior art by the applicant was not mandated in many countries, whereas some other countries requested it. The Delegation also stated that the information on INN did not fall under any patentability criteria, and that it would improve the quality of patents.

183. The Delegation of Canada, in relation to a question received from the floor on whether its proposal was incompatible with other work on the topic of patents and health, stated that it did not consider it that way because it was a different exercise. Specifically, the Delegation clarified that what it was proposing in the study would simply be an inventory of existing work and would not involve any analysis.

184. The Delegation of Nigeria referred to the proposal made by the Delegation of Canada and wished to clarify whether such study would have any impact on the ongoing activities on patents and health in the SCP.

185. The Delegation of Canada responded to the question raised by the Delegation of Nigeria that the study it had proposed would be a stand-alone work item.

AGENDA ITEM 9: CONFIDENTIALITY OF COMMUNICATIONS BETWEEN CLIENTS AND THEIR PATENT ADVISORS

186. Discussions were based on document SCP/25/4.

187. The Delegation of Iran (Islamic Republic of) reiterated its previous position that the issue was not a substantive patent law issue and that it could be governed by national laws. The Delegation was of the opinion that the issue fell outside the scope of patent law and should be treated at a national level as it was a matter in the scope of private law and the regulation of services.

188. The Delegation of Nigeria, speaking on behalf of the African Group, stated that the African Group shared the same opinion as expressed by the Delegation of Iran (Islamic Republic of) on the subject of confidentiality of communications between clients and their patent advisors.

189. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, thanked the Secretariat for providing a compilation of court cases, as presented in document SCP/25/4. The Delegation also welcomed the information provided by the Delegations of Japan and Switzerland, and thanked WIPO for making that information available on the dedicated WIPO website to that topic, namely "compilation of laws and practices regarding the scope of client attorney privilege, and its applicability to patent advisors". The Delegation further stated that, in relation to confidentiality of communications

between clients and their patent advisors, time was ripe to consider a concrete mechanism to address the recognition of foreign patent advisors' privileges. The Delegation continued that, without prejudice to the existing national legislation and in order to ensure optimal flexibility, a soft law approach should be considered, aiming at conferring in Member States the same protection to communications between a client and its foreign patent advisor, than what was currently applicable under national law in communications between a client and its national patent advisor. In the view of the Delegation, 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 the individual WIPO Member States.

190. The Delegation of Latvia, speaking on behalf of the CEBS Group, thanked the Secretariat for preparing document SCP/25/4 and the Member States that had contributed to the elaboration of the document. The Delegation noted that the CEBS Group attached great importance to the continuation of the work under that agenda item. The Delegation stated that the issue had a cross-border dimension, and that such dimension was directly relevant to the work of the Committee. The Delegation expressed its belief that work on a non-legally binding instrument would be beneficial to all the Member States. In more concrete terms, the Delegation reiterated the proposal it had made during the previous session, namely, to request the Secretariat to conduct a study that would describe and assess various types of soft law approaches in that area.

191. The Delegation of Turkey, speaking on behalf of Group B, stated that its group attached high importance to the topic of confidentiality of the communications between clients and their patent advisors. The Delegation stated that users of the patent systems from different regions including Canada, Switzerland, Brazil or India, continued to stress the need to address the subject at the international level. The Delegation stated that Group B believed that the issue, in particular the aspect of the recognition of the foreign patent advisor's privilege, should be addressed at the international level and at the SCP. The Delegation stated that the Committee should take substantive steps to address the issue in a manner which would 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 this 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, and referring to document SCP/25/4, the Delegation expressed its belief that court cases in different national legal systems, as regards the confidentiality of communications, would provide resourceful material for Member States, and would contribute to important discussions. Recognizing the different opinions that 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 conducting that work in 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 that it had suggested could be prepared, as well as further compilation of the court cases could be continued.

192. The Delegation of India reiterated that its stand on the issue had not been changed since the previous SCP meeting. In particular, the Delegation stated that neither the Paris Convention nor the TRIPS Agreement provided such privilege, and therefore, the discussion on the issue during the SCP should be discontinued. The Delegation stated there was no provision on the client-attorney privilege in the Indian Patents Act. The Delegation explained that in India, patent agents did not need to be lawyers or advocates, and individuals holding a degree in science or in engineering could also practice before a patent office as patent

agents, after qualifying in a patent agent examination. The Delegation pointed out that the Indian Evidence Act only provided protection for lawyers, or advocates from discovery proceedings, and that patent agents, being persons of scientific or technical background, did not fall under such a protection.

193. The Delegation of Indonesia thanked the Secretariat for preparing document SCP24/4, as well as Member States for their submissions contained in that document. While noting that the confidentiality of communications between clients and their patent advisors had a certain value, the Delegation also recognized that countries had different legal systems and, therefore, it was necessary to respect the various legal practices of different countries. Further, the Delegation noted that almost all patent laws requested the full disclosure of the invention and that the non-full disclosure of the invention was considered a ground for the refusal or the revocation of a patent. Therefore, the Delegation stated that it was important to maintain absolute transparency around the patent granting procedure and legislation. The Delegation supported the statements made by the Delegations of Iran (Islamic Republic of) and India in that there should not be any more discussions on that agenda item within the SCP.

194. The Delegation of China thanked the Secretariat for preparing document SCP24/4 and the Member States that provided information contained in that document. The Delegation stated that that information would assist the SCP in understanding the issue. Noting that the confidentiality of communications between clients and their patent advisors was of certain value in terms of insuring the quality of legal services and the maintenance of the public interest, the Delegation, however, stated that the differences among countries with respect to the systems to maintain confidentiality of advice should be recognized. The Delegation stated that the issue was more closely linked to the basic litigation system adopted by countries. The Delegation noted that, in many countries there was no such mechanism, particularly in patent law. Therefore, the Delegation was of the view that the different legal traditions of each country should be respected, and that their national laws should be used in deciding on the issue.

195. The Delegation of the United Kingdom thanked the Secretariat for the compilation of court cases with respect to client-patent advisor privilege in document SCP/25/4, and stated that the information relating to the case law of the United Kingdom on the issue could be found on the WIPO webpage entitled “compilation of laws and practices regarding the scope of client attorney privilege and its applicability to patent advisors”.

196. The Delegation of the Republic of Korea expressed its full recognition of the importance of the client-patent advisor privilege, in particular, of its cross-border aspects. Therefore, the Delegation supported the continuation of the discussion on the topic during the SCP, including the preparation of comprehensive studies. The Delegation also supported exploring the possibilities of a non-binding soft law approach to address the issue.

197. The Delegation of the United States of America provided an update on some work the United States Patent and Trademark Office (USPTO) had been doing within its administrative authority. In particular, the Delegation stated that applying consistent approaches to protections granted to the confidential communications of different patent practitioners across borders remained an important topic for its country. The Delegation stated that, over the previous year, there had been renewed interest in making advances in that area, which would be beneficial to all users of the United States of America patent system. The Delegation informed the Committee that the USPTO was working on a proposed rule, which was published in the Federal Register on October 18, 2016, and that public comments on that proposed rule were due on December 19, 2016. The Delegation stated that those public comments would be considered in deciding how to proceed on the proposed rule. Further, the Delegation stated that client communications with lawyers

practicing in the United States of America were protected by attorney-client privilege. However, the USPTO rules did not clarify whether the privilege applies to client communications with patent practitioners who were not lawyers of the United States of America, but who were nonetheless authorized to practice in the United States of America or other jurisdictions, such as patent agents or foreign practitioners. The Delegation stated that the proposed rule would extend the privilege to communications with those practitioners for proceedings taking place within the Patent Trial and Appeal Board (PTAB), which was an administrative tribunal within the USPTO. Those proceedings would include *inter partes* reviews, post-grants, covered business method patent reviews and derivation proceedings, which were a form of opposition proceedings in the United States of America. The Delegation stated that, specifically, the proposed rule was intended to recognize that in connection with discovery conducted in certain proceedings at the USPTO, communications between the United States of America patent agents, or foreign patent practitioners and their clients, were privileged to the same extent as communicatio6ns between clients and United States of America attorneys. The term "foreign patent practitioner" is defined, under the proposed rule, as a person who is authorized to provide legal advice on patent matters, in a jurisdiction outside of the United States of America, provided that the jurisdiction has established professional qualifications, and that the practitioner is satisfying. The Delegation emphasized that it was important to remember that the proposed rule only affected PTAB, and would not affect how the United States of America Federal and State Courts handled the questions regarding privilege. However, the Delegation anticipated that it might spur other courts to consider revisions of their own rules, in light of the administrative changes. The Delegation also noted that it was a proposed rule, that a final rule might not be approved, and that if approved, it might be different from what was presently described.

198. The Delegation of Zambia aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group, and with the statement made by the Delegation of Iran (Islamic Republic of). The Delegation further stated that, in Zambia, protection of the patent attorney and client relationship was provided through common law, which was sufficient for the current purposes. The Delegation was of the view that at that stage, it was important for the SCP to leave each country administer the issue according to the provisions in its legal systems. Finally, the Delegation was also opposed to the continuation of further discussions on the topic during the SCP.

199. The Delegation of Japan expressed its sincere appreciation to the Secretariat for its efforts in preparing the document. The Delegation stated that its country supported the statement made by the Delegation of Turkey on behalf of Group B. The Delegation reiterated that communications between patent attorneys and their clients included information that clients absolutely felt needed to be treated as strictly confidential. The Delegation stated that that included, but was not limited to, legal opinions on the validity of patents, the scope of rights, and the existence, or not, of any infringements of patent rights. Therefore, the Delegation was of the view that appropriate protection of such information was essential to ensure honest and frank communications between patent attorneys and their clients. The Delegation continued that, as had been explained by using hypothetical cases during the 23rd session of the SCP, the Delegation was of the view that the issue of client-patent attorney privilege was not limited to domestic issues and there was a need to discuss the issue in terms of cross-border aspects as well. The Delegation informed the SCP that, in 1996, Japan had revised the Code of Civil Procedures clarifying when persons had the right to refuse submission of documents to courts. In other words, the Delegation explained, under the revised law, a person possessing documents containing technical or professional secrets, and a patent attorney who had come to know of such secrets during the course of their work, had the right to refuse submission of the documents. The Delegation further stated that, as mentioned in document SCP/25/4, since the legal revision had been made, the client-patent advisor privilege had been granted to patent attorneys in Japan. Nonetheless, considering the fact that corporate activities had become more

globalized, the Delegation was of the opinion that there was a need to establish a more stable client-patent advisor privilege worldwide. To achieve that, the Delegation continued, it was important for the SCP to continue discussions with a view to establishing a feasible framework, acceptable for the greatest number of countries, for protecting such privileges worldwide.

200. The Delegation of Switzerland expressed its wish for the Secretariat to continue the excellent work that it had been doing so far in providing the Member States with important documents and studies, including the preparation of document SCP24/5. The Delegation stated that the main purpose of the client-patent attorney privilege was to encourage transparent communications between patent attorneys and their clients. The Delegation explained that attorneys or advisors needed to know all of the relevant facts in order to be able to provide their clients with the appropriate legal advice, and that providing such quality advice encouraged the clients to make informed decisions and to conform her/his behavior with the law. The Delegation stated that that principle applied in general to all legal fields including that of intellectual property. The Delegation continued that the client-attorney privilege served and promoted the broader public interest, and that it directly supported the quality of the patent prosecution process and the quality of the patent that would be issued. The Delegation stated that clients and their advisors had to work closely to prepare and file accurate applications that complied with the requirements for patent granting. In addition, the Delegation stated that the patent advisor was the contact person for the intellectual property office for questions relating to non-compliance with the requirements, deficiencies or corrections related to a patent application. Further, the Delegation continued that the privilege allowed the free flow of information between clients and their advisors, and that a limited privilege impacted the possibility of obtaining quality legal advice. Noting that insufficient legal advice, however, led to a lack of quality of a patent, the Delegation stated that that had a direct impact on the patent system and its related purpose, including, amongst others, the technology transfer. The Delegation stated that despite the territoriality of intellectual property rights, patents were global, and that legal advice regarding a patent was often sought in various jurisdictions. The Delegation explained that in a cross-border environment, clients and their patent advisors faced several issues. In that regard, the Delegation stated that a number of documents produced by the Secretariat as well as the seminar that had been held during 21st session of the SCP had given a good overview of the problems at stake. In its opinion, such problems included the fact that due to different concepts of the privilege in common law countries and civil law countries, the rules for the protection of confidentiality of one system could not comply with those of the other. The Delegation continued that another question was the acknowledgment of a privilege for a foreign patent advisor. Specifically, the Delegation explained that because of the territoriality of patent rights, clients needed to seek advice from foreign patent advisors for the patent applications and patents filed in foreign countries. While the client and his advisor might be protected by a privilege in their own country, such a privilege might not be recognized in a foreign country. The Delegation further observed that other issues were the scope of the protection of confidentiality that might differ from one jurisdiction to another and the type of communication that was protected in the foreign jurisdiction. The Delegation noted that the last question, who would qualify as a patent advisor under the foreign law, raised other issues. Furthermore, the Delegation stated that the work done by the Committee had included studies, sharing sessions and seminars on the privilege and related issues, national and regional practices regarding the cross-border aspects of the privilege, possible remedies relating to the cross-border aspects, a compilation of laws and practices, and court cases regarding the privilege. Thus, noting that a wide range of information had been produced and exchanged on the topic, the Delegation expressed its belief that it was time to take a step forward. The Delegation stated that, during the 21st session of the SCP, it had proposed to work on a non-binding soft law as a solution to the cross-border aspect of the client-attorney privilege issue. The Delegation was of the view that such framework might serve as a template for national laws, and that it would provide a widely flexible approach

allowing Member States to adapt their national legislations according to their own legal backgrounds and needs. In that regard, the Delegation proposed that interested Member States enter into the discussion on the possible content of such a framework. The Delegation stated that their contribution could be compiled by the Secretariat into a document serving as a basis for further consideration.

201. The Delegation of Australia was of the view that free and frank communications between clients and attorneys were essential to produce good and clearly articulated patent applications. The Delegation stated that in the context of the global patent system, high quality professional representation would lead to well-drafted specifications, greater certainty in the validity of granted patents, and importantly, an increase in the quality of information disseminated to the public for the purpose of innovation. The Delegation supported working on studies and information gathering done by the Secretariat, with a view to finding out from Member States which limitations, or difficulties, they might encounter in a particular jurisdiction, in order to provide for a reciprocal client-attorney privilege. The Delegation noted that while Australia's legislative provisions gave foreign innovators who sought patent protection in Australia privilege in communications with their own patent attorneys and Australian patent attorneys, the reverse situation, i.e., where Australian innovators sought protection overseas, was less certain. The Delegation concluded that in the absence of similar rights in foreign jurisdictions, Australian clients could not be confident that their communications, even with their local attorneys in Australia, would be protected against disclosure in foreign court proceedings.

202. The Representative of the AIPPI stated that the issue under discussion was a key one, and was equally important to developed countries and developing countries. The Representative stated that, in particular, it was the cross-border aspect that posed problems. Noting the importance of the issue of confidentiality of communications to those who were working with patents, the Representative stated that in the absence of such confidentiality, the patent holder, or third party, might suffer significant consequences and prejudices. The Representative was of the view that a soft law would be a good compromise. In conclusion, the Representative stated that AIPPI had spoken during a seminar on the issue, organized in the previous session, had provided a number of documents to the Secretariat, and proposed that the discussions on the issue be continued at the SCP.

203. The Representative of APAA stated that APAA comprised professionals from both developed and developing countries, and was dedicated to promoting and enhancing intellectual property protection in Asia. The Representative stated that in 2008, APAA had adopted a resolution on patent attorney-client privilege, supporting and urging international consensus on setting minimum standards, or other remedies, against the forced disclosure of confidential communications between codified intellectual property professionals and their clients. Noting that the agenda item had been under discussion since the 12th session of the SCP, and that there was a different understanding among the Member States, the Representative stated that more time was needed to fully understand and apprehend the importance of the issue. Specifically, the Representative strongly supported studying the current situation in relation to both domestic and cross-border scenarios.

204. The Representative of CIPA stressed the importance of the confidentiality of communications between clients and their patent attorneys to the clients. He emphasized that the privilege belonged effectively to the clients and not to the benefit of the patent attorneys. With regards to the statement made by the Delegation of Iran (Islamic Republic of), the Representative wished to point out that the client-attorney privilege was normally provided for in the patent law of some countries. He stated, for example, that it was the case in Canada and the United Kingdom. In conclusion, the Representative stated that CIPA as well as EPI fully supported the statement made by the Delegation of Japan on that issue.

205. The Representative of JPAA emphasized the importance of maintaining discussions on the subject in the SCP. Specifically, the Representative stated that the issue had also been discussed in so-called “Group B+” meetings, but that the SCP was the only formal body handling substantive patent law internationally. The Representative continued that the issue was a very important one for the users, applicants, patent holders and representatives. The Representative noted that the interests of patent holders would be easily destroyed in infringement lawsuits if confidentiality between clients and patent lawyers was not guaranteed. Therefore, the Representative expressed strong support for the continuation of discussions on the issue during the SCP, in order to reach an international solution. He stated that the soft law approach would be appropriate.

206. The Representative of ICC supported the statements made by the Representative of AIPPI as well as the other representatives, and requested the continuation of discussions on the topic of confidentiality of communications between clients and the patent advisors within the SCP. In addition to the statements made by previous speakers, the Representative stated that the matter was of key importance also for the correct administration of justice.

AGENDA ITEM 10: TRANSFER OF TECHNOLOGY

207. The Delegation of Chile, speaking on behalf of GRULAC, stated that a sharing session on the relationship between patent systems and transfer of technology, especially the impact of sufficiency of disclosure on transfer of technology, would allow for Member States to highlight some of the central topics for knowledge sharing for developing countries. The Delegation expressed its hope that the SCP would study examples and cases in which disclosure made the technology transfer possible, as well as ways to make information available to the public. The Delegation was looking forward to the presentation by the Secretariat, because it was of the view that the topic would be one of the central elements in technology transfer.

208. The Delegation of Nigeria, speaking on behalf of the African Group, stated that technology transfer was a significant element for facilitating growth and advancement of the needs of developing countries and less developed countries. The Delegation recalled the request of its Group on that agenda item during the previous session of the SCP, and stated that it would appreciate the opportunity to discuss the possibility of launching a study assessing the role and relationship between patents and technology transfer.

209. The Delegation of Turkey, speaking on behalf of Group B, wished to reiterate the importance it attached to transfer of technology, and WIPO’s work in promoting and facilitating technology transfer, as well as capacity-building and training activities in that area. The Delegation expressed its strong belief that intellectual property had promoted technology transfer on voluntary and mutually agreed terms, and the wide dissemination of new technologies for the benefit of society as a whole. Furthermore, the Delegation highlighted that WIPO had been actively involved in a wide range of technology transfer-related activities that had benefited developing countries, less developed countries, as well as countries with economies currently in transition. The Delegation stated that document CDIP/17/9 demonstrated a wide variety of activities and services from capacity-building and participation in international meetings to legislative assistance, as well as research that had been undertaken by WIPO during 2014 and 2015. The Delegation continued that WIPO’s work on facilitating technology transfer had been discussed extensively during the CDIP. Specifically, the Delegation noted that the project on Intellectual Property and Technology Transfer: Common Challenges - Building Solutions, which had been started in 2011, was still ongoing. Further, the Delegation stated that at the previous session of the CDIP in November 2016, the Committee had discussed two proposals on technology transfer that had been presented within the framework of the Project on Intellectual Property and Technology Transfer. The Delegation stated that the

joint proposal by the Delegations of the United States of America, Australia and Canada which had focused on the concrete steps that the WIPO should undertake in order to ensure the sustainability of the results of the Project on Intellectual Property and Technology Transfer had been approved for the most part. Furthermore, the Delegation stated that the proposal made by the Delegation of South Africa had been supported, in principle, and that a revised version of the document would be presented during the following session of the CDIP in May 2017. Noting that WIPO continued its work on the WIPO Green, WIPO Re:Search and WIPO Match, the Delegation expressed its belief that concrete issues and activities relating to the role of the WIPO in technology transfer should be discussed during the CDIP sessions and not within the SCP. In the opinion of the Delegation, the CDIP was better equipped to handle concrete projects in order to avoid the duplication of the work. The Delegation reiterated that the concrete issues relating to the role of the WIPO in technology transfer should remain in the competency of the CDIP, as it did not wish to create duplication or prejudice the outcome of the discussions on that topic during the CDIP. Thus, the Delegation concluded that the SCP should not consider future work relating to technology transfer in general, and rather, that the CDIP should remain the only platform where technology transfer would be discussed.

210. The Delegation of Latvia, speaking on behalf of the CEBS Group, stated that the transfer of technology was an important factor in fostering development. Noting that the CDIP had completed a project on transfer of technology, and had finalized a mapping exercise demonstrating the role of WIPO in that area, the Delegation stated that any new activities under that agenda item should take into account the work carried out by the CDIP, and thus avoid duplication. The Delegation welcomed the sharing session on the relationship between patent systems and transfer of technology, as well as examples and cases to be presented by experts from different regions, with a view to further deepening the understanding of the impact of sufficiency of disclosure on transfer of technology.

211. The Delegation of Argentina supported the statement made by the Delegation of Chile on behalf of GRULAC, and stated that for Argentina, technology transfer was fundamental for a balanced patent system that would encourage the development of countries. The Delegation further stated that while the Member States' capacity to absorb and reproduce technology should be taken into account in the discussion of the issue of technology transfer, the patent system played an important role in technology transfer, the sufficiency of disclosure requirement being a key aspect in that issue. The Delegation noted the fact that patent applicants did not disclose all of the necessary technical information to reproduce the invention and that led to an imbalance in the system. The Delegation stated that that was also against Article 7 of the TRIPS Agreement which established that "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The Delegation expressed its belief that it was necessary to have a holistic view of intellectual property rights, which took into consideration the existent link between issues such as the sufficiency of disclosure requirement, technology transfer, and the cooperation between patent offices. The Delegation expressed its hope that the sharing session would allow them to better understand the impact of sufficiency of disclosure on technology transfer. The Delegation was of the view that the SCP should continue addressing the topic.

212. The Delegation of Brazil aligned itself with the statement made by the Delegation of Chile, on behalf of GRULAC. The Delegation stressed that the subject, which constituted a part of a balanced patent system and also part of the *quid pro quo* of the patent system, was very important. The Delegation stated that it was not by accident that the transfer of technologies was among the objectives of the TRIPS Agreement, as had been referred to by the Delegation of Argentina. The Delegation also noted that Article 8 of the TRIPS Agreement provided that the abuse of intellectual property rights by rights holders might

adversely affect international transfer of technology. Therefore, the Delegation considered that the subject was fully within the scope of the mandate of the SCP. Noting further that the transfer of technology was part of the Sustainable Development Goals, the Delegation stated that the technology facilitation mechanism, established by paragraph 70 of the Agenda 2030 for Sustainable Development, included the participation of WIPO, along with other United Nations agencies. In conclusion, the Delegation stated that it looked forward to the sharing session in order to gain more knowledge on the sufficiency of disclosure, from the perspective of other delegations.

213. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, stated that the European Union and its Member States were of the view that an excellent overview of the work that WIPO performed in the area of transfer of technology had been presented at the CDIP, when a discussion on the evaluation of the Project on Intellectual Property and Technology Transfer: Common Challenges - Building Solutions, had been held in April 2016. The Delegation emphasized that the SCP should avoid duplicating the efforts of the CDIP in that regard. The Delegation stated that it was committed to considering proposals to deepen its understanding of the impact of patent disclosure on transfer of technology, and as a concrete step, suggested updating the existing WIPO web page on technology transfer.

214. 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, and as in 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 the crucial part transfer of technology played in the proper functioning of the patent system. In conclusion, the Delegation reiterated that it attached great importance to that agenda item. 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.

215. 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.

216. The Delegation of Kenya aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group on transfer of technology.

217. The Delegation of Turkey stated that the sufficiency of the disclosure was one of the

core patentability requirements. It noted that in exchange for limited exclusive rights, the patent holder must disclose information necessary to make and use the invention. The Delegation stated that the disclosure environment allowed the patent system to facilitate dissemination of the information and access to technological knowledge contained in the patent application. In its opinion, that in turn expanded the pool of public knowledge, helped avoid duplicative research and development, and facilitated technology transfer. The Delegation stated that in that regard, the study on the sufficiency of disclosure (document SCP/22/4) presented to the 22nd session of the Committee was informative.

218. The Delegation of the United States of America stated that document SCP/22/4 provided an excellent overview of the similarities and differences of the way various offices evaluated the requirement of sufficiency of disclosure in patent applications. The Delegation stated that the disclosure provided by the applicant was a fundamental part of the patent system, which required a full enabling disclosure of the claimed technology, in exchange for the patentee receiving the exclusive rights conferred by the patent. The Delegation continued that disclosure allowed the public to learn about the most recent technical developments and freely use the technical learnings after the expiration of the patent. If an invention was not sufficiently disclosed, the public might not derive any of the benefits intended by the patent system. The Delegation further stated that from a patent examination point of view, if an invention was not sufficiently disclosed under the United States of America patent law, then a patent could not be granted. The Delegation believed that that was the case in most jurisdictions. The Delegation explained that, in its country, the two inquiries into whether an invention was sufficiently described and enabled were codified in Section 112(a) of Title 35 of the United States Code, and if those requirements were not met, a United States of America patent would not be granted. The Delegation noted that document SCP22/4 addressed the important question that arose when evaluating the requirements for enablement, namely the support claim and written description, and provided a very thorough analysis of those issues. In conclusion, the Delegation stated that in view of the work which had already taken place on the topic, it did not believe that additional work on sufficiency of disclosure was needed in the SCP. More generally, regarding work on technology transfer, the Delegation was of the view that it should take place in the CDIP.

219. The Delegation of India expressed its belief that the sufficiency of disclosure was the heart to the patent system under '*quid pro quo'.* The Delegation recalled that according to the objective of the TRIPS Agreement, the protection and enforcement of intellectual property rights should contribute to the transfer and dissemination of technology in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The Delegation reiterated the principle of the TRIPS Agreement that appropriate measures were needed to prevent abuse of international intellectual property rights by right holders or resort to practices which adversely affected the international transfer of technology. The Delegation was of the opinion that if the technology transfer, without the accompanying trade secrets, was not possible, the basic purpose of the patent system would be forfeited, and such inability of transforming inventions into commercial reality would pose a serious threat and challenge to the very purpose of the patent system. The Delegation stated that therefore, the sufficiency of disclosure in the patent specification was fundamental for technology transfer. The Delegation noted that in many instances, especially in the healthcare sector, a product could not be produced due to insufficient disclosure in patent specification. Thus, the Delegation wondered to what extent the patent system could contribute to the technology transfer as a stand-alone system, without the aid of accompanying trade secrets. The Delegation stated that the role of patent systems in the context of transfer of technology should be carefully studied in the background of sufficiency of disclosure.

220. The Representative of KEI stated that the non-disclosure agreements used in the United States of America in the context of providing the patent landscape for biological drugs impeded technology transfer to developing countries. While for many pharmaceutical drugs, the cost fell when patents expired because of low entry barriers, the Representative stated that, for biological drugs, there were often significant barriers to entry, based upon a lack of access to know-how, materials and trade secrets. Therefore, the Representative suggested that WIPO might want to develop standards for the disclosure of trade secrets and know-how relating to the manufacture of biological drugs and vaccines following the registration of the drugs. The Representative continued that such disclosure could be required at the time of registration or after a period following the registration. He also stated that access to materials might also be necessary. He further observed that there were many advantages of such a technology transfer: it would allow governments to respond to drug or vaccine shortages, such as those that had created health problems in 2010 to 2012 for patients with the Ebola disease, and more generally, would allow governments to exercise more power in the procurement, and prevent wasteful and ethically-challenging duplicative research. The Representative stated further that instead of being faced with several biosimilars, each one being expensive to test and register, governments could work with entities that co-manufacture the products in the same way that the originator did. He continued that outside of biological drugs, technology transfer was not uncommon and that the company with the most profitable drug in the history of the pharmaceutical industry had provided technology transfer to several generic drug manufacturers for both hepatitis and HIV products. The Representative also stated that there were some other large drug manufacturers which had provided licenses on a voluntary basis. Finally, the Representative mentioned that competition authorities would sometimes mandate the technology transfer in the context of merger reviews.

221. The Secretariat presented the WIPO webpage on transfer of technology.

222. The Delegation of Chile thanked the Secretariat for updating the website on the transfer of technology and asked if that website would be available in Spanish.

223. The Delegation of Zambia thanked the Secretariat for presenting the website on transfer of technology. The Delegation raised a specific technical question to the Secretariat regarding accessing the WIPO Research for Development and Innovation (ARDI) program.

224. The Delegation of Nigeria thanked the Secretariat for updating the website on the transfer of technology.

225. The Secretariat clarified that the website on the transfer of technology would be available in French and Spanish in the near future. Further and in response to the question raised by the Delegation of Zambia, the Secretariat provided information on accessing the services under the ARDI.

226. The Delegation of Chile stated that the guidelines for examination and registration on the INAPI website extensively dealt with the sufficiency of disclosure requirement and required the patent applicant to include a description and a full disclosure in order for the public to understand how the invention worked and to enable the reproduction of the invention. The Delegation pointed out that the guidelines required the patent specification to contain a description of the prior art, a description of the drawings and/or figures, an adequate and sufficient technical description of the invention and the technical problem that was solved, and at least one example of the invention so that a person skilled in the art could reproduce the invention without any inventive effort. The Delegation highlighted that INAPI was required by law, among others, to obtain, collect and classify patent information and facilitate access to that information with the aim of promoting the transfer of technology research and technological innovation in Chile. The Delegation continued that in order to

fulfill that mandate, INAPI had developed a series of publications and platforms. The Delegation referred to INAPI Conceta which was a freely available platform on which any holder of industrial property rights could publish information about his/her technology so that the technology could be used, transferred and exploited commercially. Further, the Delegation referred to INAPI Proyecta, a freely accessible platform, providing information about the use and management of industrial property and aiming to disseminate technologies in the public domain. The Delegation explained that the platform included tools to learn, use and transfer industrial property, as well as other customizable options that sought to establish a community around industrial property and a knowledge exchange environment for members associated with each thematic area. Further, the Delegation informed that INAPI had also started an initiative called "move your innovation to the industry", aimed at industrial property holders and providing knowledge and tools on the licensing of industrial property, in order to transfer an invention to the market. Furthermore, the Delegation reported that INAPI had started a television program to promote industrial property to mass audiences. The television program described 24 Chilean inventors and their inventions.

227. The Delegation of Brazil stated that according to the Delegation's view, the SCP had a relevant role to play on the transfer of technology. Further, the Delegation stated that patent rights affected the transfer of technology and therefore a very important aspect was the adequate disclosure of the invention in patent applications, as the applicant received in return for the disclosure of his or her invention a limited monopoly, which would become available to the public, after expiration of the patent. The Delegation affirmed that this objective encouraged innovation. The Delegation reported that the Brazilian patent office offered services for interested stakeholders which helped to disseminate information contained in patent applications. Further, the Brazilian patent office supported users in the search of documents in the national patent database. The Delegation expressed that the adequate disclosure of inventions in patents was a fundamental requirement for improving the capacity of the national industry. The Delegation noted that according to its experience, the reproduction of inventions often relied on tacit knowledge that often was not even contained in a patent. The Delegation concluded that the patent system had to provide adequate tools to insure the dissemination of precursor information that served for stimulating innovation. The Delegation further stated that industries might face difficulties for the successful transfer of technology when acquiring foreign technology, as the industries might not be able to fully determine the technology and would not be able to decide which technologies the other party would be required to provide. The Delegation noted that in the context of transfer of technology, other obstacles were the definition of the background of the invention, the technical assistance to be provided after conclusion of the transfer of technology, and the know-how that was often not disclosed in patent applications. The Delegation stated that such obstacles should be further explored by the SCP. The Delegation highlighted that the necessity of strengthening innovations in developing countries in order to fight extreme poverty and social exclusion was contained in the United Nations Sustainable Development Goals, and that since the WIPO and its Member States had reached a consensual agreement in that matter, they should act immediately.

228. The Delegation of the United States of America acknowledged that one important aspect of the transfer of technology was to allow universities and research institutions to make their discoveries available in the marketplace so that society could benefit from them. Those institutions were able to play a very important role in moving forward technology in innumerable fields through the licensing of their discoveries. The Delegation associated itself with statements made by a group of universities stating essentially that a strong patent system was what allowed universities and related technology transfer organizations to transmit the knowledge and innovations they produce for the public good and broader societal benefit. The Delegation noted that in the United States of America, the Bayh-Dole Act allowed universities to hold title to intellectual property derived from federally-funded

research. It explained that prior to the enactment of the Bayh-Dole Act, the United States of America government had held patent rights to inventions derived from federally-funded research, and therefore, university inventions had failed to attract investments from private companies and fewer technologies had become available to society. The Delegation pointed out that it did not agree with the view that patenting university research limited access to academic discoveries and obstructed follow-on innovations. The Delegation underscored that the patent system of the United States of America required full disclosure of innovations, and federal funding agencies required grantees to make peer-reviewed manuscripts and data publicly available at no cost. Further, the Delegation noted that it had become clear that if patent rights were restricted, innovators would rely more and more on trade secrets and other forms of secrecy resulting in fewer open disclosures becoming available to the public, and consequently hindering the flow of knowledge. The Delegation explained that the law of the United States of America provided different checks and balances to insure that patents did not impede further research, such as the safe harbor for patent infringement for people working to obtain FDA approval of a drug or a medical device. The Delegation pointed out that it strongly believed that allowing universities to hold title to intellectual property derived from federally-funded research, with mechanisms such as the Bayh-Dole Act, was essential in fostering the flow of new technologies to society.

229. The Delegation of the Republic of Trinidad and Tobago thanked the Secretariat for updating the website on technology transfer and stated that its government, according to its patent law, was obliged to provide patent information services not just for inventors but also for those seeking technical information from patent documents. The Delegation informed that the government of the Republic of Trinidad and Tobago offered a so-called “patent mining course” to train staff working in research institutions how to use the various patent databases. Further, the Delegation mentioned that the public health service of the Republic of Trinidad and Tobago offered a so-called “chronic disease services program” to access affordable medicines. The patent office of the Republic of Trinidad and Tobago provided input to that program by providing information on the legal status of various drugs and carrying out freedom to operate searches. The Delegation informed that that information helped importers determine which medicines could be legally imported.

230. The Delegation of China thanked the Secretariat for the presentation, and expressed its hope that the Member States would provide content for the website on the transfer of technology. The Delegation believed that such a website helped to know and understand the opportunities and challenges of Member States in promoting global technology innovation and progress. The Delegation further expected that the SCP would further study the relationship between patent systems and the transfer of technology. The Delegation noted that the SCP should examine the difficulties that developing countries face in regards to sufficiency of disclosure, and should share information and experiences of the Member States to promote the transfer of technology.

231. The Delegation of Zambia expressed its gratitude to the Secretariat for updating the SCP website on the transfer of technology.

AGENDA ITEM 11: PROPOSAL OF LATIN AMERICA AND THE CARIBBEAN (GRULAC) GROUP OF COUNTRIES ON THE REVISION OF THE 1979 WIPO MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS

232. Discussions were based on document SCP/22/5.

233. The Delegation of Chile, speaking on behalf of GRULAC, stated that its proposal in document SCP/22/5 had received several reactions from other delegations. Taking the exchange of views held in various sessions of the Committee into consideration, the Delegation proposed that the review process be carried out not on the basis of the

negotiation of the terms of reference nor by modalities to be approved by the Committee, but that the revision of the 1979 WIPO Model Law for Developing Countries on Inventions be a request directly addressed to the Secretariat.

234. The Delegation of Iran (Islamic Republic of) stated that it supported the proposal by GRULAC to review the 1979 WIPO Model Law for Developing Countries.

235. The Delegation of Indonesia aligned itself with the proposal by GRULAC to revise the 1979 WIPO Model Law. The Delegation stated that it would support the suggestion that the Secretariat should prepare a revision of the 1979 WIPO Model Law for Developing Countries.

236. The Delegation of China aligned itself with the proposal on the revision of the 1979 WIPO Model Law for Developing Countries brought forward by GRULAC.

AGENDA ITEM 12: FUTURE WORK

237. The Delegation of Chile, speaking on behalf of GRULAC, recalled the topics of patents and health, transfer of technology, and exceptions and limitations for the future work. Further, the Delegation highlighted the proposal made in document SCP/14/7.

238. The Delegation of Turkey, speaking on behalf of Group B, reserved its right to make an intervention on the subsequent day, as it had not had time to discuss the issue.

239. The Delegation of Slovakia, speaking on behalf of the European Union and its Member States, reserved its right to make an intervention on the subsequent day, as it had to coordinate within the group.

240. The Delegation of China stated that it hoped to accommodate all topics mentioned by the other delegations into the future work of the SCP.

241. The Delegation of the United States of America stated that the future work of the SCP should cover, amongst others, the following topics: the proposal by the Delegation of the United States of America contained in document SCP/17/11 with regard to patents and health, and the proposals by the Delegation of the United States of America with regards to quality of patents and work sharing, in particular those contained in the documents SCP/17/10, SCP/1/4, SCP/20/11 and SCP/23/4. Further, the Delegation referred to its previous proposal to carry out a study analyzing whether work sharing helped patent offices carry out searches for chemical patent applications, in particular with regard to INNs.

242. The Delegation of Nigeria, speaking on behalf of the African Group, stated that it had made its proposal for future work in the statements and interventions made during the week. It expressed its hope that the Chair and the Secretariat would take them into account.

243. The Delegation of India, referring to the revised proposal by GRULAC on the revision of the WIPO Model Law, stated that it reserved its comment on that issue.

244. The Delegation of Indonesia expressed its wish that all of its statements during the week be reflected in the future work, and reserved its right to come back under that agenda item during the subsequent day.

245. The Representative of the CIS stressed that in future meetings, the topics of standardizations in telecommunications as well as patents for hardware and software should be included, as mobile communications were important in developing countries. He added that mobile phones were, in many cases, the only way to access the Internet. The

Representative referred to a study in which CIS found that all patents in India in relation with mobile phones were owned by non-Indian entities. The Representative stated that rising prices in the telecoms sector should not hinder access to affordable hardware.

246. The Representative of KEI pointed out that in his opinion, the proposal made by the Delegation of the United States of America, contained in document SCP/17/11, was not useful.

247. The Delegation of Japan aligned itself with the proposal by the Delegation of Spain contained in document SCP/24/3, and that of the Delegation of the United States of America, contained in document SCP/17/11.

248. After some consultations conducted by the Chair, the Committee decided on its future work, as agreed during its twenty-fourth session, as follows:

Quality of Patents, including Opposition Systems

- Based on the responses to the questionnaire referred to in document SCP/24/5, paragraph 17, Quality of Patents, including Opposition Systems, first bullet point, the Secretariat will submit a compilation of gathered information.

Patents and Health

- The Secretariat will prepare a study, as referred to in document SCP/24/5, paragraph 17, Patents and Health, second bullet point.

249. Following a proposal by the Chair, the Committee agreed to carry on discussions at its next session on the basis of the topics contained in the agenda of its twenty-fifth session, except for agenda item 2, in document SCP/25/1 Prov. Member States may submit proposals on the work of the Committee prior to its next session.

AGENDA ITEM 13: SUMMARY BY THE CHAIR

250. The Chair introduced the Summary by the Chair (document SCP/25/5 Prov.)

251. Some delegations stated that the Summary by the Chair should explicitly reflect the fact that the Committee was not able to agree on its future work.

252. Consequently, the Chair noted that the chapeau of the first paragraph under agenda item 12 should read “Failing agreement otherwise, the Committee decided its future work as agreed at its twenty-fourth session, as follows:”.

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

254. 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 14: CLOSING OF THE SESSION

255. The Delegation of India, speaking on behalf of the Asia and Pacific Group, noted that while the 25th session of the SCP was the last meeting of the year at WIPO, and incidentally also the last meeting for the Delegation as a regional coordinator of the Asia and the Pacific

Group, it was having mixed emotions: emotions of satisfaction tinted by some disappointment. The Delegation stated that its Group had made a specific suggestion regarding the United Nations High-Level Panel Report, which had explored specific policy incoherencies between intellectual property, trade, and human rights, and that some of its recommendations were specifically addressed to WIPO. In its opinion, the Report should be presented, and exploratory discussions should take place in the Committee, about access to medicines and the role that intellectual property played in that regard. The Delegation stated that the Committee was not able to agree on the future work, as some members had serious concerns, and did not want even a reference to that Report on future work. The Delegation stressed that its Group attached a great deal of importance to the work of the Committee. The Delegation therefore urged all of the SCP members to find common ground where they could work together, for the overall benefit of the Organization. The Delegation expressed its thanks to the members of the Asia and Pacific Group for the support they had provided to the Delegation as a regional coordinator, and also to the other regional coordinators for the mutually respectful relationship they shared, even if when they had not been able to agree on various issues. The Delegation informed the Committee that the new regional coordinator of its Group would be Indonesia, and expressed its hope that the new coordinator would be able to reach consensus. The Delegation concluded its closing remark by thanking the Secretariat for its hard work and the excellent preparation they had done in view of the meetings, the hard working interpreters, and the Chair.

256. The Delegation of Nigeria, speaking on behalf of the African Group and with reference to future work, reiterated that the African Group placed its priority on the subject of patents and health, in particular the patent constraints to accessing safe, affordable and sustainable medicines and essential medicines, and more generally, healthcare technology. The Delegation noted that the African Group, at the previous session, had put forward a proposal that had encompassed those issues, including the topic of antimicrobial resistance, which had been estimated that it would be the predominant cause of death, over cancer, by 2050. In that regard, the African Group had been baffled by the resistance of many developed countries to not hold that important discussion within the SCP, which was related to facilitating access to medical technologies for developing and least developed countries. Being aware of the fact that the pharmaceutical industry was one of the top three global enterprises, along with the oil and gas companies and banks, and that pharmaceutical companies were not charitable organizations, the Delegation expressed its understanding that they needed to be driven by incentive. Nevertheless, in the context of life and death situations, the Delegation expressed its hope that Member States would reflect further on the importance of that issue and the impact it had for developing and least developed countries, which were at the brunt of the lack of access to the essential medicines needed to improve healthcare. In its opinion, no one should be left behind, as had been recognized by the Sustainable Development Goals. In addition, the Delegation took the opportunity to thank the Delegation of India, with whom it had worked well during a number of sessions, and looked forward to working with the new coordinator from Indonesia.

257. The Delegation of Chile, speaking on behalf of GRULAC, expressed its appreciation to the Chair for her efforts and to the Secretariat for their support during the discussions, particularly in the attempt to come up with a future work program. The Delegation noted that while it had been ready to work as had proposed the Chair, unfortunately, the Committee had been unable to do so. The Delegation stated that GRULAC found the questions of exceptions and limitations to patent rights, patents and health and transfer of technology particular important for the Group. The Delegation expressed its hope that, at its subsequent session, the Committee would be able to agree on matters upon which it would pursue its work, together with the issues that had already been determined during the previous meeting. On the revision of the 1979 WIPO Model Law for Developing Countries, the Delegation expressed its appreciation for the support it had received from various regional groups, and for the consideration given to the alternative proposal it had made during the

25th session. In its view, the interest generated by the initial proposal showed the importance that developing countries placed in the technical assistance provided by WIPO and the tools and legal models used in that exercise. Recognizing the different views within the Committee, the Delegation stated that it would continue to analyze those issues at future meetings. Finally, the Delegation expressed its thanks to the Secretariat, the interpreters and translators, the other delegations and most particularly, the members of its Group, the other regional coordinators, for their commitment and their work, not only during the meeting but throughout the past six months. The Delegation announced that it was its last meeting as a coordinator for GRULAC, and expressed its appreciation for the support it had received.

258. The Delegation of Latvia, speaking on behalf of the CEBS Group, thanked the Chair for her tremendous efforts and the Secretariat for their continuous support on the question of the future work. While the CEBS Group regretted that the Committee was not able to reach an agreement, it expressed its hope that during the subsequent SCP session, the Committee would be able to find a middle ground on all the topics. As the present SCP session was its last meeting as a regional coordinator, the Delegation thanked the members of its Group for their support, and the other regional coordinators for their excellent cooperation.

259. The Delegation of Turkey, speaking on behalf of Group B, thanked the Chair and Vice Chairs for, inter alia, drafting the proposal on the future work. It stated that Group B had wanted to have agreed on future work and had shown, in the spirit of compromise, great flexibility. The Delegation, however, explained that the second revised proposal by the Chair had not reflected the concerns of Group B, which had been reflected in the interventions during the week, as well as in its position expressed in the previous sessions. The Delegation noted that, although it had considered the revised proposal in a constructive matter, the Group continued to not be in agreement with the Chair's proposal. Regarding the Model Law, the Delegation reiterated that while Group B thanked GRULAC for its efforts in submitting a revised proposal, the proposal was under "other issues" on the agenda. The Delegation expressed appreciation to the other regional coordinators, the Secretariat, the interpreters and the Member States.

260. The Delegation of China thanked the Chair and the Secretariat for their efforts in leading and assisting the meeting, particularly during the discussion on future work. In its opinion, the Chair had tried to strike a balance between the interests of all parties through both versions of future work proposals. The Delegation recognized that the agenda item of patents and health had always been a difficult one. On the one hand, the Delegation considered that the Committee was lucky enough that the 24th session of the SCP had laid a good foundation to make certain progress after the 25th session. On the other hand, the Delegation regretted that the Committee had not made any advancement on future work. The Delegation therefore reiterated that all delegations should show flexibility in order for the Committee to make progress on the agenda item. The Delegation noted that the 26th session that would be held in spring 2017 should garner better results.

261. The Representative of the European Commission thanked the Chair, Vice Chairs and the Secretariat for the excellent chairing and organization. The Representative regretted that it had not been possible to reach agreement on future work. It noted that the European Union would have liked to have a discussion on the contribution of innovation to the improvement of global public health, at a future session of the SCP. Referring to the statement made by the Delegation of Nigeria speaking on behalf of the African Group, the Representative noted that the AMR issue was of foremost concern for the European Union, since 25,000 people died each year from an infection due to AMR-resistant bacteria in the European Union. He explained that infections due to selected multidrug-resistant bacteria resulted in extra healthcare costs and productivity losses amounting to 1.5 billion each year, and that if the current trend was not altered, 300 million people worldwide were expected to die prematurely because of drug resistance over the subsequent 35 years. The

Representative observed that since it was an important global, economic and societal challenge that could not be tackled by any country or public administration alone, solving the problem required a comprehensive approach, i.e., a holistic multi-sectoral approach involving food, health, bio safety, environment research, bio-innovation, animal health and welfare, as well as non-therapeutic uses of antimicrobial substances. The Representative further noted that the European Union had already invested 150 million Euros over the last few years in research and development, and that it would continue to do so in the future.

262. The Delegation of Indonesia stated that it attached great importance to the topics of exceptions and limitations to patent rights, patents and health and transfer of technology. Regarding patents and health, noting that the Delegation had drawn the attention of the Committee to the Report of the United Nations High-Level Panel on Access to Medicines, it reiterated that the Committee should discuss that Report, because there were recommendations in it that were clearly making a reference to WIPO. In its view, countries needed to have a public health-sensitive intellectual property roles and mechanisms that would help address the misalignment between profit-driven innovation models and public health priorities. The Delegation stated that, while the Delegation of Turkey speaking on behalf of Group B, had mentioned they had been flexible and constructive with the second draft of the Chair's proposal, it had also been very constructive and flexible with the second draft. The Delegation thanked the Chair for drafting the future work suggestions that had already reflected a balance between all of the different interests, and expressed its deep regrets for not being able to reach an agreement on future work. The Delegation reiterated that the issue of public health and patents was very important one, not only for its country but for all of the members of the Committee, and invited all members to rethink their positions. Listening to the closing statement made by the Representative of the European Commission, the Delegation was of the view that whilst he recognized the issue, he did not want to do anything about it in the Committee. In its opinion, it had not heard any good explanation on why there was resistance when discussing the issue during the SCP. The Delegation nevertheless thanked all Member States and regional coordinators for the constructive discussions that had been held throughout the session. The Delegation was cautiously optimistic that the Committee would build consensus and agree on future work in a future session. While acknowledging the fact that the issues facing the Committee were challenging, the Delegation stated that it was important to constantly remind themselves that the SCP had been created to serve as a forum to discuss issues, facilitate coordination and provide guidance regarding the international development of patents by dealing with clusters of interlocking issues rather than by working in isolation on single issues. In its opinion, that was why WIPO's mission was to lead the development of a balanced and effective international intellectual property system that enabled innovation and creativity for the benefit of all, including development objectives that constituted an important factor for a balanced and effective international intellectual property system. In conclusion, the Delegation thanked the Chair and Vice Chairs for their leadership and guidance, and the Secretariat and interpreters for their hard work and efforts.

263. The Delegation of South Africa aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation thanked the Chair for her efforts over the last several days. The Delegation stated that it was baffled by the resistance of some developed countries to discuss issues that clearly fell within the spectra of the Committee. In its opinion, it was very important that the Committee continued to discuss problems identified in the patent system, particularly where such problems threatened to violate the integrity and legitimacy of the system, patent rights and related duties. The Delegation noted that since the Report of the United Nations Secretary General's High-Level Panel on Access to Medicines had identified such problems, it deserved to be discussed during the SCP at the least. Otherwise, in its view, the Committee

would be abrogating its duties. The Delegation considered that the failure to reach consensus on future work, particularly on patents and health, was a loss especially for developing and least developed countries that continued to grapple with such issues as the lack of access to essential, life-saving medicines, which had resulted in senseless deaths.

264. The Delegation of Egypt thanked the Chair for leading the work of the Committee in such a brilliant manner. The Delegation also expressed its appreciation to the Secretariat for their efforts to prepare all documents, and to the interpreters, particularly the Arabic interpreters, for their hard work. The Delegation regretted that it had not been possible to come to an agreement, particularly with regard to the issue of access to medicines and transfer of technology. In its opinion, certain delegations took certain pretexts since the explanations, given the fact that the non-access to medicines seemed to be a logical one and had convinced many.

265. The Delegation of Brazil supported the statement made by the Delegation of Chile on behalf of GRULAC. It expressed its appreciation to the Delegation of Chile, especially to the regional coordinator for her hard work coordinating GRULAC, and wished well to the other regional coordinators departing their positions. The Delegation regretted that no agreement could be reached on future work. In particular, the Delegation expressed its great concern on the opposition made by certain delegations in the discussion on patents and health, as access to medicine was a challenge for all countries – least developed, developing or developed. The Delegation noted that recent developments within international fora pointed to the necessity to continue to follow those discussions and to explore new ways of overcoming barriers to access to health. It indicated that those recent developments include, among others, the United Nations Sustainable Development Goals and the United Nations High-Level Panel. In its opinion, it was only natural that those discussions took place in the SCP, which was a relevant forum for multilateral discussions on patents. The Delegation expressed its hope that more constructive spirit would be shown by delegations in future sessions. With regard to exceptions and limitations, the Delegation thanked the support received from regional groups and delegations on the third phase of its proposal, as contained in document SCP/14/7. The Delegation stated that the majority of members of the Committee were in favor of the development of an exceptions and limitations manual, in a non-exhaustive manner which would serve as a reference to WIPO Member States. Considering the fact that the Member States were at different stages of development and had different national interests, the Delegation was convinced that they would all benefit from having additional inputs on the flexibilities available to countries in order to use policy space provided under the multilateral framework. The Delegation expressed its hope that an agreement could be reached in the subsequent session. Lastly, the Delegation thanked the Chair, Vice Chairs, Secretariat and interpreters for their hard work during the week. It recognized the Chair's great efforts to try to find common ground accommodating the different positions of the delegations, and in its opinion, she had created a very balanced proposal.

266. The Delegation of Nigeria noted that it was pleased to see the Chair re-elected. It also thanked the Vice Chairs and the Secretariat for their hard work during the week. The Delegation regretted that the Committee could not reach an agreement on future work during the 25th session of the SCP. Nevertheless, it remained optimistic for a better session, a more fruitful session of the SCP, in a subsequent session. The Delegation also thanked the delegates who were leaving their position coordinating a regional group.

267. 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. In that regard, the Delegation considered that the Report of the United Nations Secretary General's High-Level Panel on Access to Medicines was of most significance. The Delegation regretted that the Committee could not reach consensus on future work, in particular with

regard to the said Report. The Delegation noted that it would keep its fingers crossed to see constructive and substantive discussions on that Report in a future session of the Committee, because the SCP was the only global forum where patent matters related to health were discussed. The Delegation expressed its appreciation to its regional coordinator, the Delegation of India, for its hard work, and welcomed its new coordinator, the Delegation of Indonesia, which had full support and confidence from the Delegation.

268. The Delegation of Chile thanked the Chair for her efforts in leading the session and the delegations that participated in the discussions throughout the week. The Delegation expressed its support to the statement made by its Delegation on behalf of GRULAC. The Delegation recalled that, as it had stated in its opening remarks, it attached the greatest importance to patents and health, and regretted that it had not been possible to reach an agreement on future work on that issue because the pertinence of the debate had even been questioned. In its opinion, the SCP had a lot to contribute to the discussions in other fora in terms of its expertise on addressing the issues between patents and health. It presumed that if the Committee decided to withdraw from such discussions, it would give other fora the possibility of discussing such a link between those two, since the issue was of great interest to many delegations. As a result, the Delegation stated that those discussions would continue without the invaluable contribution of WIPO and without participation of the SCP members. Therefore, the Delegation stressed the importance of continued discussions in the SCP, and of reflecting the various differing positions on that issue.

269. The Delegation of Uganda aligned itself with the statement made by the Delegation of Nigeria on behalf of the African Group. The Delegation reiterated that the new global challenges to public health, including pandemics that could affect different parts of the world and all countries whether rich or poor, demanded a shared, coordinated and cooperative international response. The Delegation noted that 193 Member States of the United Nations had acknowledged, without reservation, that transforming the world would require concerted efforts by all stakeholders, including governments, NGOs, independent consultants and the private sector working together through all modalities. Consequently, the United Nations Secretary General had established a High-Level Panel on Access to Medicines. The Delegation stated that whereas the establishment of the Panel had not been a member-driven process, there was a precedent in the Committee and WIPO, where a study that had not been commissioned by Member States, for example, a joint study by the WHO, WTO and WIPO, had been discussed. Therefore, the Delegation was of the view that it was not appropriate to say that because the Panel had not been established through a member-driven process, its recommendations could not be discussed. The Delegation reiterated that it placed great importance on the issue of patents and health. It explained that the proposal by the African Group on that issue was intended to ensure access to affordable and essential medicines to all, most importantly to poor children and women in the remotest parts of the world, including those in war ravaged countries.

270. The Delegation of Sudan thanked the Chair, Vice Chairs and Secretariat for their tireless efforts. It aligned itself with the statement delivered by the Delegation of Nigeria on behalf of the African Group. The Delegation regretted that the Committee did not reach an agreement regarding future work of the SCP, and echoed the statement delivered by the Delegation of South Africa.

271. The Delegation of Japan appreciated the efforts made by the Chair to assist the Committee to seek the possibility of a common ground on future work. The Delegation also thanked the Secretariat for its valuable efforts. The Delegation was pleased that during its 25th session, the Committee had seen useful presentations, which had enabled delegations better understand substantive issues. The Delegation, however, expressed its regret that the

Committee was not able to reach a consensus on future work. In its view, for the functioning Committee, a comprehensive approach and balanced future work were necessary. The Delegation hoped that a good outcome would be achieved at the subsequent session of the SCP.

272. The Delegation of Slovakia thanked the Chair for the efforts she had put into the Committee and for drafting the future work. The Delegation expressed its regret that a consensus on future work had not been reached. The Delegation, however, hoped that at the subsequent session, the Committee would be able to find a common ground. Since the 25th session was the last session and last committee under the Slovak Presidency of the European Union, the Delegation thanked its colleagues from the European Union for their support and cooperation and for all other Member States, especially the European Union Member States, for being so well prepared for the various WIPO committees, as well as the regional coordinators.

273. The Secretariat expressed its thanks to the attending delegations for their appreciation. Noting that the delegations had worked hard and diligently toward an outcome that unfortunately had eluded the Committee, the Secretariat shared the regrets of all delegations that the SCP had not been able to reach an agreement on a future work program for the subsequent meetings. Nevertheless, the Secretariat noted that for most of the world, the end of one year and the beginning of another year was a time for pause and reflection, and also for hope. Therefore, the Secretariat shared the hope expressed by the delegations that when the Committee would reconvene in June 2017, it would find a way to overcome the present difficulties, and that the Committee could continue to perform its important function and role in WIPO. The Secretariat thanked the Chair who had been carrying out the most difficult job during a number of sessions. It noted that the Chair was determined and diligent, and that it was a pleasure for the Secretariat to support her.

274. The Chair stated that she had been optimistic at the beginning of the 25th session of the SCP, as delegations would not repeat the experience they had had in December 2015. She therefore had been confident that there would have been flexibility for agreeing on its common future. The Chair noted that it had not turned out to be exactly what she had hoped for and the Committee had unfortunately repeated the same experience. The Chair expressed its hope that the Committee would have the wisdom to find a common dream in spring 2017, because otherwise, the Committee would not be able to continue its work. The Chair considered that the Committee had been successful in the sense that valuable information had been exchanged among high-level specialists. The Chair thanked the Vice Chair who had replaced her the previous day and had done an excellent job. She then expressed her appreciation to the regional coordinators, to those delegates who had accompanied the regional coordinators during the informal consultations, to all the other delegates, the Secretariat and the interpreters. The Chair then closed the session.

275. *The Committee unanimously adopted this report at its twenty-sixth session on July 3, 2017.*

[Annex follows]

LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

I. MEMBRES/MEMBERS

AFRIQUE DU SUD/SOUTH AFRICA

Tilana GROBBELAAR (Ms.), Deputy Director, Directorate Multilateral Trade Relations, Department of International Relations and Cooperation, Pretoria

Trod Moyahabo LEHONG, Registrar, Patents and Design Register, Companies and Intellectual Property Commission (CIPC), Pretoria

ALGÉRIE/ALGERIA

Fayssal ALLEK, premier secrétaire, Mission permanente, Genève

ALLEMAGNE/GERMANY

Pamela WILLE (Ms.), Counsellor, Economic Affairs Division, Permanent Mission, Geneva

ANGOLA

Alberto Samy GUIMARÃES, Second Secretary, Permanent Mission, Geneva

ARGENTINE/ARGENTINA

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

María Inés RODRÍGUEZ (Sra.), Consejera, Misión Permanente, Ginebra

AUSTRALIE/AUSTRALIA

George VUCKOVIC, General Manager, Patents Mechanical and Oppositions Group, IP Australia, Canberra

Felicity HAMMOND (Ms.), First Secretary, Permanent Mission, Geneva

BAHAMAS

Bernadette BUTLER (Ms.), Minister Counsellor, Permanent Mission, Geneva

BÉLARUS/BELARUS

Tatsiana KAVALEUSKAYA (Ms.), Head, Department of Law and International Treaties, National Center of Intellectual Property (NCIP), Minsk

BELGIQUE/BELGIUM

Sandrine PLATTEAU (Ms.), First Secretary, Permanent Mission, Geneva

BOLIVIE (ÉTAT PLURINATIONAL DE)/BOLIVIA (PLURINATIONAL STATE OF)

Genoveva Trinidad CAMPOS DE MAZZONE (Sra.), Consejera, Misión Permanente, Ginebra

BRÉSIL/BRAZIL

Flavia ELIAS TRIGUEIRO (Ms.), Head, Division of Pharmaceuticals Patents, Directorate of Patents, National Institute of Industrial Property, Ministry of Development, Industry and Foreign Trade (INPI), Rio de Janeiro

Caue OLIVEIRA FANHA, Secretary, Permanent Mission, Geneva

BULGARIE/BULGARIA

Rakovski LASHEV, Ambassador, Deputy Permanent Representative, Permanent Mission, Geneva

CAMBODGE/CAMBODIA

PHE Chantravuta, Director, Department of Industrial Property (DIP), Ministry of Industry and Handicraft (MIH), Phnom Penh

CAMEROUN/CAMEROON

Boubakar LIKIBY, secrétaire permanent, Comité national de développement des technologies, Ministère de la recherche scientifique et de l'innovation, Yaoundé

Edwige Christelle NAAMBOW ANABA (Mme), expert, Comité national de développement des technologies, Yaoundé

Bastos BAZLNA, ingénieur d'études, Service des brevets et des signes distinctifs, Ministère des mines, de l'industrie et du développement technologique, Yaoundé

CANADA

Cary SEIPP, Senior Trade Policy Officer, Intellectual Property Trade Policy Division, Global Affairs Canada, Ottawa

Mark KOHRAS, Policy Analyst, Marketplace Framework Policy Branch, Innovation, Science and Economic Development, Ottawa

CHILI/CHILE

Felipe FERREIRA, Asesor Legal, Dirección General de Relaciones Económicas Internacionales, Departamento de Propiedad Intelectual, Ministerio de Relaciones Exteriores, Santiago de Chile

Rogelio CAMPUSANO SAEZ, Secretario Abogado, Subdirección de Patentes, Instituto Nacional de Propiedad Industrial (INAPI), Ministerio de Economía, Santiago de Chile

Marcela PAIVA (Sra.), Consejera, Misión Permanente, Ginebra

CHINE/CHINA

HU Anqi (Ms.), Deputy Division Director, Legal Affairs Department, State Intellectual Property Office (SIPO), Beijing

LIU Kai, Program Administrator, International Cooperation Department, State Intellectual Property Office (SIPO), Beijing

WANG Wei, Program Administrator, International Cooperation Department, State Intellectual Property Office (SIPO), Beijing

CHYPRE/CYPRUS

Andreas IGNATIOU, Ambassador, Permanent Representative, Permanent Mission, Geneva

Demetris SAMUEL, Counselor, Deputy Permanent Representative, Permanent Mission, Geneva

Christina TSENTA (Ms.), Second Secretary, Permanent Mission, Geneva

COLOMBIE/COLOMBIA

Beatriz LONDOÑO SOTO (Sra.), Embajadora, Representante Permanente, Misión Permanente, Ginebra

Juan Carlos GONZÁLEZ, Embajador, Representante Permanente, Misión Permanente de Colombia ante la OMC, Ginebra

José Luis LONDOÑO FERNÁNDEZ, Superintendente Delegado para la Propiedad Industrial,
Superintendencia de Industria y Comercio, Ministerio de Comercio, Industria y Turismo, Bogotá D.C.

José Luis SALAZAR LÓPEZ, Director de Nuevas Creaciones, Superintendencia de Industria y Comercio, Ministerio de Comercio, Industria y Turismo, Bogotá D.C.

Juan Camilo SARETZKI FORERO, Consejero, Misión Permanente, Ginebra

Manuel CHACON, Consejero Comercial, Misión Permanente de Colombia ante la OMC, Ginebra

CONGO

Bernard MBEMBA, conseiller, Mission permanente, Genève

COSTA RICA

Jonathan BONILLA CÓRDOBA, Junta Administrativa, Registro Nacional, Ministerio de Justicia y Paz, San José

Karen QUESADA (Sra.), Jefe, Oficina de Patentes, Registro de Propiedad Industrial, Ministerio de Justicia y Paz, San José

CÔTE D'IVOIRE

Alexis KOUAME, sous-directeur en charge des brevets d'invention, Office ivoirien de la propriété intellectuelle (OIPI), Abidjan

Kumou MANKONGA, premier secrétaire chargé des questions de l'OMPI, Mission permanente, Genève

DANEMARK/DENMARK

Mette Wiuff KORSHOLM (Ms.), Legal Advisor, Danish Patent and Trademark Office, Ministry of Business and Growth, Taastrup

EL SALVADOR

Diana HASBUN (Sra.), Ministra Consejera, Misión Permanente, Geneva

ÉMIRATS ARABES UNIS/UNITED ARAB EMIRATES

Khalfan AL SUWAIDI, Director, Industrial Property Department, Ministry of Economy, Abu Dhabi

Ali AL HOSANI, Under Secretary Assistant, Intellectual Property Sector, Ministry of Economy, Abu Dhabi

ÉQUATEUR/ECUADOR

Ñusta MALDONADO (Sra.), Tercer Secretario, Misión Pemanente, Ginebra

ESPAGNE/SPAIN

Leopoldo BELDA SORIANO, Jefe de Area de Patentes de Mecánica General y Construcción, Oficina Española de Patentes y Marcas, Ministerio de Energía y Turismo, Madrid

Beatriz PÉREZ ESTEBAN (Sra.), Jefe de Servicio de Patentes Químicas II (Biotecnología y Alimentación), Ministerio de Economía, Industria y Competitividad, Madrid

Oriol ESCALAS NOLLA, Primer Secretario, Misión Pemanente, Asuntos Exteriores y Cooperación, Ginebra

ESTONIE/ESTONIA

Raul KARTUS, Advisor, Patent Department, Estonian Patent Office, Tallinn

Veikko MONTONEN, Second Secretary, Permanent Mission, Geneva

ÉTATS-UNIS D'AMÉRIQUE/UNITED STATES OF AMERICA

Richard COLE, Deputy Director, International Patent Legal Administration, United States Patent and Trademark Office (USPTO), Alexandria, Virginia

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

Jesus HERNANDEZ, Patent Attorney, Office of Policy and International Affairs, United States Department of Commerce, United States Patent and Trademark Office (USPTO), Alexandria, Virginia

Yasmine FULENA (Ms.), IP Assistant, Economic and Science Affairs, Permanent Mission, Geneva

FÉDÉRATION DE RUSSIE/RUSSIAN FEDERATION

Olga ALEKSEEVA (Ms.), Deputy Director, Federal Institute of Industrial Property, Rospatent, Moscow

Victoria GALKOVSKAYA (Ms.), Head of Division, Law Department, Federal Institute of Industrial Property, Rospatent, Moscow

FINLANDE/FINLAND

Marjo AALTO-SETÄLÄ (Ms.), Chief Legal Counsel, Patents and Trademarks, Finnish Patent and Registration Office, Helsinki

Riitta LARJA (Ms.), Head of Unit, Patents and Trademarks, Finnish Patent and Registration Office, Helsinki

FRANCE

Jonathan WITT, chargé de mission, Département des brevets, Institut national de la propriété industrielle (INPI), Courbevoie

Indira LEMONT SPIRE (Mme), conseillère juridique, Affaires juridiques et internationales, Institut national de la propriété industrielle (INPI), Courbevoie

Francis GUÉNON, conseiller, Mission permanente, Genève

GABON

Marianne Odette BIBALOU BOUNDA (Mme), ambassadeur, représentant permanent, Mission permanente, Genève

Edwige KOUMBY MISSAMBO (Mme), premier conseiller, Mission permanente, Genève

GÉORGIE/GEORGIA

Temuri PIPIA, First Secretary, Permanent Mission, Geneva

GHANA

Alexander BEN-ACQUAAH, Minister Counsellor, Permanent Mission, Geneva

Joseph OWUSU-ANSAH, First Secretary, Permanent Mission, Geneva

GRÈCE/GREECE

Myrto LAMBROU MAURER (Ms.), Head, Department of International Affairs, Industrial Property Organization (OBI), Athens

GUATEMALA

Flor de María GARCÍA DIAZ (Sra.), Consejera, Misión Permanente, Ginebra

HONGRIE/HUNGARY

Laszlo Adam VASS, Legal Officer, Industrial Property Law Section, Hungarian Intellectual Property Office (HIPO), Budapest

INDE/INDIA

Paul VIRANDER, Ambassador, Deputy Permanent Representative, Permanent Mission, Geneva

Sumit SETH, First Secretary, Permanent Mission, Geneva

Srinivas RACHABATTUNI, Deputy Controller, Patents and Designs, Ministry of Commerce and Industry, Tamilnadu

INDONÉSIE/INDONESIA

Rahma IRYANTI (Ms.), Deputy Minister, Deputy of Demography and Labor, Ministry of National Development Planning, Jakarta

Erry Wahyu PRASETYO, Third Secretary, Permanent Mission, Geneva

Mercy MARVEL, Directorate of Patent, Directorate General of Industrial Property Rights. Ministry of Law and Human Rights, Jakarta

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

Reza DEHGHANI, First Secretary, Permanent Mission, Geneva

Alireza SADEGHI GHADI, Examiner and IP Expert, Industrial Property General Office, State Organization for Registration of Deeds and Properties of Iran, Tehran

IRLANDE/IRELAND

Michael LYDON, Head of Patent Examination, Department of Jobs, Enterprise and Innovation, Irish Patents Office, Kilkenny

ISRAËL/ISRAEL

Dan ZAFRIR, Advisor, Permanent Mission, Geneva

Judith GALILEE-METZER (Ms.), Counselor, Permanent Mission, Geneva

ITALIE/ITALY

Matteo EVANGELISTA, First Secretary, Permanent Mission, Geneva

Alessandro MANDANICI, First Secretary, Permanent Mission, Geneva

Ivana PUGLIESE (Ms.), Senior Patent Examiner, National and European Patent - International Applications, Directorate General for the Fight Against Counterfeiting, Italian Patent and Trademark Office, Ministry of Economic Development, Rome

Carlo FAVARETTO, Intern, Permanent Mission, Geneva

JAPON/JAPAN

Tatsuo TAKESHIGE, Director, International Policy Division, Policy Planning and Coordination Department, Japan Patent Office (JPO), Tokyo

Yuki TAKEUCHI, Assistant Director, International Policy Division, Policy Planning and Coordination Department, Japan Patent Office (JPO), Tokyo

JORDANIE/JORDAN

Zain AL AWAMLEH, Director, Industrial Property Protection Directorate, Ministry of Industry and Trade, Amman

KENYA

Cleophas OJODE, Patent Examiner, Patent Department, Kenya Industrial Property Institute (KIPI), Ministry of Industry, Trade and Cooperatives, Nairobi

LETTONIE/LATVIA

Janis KARKLINS, Ambassador, Permanent Representative, Permanent Mission, Geneva

Liene GRIKE (Ms.), Advisor, Economic and Intellectual Property Affairs, Permanent Mission, Geneva

LITUANIE/LITHUANIA

Zilvinas DANYS, Deputy Director, State Patent Bureau, Vilnius

MALAWI

Loudon Overson MATTIYA, Minister Counsellor, Deputy Permanent Representative, Permanent Mission, Geneva

MALTE/MALTA

Edward GRIMA BALDACCHINO, Attaché, Intellectual Property, Permanent Mission, Geneva

MAROC/MOROCCO

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

Mohamed Reda OUDGHIRI IDRISSI, conseiller, Mission permanente, Genève

MEXIQUE/MEXICO

Jorge LOMÓNACO, Embajador, Representante Permanente, Misión Permanente, Ginebra

Juan Raúl HEREDIA ACOSTA, Embajador, Representante Permanente Alterno, Misión Permanente, Ginebra

María Del Pilar ESCOBAR BAUTISTA (Sra.), Consejera, Misión Permanente, Ginebra

Ricardo GALLEGOS MATHEY, Jefe, Asuntos Multilaterales, Divisional de Relaciones Internacionales, Instituto Mexicano de la Propiedad Industrial (IMPI), Ciudad de México

Federico SAAVEDRA, Asistente, Misión Permanente, Ginebra

MONACO

Gilles REALINI, premier secrétaire, Mission permanente, Genève

NIGÉRIA/NIGERIA

Peters S.O. EMUZE, Chargé d'Affaires ad Interim, Permanent Mission, Geneva

Chichi UMESI (Ms.), First Secretary, Permanent Mission, Geneva

Nkiru Felicia OBIEKII (Ms.), Senior Assistant Registrar, Trademarks, Patents and Designs Registry, Commercial Law Department, Federal Ministry of Industry Trade and Investment, Abuja

NORVÈGE/NORWAY

Ingrid MAURITZEN (Ms.), Head, Legal Section, Patent Department, Norwegian Industrial Property Office (NIPO), Oslo

OUGANDA/UGANDA

George TEBAGANA, Third Secretary, Permanent Mission, Geneva

OUZBÉKISTAN/UZBEKISTAN

Sevara KARIMOVA (Ms.), Head, Invention Department, Agency on Intellectual Property of the Republic of Uzbekistan, Tashkent

PAKISTAN

Tehmina JANJUA (Ms.), Ambassador, Permanent Representative, Permanent Mission, Geneva

Aamar Aftab QURESHI, Deputy Permanent Representative, Permanent Mission, Geneva

Mariam SAEED (Ms.), First Secretary, Permanent Mission, Geneva

PÉROU/PERU

Luis MAYAUTE, Ministro Consejero, Misión Permanente, Ginebra

Manuel Javier CASTRO CALDERÓN, Director, Invenciones y Nuevas Tecnologias, Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (INDECOPI), Lima

PHILIPPINES

Epifanio EVASCO, Director, Bureau of Patents, Intellectual Property Office of the Philippines (IPOPHIL), Taguig City

Jayroma BAYOTAS (Ms.), Attachée, Permanent Mission, Geneva

Arnel TALISAYON, First Secretary, Permanent Mission, Geneva

POLOGNE/POLAND

Grażyna LACHOWICZ (Ms.), Advisor to the President, Cabinet of the President, Patent Office, Warsaw

Wojciech PIATKOWSKI, Minister Counsellor, Permanent Mission, Geneva

PORTUGAL

Ana BANDEIRA (Ms.), Director, Trademarks and Patents Directorate, National Institute of Industrial Property (INPI), Ministry of Justice, Lisbon

João PINA DE MORAIS, First Secretary, Permanent Mission, Geneva

RÉPUBLIQUE DE CORÉE/REPUBLIC OF KOREA

YANG Woongchul, Deputy Director, Patent System Administration Division, Korean Intellectual Property Office (KIPO), Daejeon

CHOI Cho (Ms.), Deputy Director, International Legal Affairs Division, Ministry of Justice, Seoul

JUNG Daesoon, Intellectual Property Attaché, Permanent Mission, Geneva

YI Chihyun, Prosecutor, Department of Criminal Case, Central District Prosecutor's Office, Seoul

LIM Sangmin (Ms.), Judge Panel, Busan High Court, Busan

JONG Myong Hak, Counsellor, Permanent Mission, Geneva

RÉPUBLIQUE DE MOLDOVA/REPUBLIC OF MOLDOVA

Diana STICI (Ms.), Head, Legal Department, State Agency on Intellectual Property (AGEPI), Chisinau

RÉPUBLIQUE DOMINICAINE/DOMINICAN REPUBLIC

Ysset ROMAN (Ms.), Minister Counselor, Permanent Mission, Geneva

Luisa CASTILLO DE ESPINAL (Ms.), Director, Department of Inventions, National Office of Industrial Property (ONAPI), Santo Domingo

RÉPUBLIQUE TCHÈQUE/CZECH REPUBLIC

Lucie ZAMYKALOVA (Ms.), Desk Officer, Patent Law Related Issues, International Department, Industrial Property Office, Prague

ROUMANIE/ROMANIA

Bucura IONESCU (Ms.), Director General, State Office for Inventions and Trademarks (OSIM), Bucharest

Anca DEACONU (Ms.), Director, Patent Directorate, State Office for Inventions and Trademarks (OSIM), Bucharest

Adela CONSTANTINESCU (Ms.), Pharmaceutical Chemistry, State Office for Inventions and Trademarks (OSIM), Bucharest

ROYAUME-UNI/UNITED KINGDOM

Nicholas SMITH, Senior Policy Advisor, Intellectual Property Office (UKIPO), Newport

Walter JAN, Senior Policy Advisor, International Policy Directorate, Intellectual Property Office (UKIPO), Geneva

Michael SHERLOCK, International Institutions and Strategy, Intellectual Property Office (UKIPO), Newport

Virgil SCOTT, Legal Advisor, Intellectual Property Office (UKIPO), Cardiff

SAINT-SIÈGE/HOLY SEE

Carlo Maria MARENGHI, Attaché, Permanent Mission, Geneva

SÉNÉGAL/SENEGAL

Lamine Ka MBAYE, premier secrétaire, Mission permanente, Genève

SERBIE/SERBIA

Aleksandra MIHAILOVIC (Ms.), Head, Department for Legal Issues of Patents, Patent Sector, Intellectual Property Office, Belgrade

SINGAPOUR/SINGAPORE

Alfred YIP, Director, Registries of Patents, Designs and Plant Varieties Protection, Intellectual Property Office (IPOS), Singapore

Mei Hui CHAN (Ms.), Trademark Examiner, Intellectual Property Office (IPOS), Singapore

SLOVAQUIE/SLOVAKIA

Emil ZATKULIAK, First Secretary, Permanent Representation to the European Union in Brussels

Jakub SLOVÁK, Third Secretary, Permanent Mission, Geneva

SOUDAN/SUDAN

Hadeya Zeyada Abdalla TAHA, Legal Advisor, Registrar General of Intellectual Property, Ministry of Justice, Khartoum

SRI LANKA

Kumudu Bandara TENNEKOON, Secretary, Ministry of Industry and Commerce, Pitakotte

Aryasinha RAVINATHA, Ambassador, Permanent Representative, Permanent Mission, Geneva

Dilini GUNASEKERA (Ms.), Second Secretary, Permanent Mission, Geneva

Shashika SOMARATNE (Ms.), Counsellor, Permanent Mission, Geneva

SUÈDE/SWEDEN

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

Lisa SELLGREN (Ms.), Senior Patent Examiner, Swedish Patent and Registration Office (SPRO), Ministry of Justice, Stockholm

SUISSE/SWITZERLAND

Beatrice STIRNER (Mme), conseillère juridique, Division droit et affaires internationales, Institut fédéral de la propriété intellectuelle (IPI), Berne

Alebe LINHARES MESQUITA, stagiaire, Division droit et affaires internationales, Institut fédéral de la propriété intellectuelle (IPI), Berne

Reynald VEILLARD, conseiller, Mission permanente, Genève

THAÏLANDE/THAILAND

Taksaorn SOMBOONSUB (Ms.), Senior Legal Officer, Department of Intellectual Property (DIP), Ministry of Commerce, Nonthaburi

TRINITÉ-ET-TOBAGO/TRINIDAD AND TOBAGO

Richard ACHING, Manager, Technical Examination, Intellectual Property Office, Ministry of Legal Affairs, Port of Spain

TUNISIE/TUNISIA

Nafaa BOUTITI, directeur adjoint, Département de la propriété industrielle, Institut national de la normalisation et de la propriété industrielle (INORPI), Ministère de l'industrie, Tunis

Nasreddine NAOUALI, conseiller, Mission permanente, Genève

TURQUIE/TURKEY

Serkan ÖZKAN, Patent Examiner, Turkish Patent Institute, Ministry of Science, Industry and Technology, Ankara

Ceren BORA ORÇUN (Ms.), Junior Patent Examiner, Turkish Patent Institute, Ministry of Science, Industry and Technology, Ankara

Osman GOKTURK, Second Secretary, Permanent Mission, Geneva

UKRAINE

Anatolii GORNISEVYCH, Director, Development in Intellectual Property, State Intellectual Property Service of Ukraine, Ukrainian Intellectual Property Institute (Ukrpatent), Kyiv

Mariia VASYLENKO (Ms.), Head, Department of Methodology of the Law Intellectual Property, State Intellectual Property Service of Ukraine, Ukrainian Intellectual Property Institute (Ukrpatent), Kyiv

YÉMEN/YEMEN

Hussein Taher Ahmed AL-ASHWAL, Third Secretary, Permanent Mission, Geneva

ZAMBIE/ZAMBIA

Peter Chewe CHILUFYA, Examiner, Patents and Designs, Patents and Companies Registration Agency, Ministry of Commerce, Trade and Industry, Lusaka

II. OBSERVATEUR/OBSERVER

PALESTINE

Ali THOUQAN, Registrar of Patents and Trademarks, Ramallah

Ibrahim MUSA, Counsellor, Permanent Observer Mission, Geneva

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Bing HAN (Ms.), Research Fellow, Geneva

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ORGANISATION DES NATIONS UNIES (ONU)/UNITED NATIONS (UN)

Christoph SPENNEMANN, Legal Officer and Officer-in-Charge, Intellectual Property Unit, Division on Investment and Enterprise, United Nations Conference on Trade and Development (UNCTAD), Geneva

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Alessia VOLPE (Ms.), Coordinator, International Cooperation, Munich

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Xiaoping WU (Ms.), Counsellor, IP Division, Geneva

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Satoru DENO, JPAA International Activities Center, Tokyo

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

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Greg PERRY, Executive Director, Geneva
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Third World Network Berhad (TWN)
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Aida DOLOTBAEVA (Mlle/Ms.), juriste, Section du droit des brevets/Legal Officer,
Patent Law Section

Atif BHATTI, juriste adjoint, Section du droit des brevets/Associate Legal Officer,
Patent Law Section

Daria NOVOZHILKINA (Mlle/Ms.), stagiaire, Section du droit des brevets/Intern, Patent Law Section

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