



Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 1-2 MARCH 2017

Chairperson: Ambassador Alfredo Suescum (Panama)

Addendum

The present document contains the statements made during the Council for TRIPS meetings held on 1-2 March 2017.

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\* A record of statements as delivered in the formal session of the Council. Some statements have been lightly edited as appropriate to ensure the consistency of presentation.

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## **AGENDA ITEM 1: ELECTION OF CHAIRPERSON**

### **1.1 United States**

1. On behalf of the United States, we are happy to agree to the appointment of Ambassador Suescum to serve as our interim Chair of the meeting of the Council. Thank you Ambassador for your willingness to step in and serve in this important role. However, we wish to signal the concern of the United States with the unfortunate developments that have left the General Council unable to agree on a slate of Chairs for WTO Councils and Committees this year. As a Member that is dedicated to the effective and improved functioning of our WTO committee structures, it is a matter of considerable concern to the United States that we find ourselves unable to succeed in whatever most basic tasks as Members, the selection of Chairs.

2. Again we thank Ambassador Suescum for making himself available, and we hope that the Organization as a whole can quickly move towards a satisfactory resolution of the current destructive standoff over chairmanships. The United States looks forward to working with the interim Chairman on promoting our common objective ensuring that the TRIPS Council is a productive, constructive body where we engage in discussion of relevant IPR issues.

## **AGENDA ITEM 2: NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT**

### **2.1 WTO Secretariat**

3. Under Article 63.2. of the Agreement, the Council has received the following notifications:

- From China, the revised Trademark Law and the revised Regulations for its implementation;
- From Montenegro, amendments to the Law on Copyright and Related Rights, to the Law on Trademarks, to the Law on Legal Protection of Industrial Design, and to the Law on Protection of Topographies of Semiconductors;
- From Ecuador, the consolidated Intellectual Property Act and its Implementing Regulations, the Law on Books, the Publication of a Certified Copy of UPOV 1978, an Amendment to Resolution No. 003 on Patent Fees, the Instructions for the Grant of Compulsory Licences for Pharmaceutical Patents, the Declaration of Public Interest Regarding Access to Medicines for Human Use, a Regulation Establishing the Ecuador Country Brand Licensing Procedure, and a number of other laws and regulations;
- From Greece, an amendment to the Law on Reinforcement and Development of Film Art and Other Provisions, a Law implementing certain EU Directives in the field of copyright and amending the Law on Copyright, Related Rights and Other Cultural Issues, an amendment to the Presidential Decree in application of the Act Revising the Convention on the Grant of European Patents, a Ministerial Decision regarding the Electronic Distribution of Documents to and from the Industrial Property Organization and Electronic Filing of Industrial Design or Model Registration, an amendment to provisions in Law 3377/2055 dealing with counterfeit goods, and a Presidential Decree setting out the administrative process of imposing fines to collecting societies and collective protection societies;
- From Mexico, a Decree Amending, Adding and Repealing Certain Provisions of the Regulations under the Industrial Property Law (IP/N/1/MEX/I/12); and
- From Japan, the Act on the Protection of the Names of Specific Agricultural, Forestry and Fishery Products and Foodstuffs and the Amendment of the Act.

4. These notifications are referred to on the revised agenda for this meeting. They are available in the IP/N/1- series of documents, and the actual texts of laws are on the Documents Online database.

5. Since the distribution of the revised agenda the delegation of Switzerland has also notified an update of the list of laws and regulations in force dealing with intellectual property and legislative

amendments that have been made since May 2013. These notifications will also be made available to Members in this series of documents IP/N/1- as quickly as possible.

6. Also, Saint Kitts and Nevis has notified its initial responses to the Checklist of Issues on Enforcement.<sup>1</sup> No other initial responses or updates to earlier responses have been submitted since our last meeting.

7. Finally, Benin has submitted information regarding contact points under Article 69 for the exchange of information and cooperation on trade in infringing goods.<sup>2</sup> The information on the Members' transparency toolkit page has been updated accordingly.

## **2.2 Switzerland**

8. I would like to thank the Secretariat for informing the Council about the recent update of our notification in accordance with Article 63.2 of the TRIPS Agreement.

9. This update concerns the period since our last notification in and up to 2012 and covers amendments in the field of TRIPS relevant Swiss IP legislation in force on the 1 January 2017. We won't impose on the Council a lengthy presentation of the notified changes. A short description of every notified amendment is contained in the written document submitted to the WTO Secretariat.

10. Two developments in the Swiss IP framework since 2012 might nevertheless be worthwhile to be shortly mentioned. On one hand, this concerns the establishment of a specialized Federal Patent Court competent for patent litigation at first instance, which replaces the 26 cantonal courts. In the new Patent Court, proceedings and pre-trial procedural acts may be conducted in English.

11. Further, the amendment of the national legislation regulating in more detail the use of the indication of source "Swiss", of the Swiss cross and of the Swiss coat of arms on goods and services which entered into force on 1 January 2017. This set of new legislation provided also a new register for geographical indications for non-agricultural products.

12. For more details on our notification, we refer Members to the document notified and we thank the WTO Secretariat for editing and circulating the documents among the Membership.

## **2.3 Ecuador**

13. As explained by my delegation at the TRIPS Council meeting in November last year, Ecuador has submitted to the WTO Central Registry of Notifications the notification of various intellectual property laws and regulations, in accordance with Article 63.2 of the TRIPS Agreement.

14. Fifteen notifications were submitted on various intellectual property related laws, regulations and decrees, the details of which are described in the documents listed on the agenda. The notifications most worthy of note were undoubtedly those referring to amendments made to the Intellectual Property Act and the Regulations thereto, which establish a set of standards and rules issued by the competent authority to improve the enforcement and implementation of the Act; and the amendments to the Law on Books, which declares literary creation and the production, publication and distribution of books, considered key means of strengthening national identity, to be of national interest.

15. Also notified is the Decree providing that access to medicines used for the treatment of diseases affecting the Ecuadorian population is a matter of public interest, and that compulsory licences may accordingly be issued on patents of such drugs for human use as are needed for their treatment.

16. These notifications on intellectual property bring Ecuador up to date as regards the fulfilment of its commitments.

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<sup>1</sup> Circulated in document IP/N/6/KNA/1.

<sup>2</sup> Circulated in document IP/N/3/BEN/1.

## 2.4 China

17. The revised Trademark Law entered into force on 1 May 2014. It is the third revision to the Trademark Law since it was first adopted in 1982. This revision aims to facilitate the trademark registration, promote a fair and competitive market and strengthen the protection on trademark rights.

18. Among others, it specifies the following rules:

- enriching elements applicable for trademark registration, for example sound;
- offering opportunities for applicants to explain or correct their filed application;
- allowing applicants to apply for registration of the same trademark for multiple types of goods in one application;
- improving the objection procedure and the protection on well-known trademarks;
- providing a heavier punishment if a party has committed trademark infringement on two or more occasions within five years or falls under any other serious circumstances;
- increasing the amount of compensation for damages caused by infringement of trademark rights.

19. According to the amendments to the Trademark law, the regulations for the implementation of the trademark law were so amended.

## 2.5 Montenegro

20. Thank you for giving me the opportunity to present the latest Montenegrin Intellectual Property legislation submitted to the WTO and the Members on 13 December 2016. During 2016, Montenegro adopted Amendments to the Law on Copyright and Related Rights, to the Law on Trademarks, to the Law on Legal Protection of Industrial Design, and to the Law on Protection of Topographies of Semiconductors. The primary objective of these amendments was further strengthening of the protection of intellectual property rights in Montenegro, as well as fulfilment of the obligations in the process of accession of Montenegro to the European Union, through harmonisations and alignment with the European Union legislation and relevant international standards.

21. The following is a short description of the amendments which entered into force in 2016. The most important novelties in the law on the amendment to the Law on Copyright and Related Rights are regulating issues related to the issues of child labour and orphan works, increasing terms of protection of the rights of phonogram producers from 50 to 70 years, more detailed regulations *sui generis* rights of makers of databases and introducing community exhaustion of rights from the rights of the accession of Montenegro to the European Union. This law determines strict restrictions on the use of orphan works, the end of orphan works status and the issue of fair compensation for their use. The law also prescribes collective management of rights on voluntary basis with extended effect, as well as granting multi territorial licences for online rights in musical works. The law prescribes the possibility for a right holder, whose copyright or related rights has been infringed to file a claim requesting an injunction against an intermediary whose services was used by a third party on infringing his or her right.

22. The most important novelties in the Law on Amendments the Law on Trademarks are in more detailed regulations of the inspection supervision procedures in case of infringement of rights, extension of validity to the territory of Montenegro of community trademark applications and community trademarks from the date of accession of Montenegro the European Union and introducing community exhaustion of rights from the date of accession of Montenegro to the European Union. The law prescribes that licence agreement, the transfer of trademark, the pledge and the levy of execution produce the legal effect against a third parties after entry into the register.

23. Finally, the Law on Amendments to the Law on Legal Protection of Industrial Design describes in detail inspection supervision procedures in the case of infringement of rights. This law extends

validity to the territory of Montenegro of community design applications and community designs from the date of accession of Montenegro to the European Union and introduces community exhaustion applies from the date of accession of Montenegro to the EU. Procedure for declaration of invalidity of industrial design has also been described. Lastly, the Law on Amendments to the Law on Protection of Topographies of Semiconductors describes the misdemeanours for violation of topography introduces community exhaustion of price from the date of access of Montenegro to the European Union and specifies the component inspections supervision authority.

24. Montenegro is fully dedicated to the implementation of this important amendments and further improvements of legislative and institutional framework for the protection of intellectual property rights. In addition, Montenegro intends to further strengthen cooperation regarding the respect of all intellectual property rights, since this is one of the conditions for effective enforcement of IP rights.

## **2.6 Mexico**

25. We would like to thank the Secretariat for the ongoing work and efforts they have deployed with regards to Members notifications. Mexico, in compliance with its obligations on notifications, has submitted to the Council the recent amendments which have been made to the regulation on the industrial property law. These can found in document IP/N/1/MEX/I/2. Modifications or amendments here, amongst other aspects, refer to the periods of time and provisions which relate to the submission and processing of requests submitted to the Mexican Institute of Industrial Property, in the name of simplifying and expediting these procedures.

## **2.7 Japan**

26. This delegation is pleased to inform the Council that Japan enacted the Act on Protection of the Names of Specific Agricultural, Forestry and Fishery Products and Foodstuffs of 2014. The Act entered into force in June 2015. This has been notified to this Council in accordance with Article 63.2. The reference number of this document is IP/N/1/JPN/G/2. The purpose of this Act was to establish a sui generis system to protect geographical indications based on the TRIPS Agreement. It is designed to ensure producers profit, develop agricultural forestry and fishery industries and protect the interests of consumers.

27. The main points of the GI Act are as follows:

28. First, the Act establishes procedures such as a three-month opposition period so that GIs can be registered in a transparent manner. It also provides transparent rules conforming to the TRIPS Agreement. In particular, if applications to register GIs contain product names that are generic, or are identical with or similar to registered trademarks, the applications shall be rejected.

29. Second, Japan's GI Act provides the same level of protection as in TRIPS Article 23 to the registered GIs. Third, administrative actions are able to protect registered GIs from infringements.

30. This delegation is also pleased to inform the Council that Japan amended the GI Act in December 2016. This revision has been notified to this Council in accordance with Article 63.2. The reference number of the document is IP/N/1/JPN/G/3.

31. The Act was amended to realize the protection of geographical indications of agricultural products through an international agreement. The basic procedures and the level of protection is essentially the same as under the existing direct application system. The Government of Japan is committed to continue to fulfil its obligation to ensure the accessibility and the transparency of the Japanese intellectual property system.

## **AGENDA ITEM 3: REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION**

### **Agenda Item 3.1 Follow-up to reviews already undertaken**

#### **3.1 Switzerland**

32. Switzerland would like to thank the delegation of St Kitts and Nevis for engaging in an active and constructive manner in the review process, and for the work carried out. We appreciate the

written responses received to the questions and have reviewed them. We consider the review procedure to be an important element to ensure consistency and transparency of the WTO legal system and its implementation in national legislation. We do not have further questions to St Kitts and Nevis at present.

### **3.2 Canada**

33. Canada would like to take this opportunity to thank St Kitts and Nevis for its communication of 19 December 2016 responding to questions posed by Japan, Canada, Switzerland, the United States and the European Union as contained in document IP/C/W/623. Canada would also like to acknowledge St Kitts and Nevis' continued efforts in implementing its obligations under the TRIPS Agreement in domestic legislation, and note our appreciation for the recent updates on this process under this agenda item of the TRIPS Council. In particular, we note the ongoing legislative review of the Government of St Kitts and Nevis, notably in respect of copyright protection, and look forward to any updates that St Kitts and Nevis may be able to share on this topic in the future as the review process continues. Canada continues to review the responses to our questions, gratefully received from St Kitts and Nevis, and will communicate any follow-up questions if necessary before the next meeting of the TRIPS Council.

### **Agenda Item 3.2 Review of the national implementing legislation of Seychelles**

#### **3.3 Seychelles**

34. The delegation of Seychelles would like to take this opportunity to thank all Members for their consideration of our TRIPS legislations. After Seychelles had notified its TRIPS related legislation to WTO in 2016, Members were invited to submit any questions they may have on these legislation. In November 2016, Seychelles received questions from Switzerland focusing on patent and the protection of undisclosed information which is covered under the Industrial Property Act, 2014 and on provisional measures and enforcement of IP laws which is catered for under the Copyright Act, 2014, the Industrial Property Act, 2014 and Customs Management (Border Measures) Regulation, 2014. The latter regulation deals with the treatment of goods deemed to be "counterfeit", "pirated" and "infringing", at the border. The questions submitted were already catered for under our current legislations.

35. The delegation of Seychelles would like to take this opportunity to inform the TRIPS Council that the Government of Seychelles had undergone a complete overhaul of the IP regime, during its accession process, with a view to modernise the old regime and bringing it into full conformity with the requirements of the TRIPS Agreement. This was done with the assistance of WIPO and the WTO Secretariat. However, we continue to review our IP regime and the relevant regulations to ensure that implementation of these legislations are in conformity to the TRIPS Agreement. Finally, the delegation of Seychelles would like to take this opportunity to thank the respective organisations for their kind assistance during this process.

#### **3.4 Switzerland**

36. We would like to thank the delegation of Seychelles for its presentation and for the responses to our questions and also for the effort put into the process of answering them. We have received and reviewed the responses and do not have follow-up questions for the time being. Switzerland would get back to the delegation of the Seychelles bilaterally if need be.

### **Agenda Item 3.3 Review of the national implementing legislation of Kazakhstan**

#### **3.5 Kazakhstan**

37. Kazakhstan became a Member to the WTO in November 2015, and in its obligations, Kazakhstan agreed to fully apply the provisions of the TRIPS Agreement from the date of accession to the WTO without recourse to any transitional period. However, during the process of its accession to the WTO, Kazakhstan already ensured full compliance of its legislation with commitments undertaken in accordance with the TRIPS Agreement and the Protocol on Accession of Kazakhstan to the WTO.



38. At the present moment, Kazakhstan has submitted around 30 notifications that describe our intellectual property systems in detail. We would like to thank Switzerland for the attention paid to Kazakhstan's intellectual property systems, and questions that were raised by their delegation during the review process. We are also grateful to the WTO Secretariat for their support and help provided during this process. Kazakhstan has submitted responses to the questions raised by Switzerland in February 2016, special attention was paid to the issues on patents, protection of undisclosed information, provisional measures and enforcement of intellectual property rights. Our detailed responses to the questions of Switzerland can be found in the relevant documents submitted to the WTO Secretariat.

39. After our accession to the WTO, Kazakhstan continues its efforts on further improvement of the legislation in the field of intellectual property. The Minister of Justice of Kazakhstan submitted to the Parliament of Kazakhstan in November 2016 a draft law and a development of the scientific and technological process simplification of registration procedures, and management of legal gaps and provisions that may create administrative barriers in the field of intellectual property.

40. In the future, Kazakhstan plans to continue its work on further improvement of legislation and enforcement of intellectual property and we are open to any collaboration on these issues with WTO Members. We are also open to any further questions that WTO Members may have on our intellectual property system.

### **3.6 Switzerland**

41. We would like to thank the delegation of Kazakhstan for its extensive and carefully drafted responses to our questions. We are still examining them, and might get back bilaterally. We understand that Kazakhstan will submit its checklist on issues of enforcement after this Council's meeting. As the national regime of enforcement is a relevant component of the review of IP legislation, we thank Kazakhstan for preparing its responses to the checklist and would ask questions if need be in view of the next meeting of the Council.

### **3.7 United States**

42. The United States welcomes the review of Kazakhstan and appreciates the implementation efforts of the Government of Kazakhstan concerning the TRIPS Agreement. In furtherance of Kazakhstan's implementation efforts, the United States looks forward to Kazakhstan's upcoming responses to the enforcement checklist and similarly to Switzerland we will revert at the next meeting of the Council should we have any questions. Also in reviewing Kazakhstan's amended copyright law, we do have some additional questions that we are in the process of circulating to the Secretariat and to the Government of Kazakhstan for responses, and we look forward to receiving those responses.

## **AGENDA ITEM 4. REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)**

### **AGENDA ITEM 5: RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY**

### **AGENDA ITEM 6: PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE**

#### **6.1 Brazil**

43. Brazil has a well-known position regarding the promotion of mutual support between TRIPS and the CBD. In our view, the best way to ensure the proper use of genetic resources and associated traditional knowledge is through an amendment to the TRIPS Agreement as set out in document TN/C/W/59. The amendment will introduce a mandatory requirement for the disclosure of the origin of these resources in patent applications. This would create a multilateral and efficient mechanism to combat misappropriation, a concern that remains, especially in developing countries.

44. The issue this amendment intends to address remains very much alive. A recent academic study shows that patent applications related to "bauhinia." were filed in several countries. Bauhinia is a plant found in Brazil and other countries in the Amazon region. Its tea is used by indigenous and local communities to treat diabetes. This example with other, older cases, such as that of turmeric in India and the Phyllomedusa bicolor toad, whose venom has analgesic effects.

45. A mandatory multilateral disclosure requirement would enable a clear assessment of whether those patents related to the baubinia complied with the legal requirements in the country of origin. It would also contribute to enhancing transparency about the utilization of genetic resources and associated traditional knowledge, dispelling questions regarding the misappropriation of valuable national resources.

46. The disclosure requirement as provided in document TN/C/W/59 will not be burdensome for industrial property offices, since they will be simple "check points" in the new system. To illustrate it, the Brazilian Biodiversity Law, which entered into force in 2016, attributes to the Council for Management of Genetic Heritage the task of authorizing access to genetic resources and associated traditional knowledge. The Council is composed of representatives from the government, industry, academia, indigenous peoples and local communities.

47. The National Institute of Industrial Property merely requires from patent applicants, when applicable, the document from the Council that authorized access to genetic resources and associated traditional knowledge. This allows INPI to focus on its core activities of substantive examination of patent applications. It creates no obligation for the patent examiner to conduct a thorough review of the document provided by the applicant.

48. A mandatory disclosure requirement will meet the objectives of the CBD and the intellectual property system by providing appropriate incentives and rewards for traditional knowledge holders, in recognition of their contribution to society. For these reasons, Brazil joined China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group in supporting the amendment of the TRIPS Agreement with the introduction of a mandatory requirement for the disclosure of origin of genetic resources and traditional knowledge in patent applications.

## **6.2 Plurinational State of Bolivia**

49. Bolivia considers it extremely important to prevent the patentability of life forms and genetic resources simply because they have been isolated or described. This practice is permitted by Article 27.3(b) and, unlike any other international rule, it encourages undue appropriation of such resources through the patent system.

50. The adoption of Article 27.3(b) has permitted the proliferation of private monopolies over life, genetic resources, gene sequences, seeds, animals, plants and even fundamental components of human life, leading to a worrying concentration of control over them by some multinationals, with negative consequences for the innovation itself and for scientific research, as well as access to its findings.

51. Preventing the patentability of life forms and genetic resources would help to prevent biopiracy and would act as a complement to a mechanism for disclosing sources of origin. A proposal in this respect for the 11<sup>th</sup> Ministerial Conference in Buenos Aires would be a most appropriate step in favour of a pro-development outcome. Document IP/C/W/59 would be a good basis for this.

52. We would also like to stress that Bolivia supports the idea that the Secretariat of the Convention on Biological Diversity be asked to address this Council so that we can be updated on what is happening in that forum, and we are also in favour of updating the Secretariat's factual notes describing relevant developments in recent years.

## **6.3 Bangladesh on behalf of the LDC Group**

53. The delegation of Bangladesh does not support the patenting of life forms comprising plants and animals and living beings for ethical reasons. We therefore call for the review of Article 27.3(b) in order to protect developing countries and LDCs from the negative effects of this provision on the key sectors that affect livelihoods in these countries such as agriculture, health, food and climate change. This would help, inter alia, food security and preserve the integrity of rural and local communities. Patenting of life forms at a multilateral level should be prohibited.

54. On the relationship between the TRIPS Agreement and the CBD, we hold that States have the right and duty to protect their traditional knowledge and genetic resources. There is therefore a need to amend the TRIPS Agreement to ensure this, with a view to require patent applicants relying on biological materials to provide information on the source and country of origin of biological resources and traditional knowledge used in the invention. Along the same lines, the applicants must show evidence of prior informed consent from and benefit sharing arrangements with the concerned authorities or holders under the relevant national regime. This requirement, which is consistent with the transparency principle established in the multilateral trading system, will help reduce the number of erroneous patents. We believe that while traditional knowledge should receive legal recognition, its protection and proper use would contribute significantly to achievement of development goals, especially SDGs.

55. For LDCs this is a core issue, and they are hardest hit by cases of biopiracy and misappropriation of the traditional knowledge and folklore, due to their lack of capacity to protect these resources. Action on this important issue has been unanimously recommended by our Ministers in Doha and Hong Kong, and they were right to consider this as a doable option. So we believe that these proposals and subsequent action in line with IP/C/W/59 would be a good way to start our next course of action. The LDC Group has also extended their support to IP/C/W/59.

56. In the same vein, we consider that the CBD Secretariat could brief the Council so that we can base our future deliberations on their briefing. These are long-standing issues, as has been mentioned, and we would like to see sincere political will from the Members to resolve the problem.

#### **6.4 India**

57. India is one of the seventeen identified mega bio-diverse countries of the world. India is also rich in traditional knowledge associated with biological resources. This traditional knowledge is both coded, as in the texts of Indian systems of medicine such as Ayurveda, Unani and Siddha; and non-coded, which exists in the oral undocumented traditions.

58. India has been a major victim of bio-piracy. Pursuant to its ratification of the Convention on Biological Diversity (CBD), India developed a comprehensive legislation on biodiversity, including a Traditional Knowledge Digital Library (TKDL) database to prevent misappropriation of traditional knowledge at international patent offices so that cases of biopiracy can be prevented. India has signed a TKDL Access Agreement with nine International Patent Offices. While India has pioneered the TKDL to overcome language and format barriers, the results could only be limited. Improving prior art searches through the TKDL is only one part of the solution. Further, the TKDL represents a subset of the universe of available traditional knowledge. The realm of traditional knowledge in areas other than herbal cures and genetic resources is not covered by the TKDL.

59. While India is undertaking a number of measures at the national level in order to prevent misappropriation of genetic resources and/or associated traditional knowledge, the problem has an obvious international dimension and needs an international solution in order to be addressed effectively. The TRIPS Agreement continues to ignore the numerous IPR-related obligations in the CBD which are of interest to the developing countries. The disclosure proposal (IP/C/W/474) which was submitted in 2006 was followed up by the submission TN/C/W/52 in June 2008 with the support of 109 members. The latest submission on this issue TN/C/W/59 in April 2011, which is a draft decision to enhance mutual supportiveness between TRIPS Agreement and CBD, has been proposed by a vast majority of WTO Membership, including India. This proposal seeks an amendment of the TRIPS Agreement by inclusion of a new Article 29bis for disclosure of origin of genetic resources and/or associated traditional knowledge. A mandatory disclosure requirement in patent applications to include disclosure of origin and evidence of prior informed consent and access and benefit sharing, would, in addition to combating biopiracy, further strengthen the credibility of the patent system by facilitating assessment of the novelty and inventiveness criteria.

60. The Nagoya Protocol of the Convention on Biodiversity (CBD) entered into force on 12<sup>th</sup> October 2014. So far 96 Countries, including India, have ratified the Protocol. According to the CBD website, the Access and Benefit-sharing Clearing-House (ABS-CH), which is a platform for exchanging information on access and benefit-sharing established by Article 14 of the Protocol, is now fully operational. The ABS-CH is a key tool for facilitating the implementation of the Nagoya

Protocol, by enhancing legal certainty and transparency on procedures for access, and for monitoring the utilization of genetic resources along the value chain, including through the internationally recognized certificate of compliance. So far, four countries (Guatemala, India, Mexico and South Africa) have published 50 internationally recognized certificate of compliance (IRCC) with details of prior informed consent for access to genetic resources and benefit sharing on mutually agreed terms.

61. In the 2030 Agenda for Sustainable Development, two targets (SDG 2.5 and 15.6) related to genetic diversity and the fair and equitable sharing of benefits have been included. This demonstrates that ABS and the Nagoya Protocol are making an important contribution to the conservation of biodiversity and sustainable economic development for all. Furthermore, the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing was held in Cancun, Mexico from 4-17 December 2016. According to the CBD website, decisions that were adopted at this Meeting include progress made towards Aichi Biodiversity Target 16, the Access and Benefit-sharing Clearing-House, measures to assist in capacity-building and cooperation with other international organizations or initiatives.

62. It would be quite useful to the delegates of the TRIPS Council if the CBD Secretariat is requested to brief the TRIPS Council in the June session on the latest developments in the implementation of the Nagoya Protocol, including the decisions that were taken at the December Meeting at Cancun in Mexico. The briefing by the CBD Secretariat would be very important to understand the implications of the entry into force of the Nagoya Protocol on the TRIPS Agreement. We reiterate our demand for a formal briefing by the CBD Secretariat in the interest of the large majority of developing countries. We also support Ecuador's proposal for updating the three factual briefs by the Secretariat.

63. I conclude by stating that the TRIPS-CBD issue is one of the outstanding implementation issues and positive outcomes on outstanding implementation issues are one of the most important deliverables of the Doha Round for the developing countries.

## **6.5 Ecuador**

64. My country's position has been expressed repeatedly in this Council. We believe that it should be possible to review Article 27.3(b) so as to enable the Council to examine the patentability of all life forms or parts thereof. Ecuador's view is that this type of patent should be prohibited, since life or parts thereof should not be considered a tradeable good subject to inventions or patents.

65. We have also said that we consider that there is a close relationship between the TRIPS Agreement and the CBD, and we therefore reiterate the need for multilateral legal instruments that can improve the use of genetic resources, traditional knowledge and traditional cultural expressions, and give them effective and adequate protection. In this regard, Ecuador believes there is a need to establish legal mechanisms to allow disclosure of the source of origin, prior informed consent, and access to, and the equitable sharing of, benefits in order to protect genetic resources and traditional knowledge.

66. We reiterate our support for the proposal that the CBD Secretariat inform this Council of the negotiations conducted in the framework of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The information provided will help to enhance our judgement, thus improving the quality of our discussions.

67. Lastly, several years ago, Ecuador suggested that the Secretariat prepare an update of the factual notes on previous topics, since the last compilation of the ideas discussed was produced in 2006. We believe that updated versions of documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1 would provide us with a clearer idea of what was already discussed a number of years ago, the aim being for Members to have an updated picture that could contribute to informing the debate on these issues, thus enabling us to move forward in our discussions. We will see if we were right or not and if this updating actually takes place, but we must be given the opportunity to conduct discussions on the basis of more detailed information that could be presented by the Secretariat in a neutral manner without compromising any of the Members' positions.

## 6.6 Egypt

68. We would like to make reference to our statements as delivered during the previous meeting of the TRIPS Council. The protection of biological resources, traditional knowledge and folklore presents an important developmental issue for Egypt. In view of the importance of this issue, we continue to support engagement in full negotiations on the relationship between the TRIPS Agreement and the CBD, which is a critical part of the implementation-related issues and concerns, as contained in the Doha Work Programme. Therefore, we urge all Members to engage in this issue of high importance to both developing countries and LDCs.

69. We believe that the TRIPS Agreement should be amended in order to provide that Members shall require a patent applicant using biological materials or associated traditional knowledge in the invention to disclose the source and the country of origin of the biological resources and associated traditional knowledge. Furthermore, the applicant shall also provide evidence of prior consent and evidence of fair and equitable benefit sharing under the relevant national regime.

70. Finally, we also support inviting the CBD Secretariat to provide us with a briefing on the Nagoya Protocol and all the progress and the developments in this area.

## 6.7 Indonesia

71. The delegation of the Republic of Indonesia attaches importance to the negotiation of the relationship between the TRIPS Agreement and the CBD, as well as the protection of TK and folklore under these agenda items. Indonesia emphasises the need for cohesion, coherence and consistency of the TRIPS Agreement and the CBD. The TRIPS Agreement should be complementary and support the international instruments. Our delegation believes that TRIPS should be in line with the proposed objectives of the CBD and the Nagoya Protocol, in particular the provision of prior informed consent and access and benefit sharing. Our delegation is of the view that Article 27.3(b) of the TRIPS Agreement does not contain any legal obligation for its Members to take on necessary measures for fair and equitable sharing of benefits as required by the CBD and the Nagoya Protocol. Such legal inequality provides a room for misappropriation and misuse of genetic resources and traditional knowledge. The lack of such legal norms in TRIPS will defeat the proposed objectives of the CBD and the Nagoya Protocol.

72. The Government of the Republic of Indonesia reiterates the urgency of including a mandatory disclosure requirement, including on prior informed consent and access and benefit sharing, into Article 29 of the TRIPS Agreement. As stipulated in the IP/C/W/59 document, Indonesia is of the view that a mandatory disclosure requirement is important to prevent misappropriation of genetic resources and traditional knowledge. Our delegation believes that such a requirement can provide a greater transparency and efficacy in the patent system. The Government of the Republic of Indonesia is developing national laws on GRTKF, and several consultations have been conducted internally.

73. We urge this Council to provide guidance to the TRIPS Special Session on modalities on how to move forward the triplets' negotiations. The delegation of the Republic of Indonesia would like to request that the WTO norm-setting process be in line with the negotiation process in sustainable development goals and intergovernmental committee on GRTKF in WIPO. The WTO cannot be isolated in a vacuum, with its legal system separated from the multilateral processes both in SDGs and intergovernmental Committee on GRTKF in WIPO. We are open to discuss our efforts to revitalise the negotiation of GRTKF in the WTO.

## 6.8 China

74. The relationship between the TRIPS Agreement and CBD is an important issue in the TRIPS Council. China always attaches importance to this issue and actively participates in the discussions. China hopes that Members could further constructively take part in the discussion.

75. Regarding the substantial issues, China notes that the majority of Members support an amendment to the TRIPS Agreement so as to ensure the mutually supportiveness of the TRIPS Agreement, the CBD and the Nagoya Protocol. China believes that the introduction of a mandatory disclosure requirement, including on benefit sharing, could prevent misappropriation and

erroneous patents. And providing the information concerning the prior informed consent and benefit-sharing would not be burdensome. However, the benefit-sharing arrangements on contractual basis and the database solutions could not serve the purpose of sufficient protection for genetic resources.

76. As to disclosure, two documents TN/C/W/52 and TN/C/W/59 co-sponsored by Members, including China, have provided the detailed suggestions on improving the transparency on genetic resources utilization, preventing the misappropriation of genetic resources and traditional knowledge, and preventing the grant of erroneous patents.

77. As regards procedure, China thinks that the discussion and negotiation in WIPO/IGC could not hinder members from finding a solution in the WTO. Furthermore, the mandate to examine the relationship between TRIPS and CBD has been given to this Council by the Ministers, and therefore members should follow the instructions and mandate to work to find the solution. In this regard, in order to strengthen the understanding so as to carry on a constructive discussion in this Council, China supports the proposal to invite the CBD Secretariat to brief on the Nagoya Protocol. China also hopes that the Secretariat could renew the three factual notes.

### **6.9 Nigeria, on behalf of the Africa Group**

78. The Africa Group agrees that there should be a legal obligation establishing a mandatory requirement in patent applications. We believe that the measure would prevent misappropriation of genetic resources and also enhance transparency in the utilisation of genetic resources. In this context, the Africa Group, together with a large group of developing countries, have submitted a series of proposals, in particular the document TN/C/W/59. In order to move the process forward, we suggest that the Chairman of the TRIPS Council undertake urgent consultations with a view to determine how to move the proposal forward, so that we would be able to have an early harvest at MC11. Regarding the participation of the CBD Secretariat, in the context of the TRIPS Council and in particular the developments regarding the implementation of the Nagoya Protocol, we believe that it is high time that the CBD Secretariat be allowed to come and brief us on developments that are taking place on the Nagoya Protocol.

### **6.10 Australia**

79. Australia considers that following the renewal of the mandate of the WIPO's Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore as agreed by WIPO Members in October 2015, WIPO is best placed to consider the complex intellectual property issues relating to genetic resources and associated traditional knowledge.

80. In relation to TRIPS and the CBD, as we have said at previous TRIPS Council sessions, Australia considers that the TRIPS Agreement and the CBD are consistent. Australia fully implements its obligations under both agreements, which we view as mutually supportive.

### **6.11 United States**

81. The United States' views on these issues are well-known, but let me make some brief remarks today. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues. The WIPO IGC is looking at unresolved issues - in fact, just this week, less than a 15 minute walk away - and working on a common understanding of these core issues, using an evidence-based approach and examples of national experiences. The United States will continue to engage in technical discussions at WIPO's IGC and looks forward to hearing more from the demandeurs regarding data supporting their positions on this issue.

82. With respect to the various requests from the previous speakers that we have heard today, we are not in a position to support their requests, but we remain open to discussions, including bilaterally with delegations, in between and at the margins of the TRIPS Council meetings.

### **6.12 Switzerland**

83. My delegation takes the floor in respect of agenda item 5. Let me first revert to the two procedural proposals that have been submitted to the Council earlier and that you reminded the Council of in your introductory remarks.

84. My delegation would like to express its support for the proposal that the CBD Secretariat attend the next TRIPS Council meeting to give a presentation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the CBD. One way to achieve agreement on this proposal in the Council could be to organize such a presentation when the Council meets in an informal mode.

85. We also support Ecuador's proposal for updating the three factual notes by the WTO Secretariat to reflect any new ideas and thinking in the Council's discussion since the factual briefs were last circulated among the Membership.

86. Switzerland is a Member of the W/52 coalition, a group 109 WTO members which are promoting and proposing solutions on the three TRIPS issues in favour of better and more equitable protection for geographical indications and genetic resources, traditional knowledge and folklore under the TRIPS Agreement. This coalition of WTO Members, representing 2/3 of the Membership, proposed relevant modalities solutions on the three TRIPS issues in TN/C/W/52 in July 2008. These are long outstanding implementation issues: they remain of great concern to a large part of the Membership and need to be addressed by the WTO work programme. Our position on TRIPS/CBD is part of this greater whole. Switzerland considers the CBD and the TRIPS Agreement to be mutually supportive. We consider that a non-burdensome requirement to disclose the source of genetic resources or TK in patent applications in the TRIPS Agreement is a useful tool to further enhance this mutual supportiveness of the TRIPS Agreement and the CBD.

### **6.13 Korea, Republic of**

87. As for the three items, Korea maintains the same positions as my delegation has shared at these Council meetings since long. Korea is of the opinion that the current provisions of the TRIPS Agreement offer flexibilities for both biotechnological innovation and protection of life-forms. There is no need to review the TRIPS Agreement for implementing CBD as the two instruments have different purposes and subject matters, while supporting each other in their respective implementation. We are of the opinion that WIPO is the right forum to discuss the protection of traditional knowledge and folklore.

### **6.14 Japan**

88. Japan's view is well known. This delegation believes that the WIPO IGC is the most appropriate forum for holding technical discussions on IP aspects. The 33rd Session of IGC is being held this week. Japan remains willing to contribute to discussions on these issues in a constructive manner.

### **6.15 Canada**

89. Canada continues to firmly believe that the TRIPS Agreement and the CBD are mutually supportive, and that there is therefore no need to amend the TRIPS Agreement in this regard.

90. At the same time, and without prejudice to Canada's position on substantive matters, Canada is not opposed from a procedural standpoint to a briefing from the CBD Secretariat to the TRIPS Council, should there be sufficient interest from other Members on this matter. Similarly, Canada could support the compilation of the three factual notes on the TRIPS Agreement and the CBD by the Secretariat. We remain of the understanding that this would remain a purely factual collating exercise. In both cases, this is without prejudice to national positions on these issues.

91. Canada would also like to note its continued support for the important work of the WIPO IGC, particularly the discussions underway this week at WIPO. Canada continues to believe that WIPO, and particularly the IGC, is the best and most appropriate forum for multilateral and expert engagement on these complex issues. Canada remains an active and committed participant in this

important work, and welcomes both the concrete discussions and exchanges of national experiences at WIPO on these issues. Canada believes that the expert discussions and exchanges that are so integral to the IGC's work are key to accurately pinpointing the issues at hand, and to identifying evidence-based balanced, appropriate, and mutually beneficial approaches to addressing these complex issues.

92. Canada would also wish to reiterate our view that matters relating to Article 27.3(b) of the TRIPS Agreement are an implementation issue as outlined in the Doha Ministerial Declaration, as is also the case with respect to the relationship between TRIPS and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore. Canada continues to support an approach that provides for national flexibility on these matters.

#### **6.16 European Union**

93. The European Union supports the work of the WIPO IGC related to the three separate issues of genetic resources, traditional knowledge and traditional cultural expressions. We look forward to its upcoming sessions on Traditional Cultural Expressions. We also stand by our commitment to implement the Nagoya Protocol, and this was done in the EU by Regulation (EU) No 511/2014.

#### **6.17 Ecuador**

94. I apologise for taking the floor again, but I would like to refer to a very relevant issue that I made reference to in my statement, and that is to update the factual notes. If I am not mistaken, I believe that there is a majority of Members who have expressed themselves in favour of this update that we have been requesting for several meetings now. If I am not mistaken, it is only the US that does not agree with making this update, so I would really like to make a special request to the US to please explain the reasons behind their thinking. We have been quite clear in indicating that this would not compromise the positions of any delegation here in this room, and that it is just a task that we are asking the Secretariat to do in a very neutral, objective way, so that we can have more elements that have been provided over the last 10 years allowing us a more open, frank and transparent discussion, and, so I would like to request your indulgence Chairman, to please request that the United States explain the reasons why they are opposing this update. We have only heard their opposition at various meetings and we have never heard what the foundation for it is. Perhaps we might also think about having bilateral meetings to look further into this.

#### **6.18 United States**

95. The United States acknowledges Ecuador's request to have the Secretariat update the three 2006 documents with information from recent TRIPS Council meetings. We have raised concerns in the past about the utility of the Secretariat pulling Members' interventions from the Minutes of TRIPS Council meetings which are already available to Members, on the internet, online, and place citations to these interventions in a revised report. As we have noted in the past, we are available to talk to Ecuador and others after this meeting about their request with the hope of making progress towards reaching agreement and we have maintained that openness intersessionally, but regrettably no request has been received by our delegation. However, I would just repeat that we have very strong openness to discussing this bilaterally after this meeting should any Member wish to discuss this with us.

#### **6.19 Ecuador**

96. We are very much open to having bilateral meetings with the United States, but at least, if I am not mistaken, we have not yet heard the foundational basis, the real reason why there is opposition to this proposal. Of course we can talk about it bilaterally, but we would like to have more details and the reasoning behind their position please.

#### **6.20 United States**

97. We would just reiterate our intervention, and also again reiterate our very openness to discussing this. And I must maintain, yet again, that we have not received any request inter-



sessionally to deal with this issue, and we happily remain open to discuss bilaterally with Ecuador, should they wish to discuss with us.

### **6.21 Nigeria, on behalf of the Africa Group**

98. I have listened carefully to the explanation by the delegation of the United States, saying that these issues are already in the minutes of the TRIPS Council meetings. But I think there is a need for sympathy. Some of us have one person covering WTO, UNCTAD, WIPO and perhaps the Human Rights Council, and I think it is humanly impossible for a delegation to digest the minutes here and there. I believe that such an item, once it is done, will assist us to get a handy document in a summary form that could help us, at least those of us from poor nations. I think it would be good if we could be helped, because the capacity is not there. We have one delegate, or Ambassador plus one, so it is a difficult thing and I think it is a humanitarian issue. There is a need for us to begin to be realistic, because blocking A and then blocking B, now the goal on this issue has been blocked, and we have listened, and the underlying reason, at least coming from the Africa Group is not convincing, rather it is adding more work on our side.

99. When we move to the non-violation and situation complaints, there will be another tit-for-tat, so I think we are not helping ourselves, we are not telling the outside world that we are willing move, so I don't know where we are heading to, but we are appealing at least, on behalf of the African Group to assist us to have this compilation so that we will be able to decipher these things in good time.

### **6.22 Chair**

100. I have heard a call that the Chair of the TRIPS Council should engage in consultations with delegations. I think that is a good beginning. I have heard willingness to engage in bilateral or inter-sessional dialogue meetings as well. Let me take up the point of consultations and suggest that unless we have any objections to this, that the Chair of the TRIPS Council - I am the jobbing captain here - once we have the Chairs slate resolved, should engage in consultations with delegations to find a way forward on these issues.

### **6.23 United States**

101. We do appreciate very much your efforts to move, or try to make progress on this long-standing issue, but at the same time we must recognise that it is an issue where there are deep divergences amongst Members, but also where there is tremendous amount of work going on in another forum where these issues are being debated this very day, and this very week, and where all the delegations represented are working closely together, so we do not see the necessity for such consultations. Of course to the extent that the Chair wishes to talk to delegations, that is his or her right, but in terms of this issue, our position has been well-known, the positions of the demandeurs are well known, positions of other delegations around the room are well known, so we would just raise that as an area of concern from our end.

### **6.24 Chair**

102. Thank you, United States, you do recognise the Chair's powers to approach delegations and I will pass that on. I do want also to encourage delegations to take each other up on these offers for continued discussions bilaterally, in smaller groups and I guess the expression here is groups of variable configuration, take the initiative, and really, come up with creative ways to move forward on this thing. If people have concerns, it is our job as diplomats, as negotiators, to try to find a way that we can address concerns and keep everybody happy. Please do engage in those bilateral discussions.

### **6.25 Nigeria on behalf of the Africa Group**

103. I was hesitating - in fact we have listened carefully - but I think it is very clear, when you look at the patents that we are trying to address and the issue of misappropriation of genetic resources through patents, I think if there is any impairment or nullification of Members rights in the WTO, in terms of a patent, they run to the DSB. And I believe where there is misappropriation you take that instrument of patent, and then you use it to misappropriate genetic resources.

Certainly we will want also our voice and complaint to be heard in the DSB, so while we believe that the IGC is important, the solution to misappropriation as we have seen it only lies in the WTO, because we have seen material transfer agreement has not resolved these problems, and we have been talking about these things since the 1990s. So I believe that the only way out is through the WTO.

104. We have put in a proposal - I don't know - does it mean that now there will not be a discussion in this forum of W/59? I think this is the question, because we have put in a proposal, we have asked the Chair to see how we are going to move forward on this proposal. Certainly if there is no right of Members to submit their documents or proposals in this Council, and no discussion takes place, then I don't know, I think this is what we want to hear.

## **6.26 Chair**

105. Thank you for your contributions. If I recall correctly, and again I am showing my age here, this W document is one that has been set before the TNC, and though I want to keep an open mind about the possibility of elements that can be discussed here, I don't want to prejudge that. Delegations are always free to bring up issues that they feel are relevant to our discussions in the regular TRIPS Council, and I would encourage you and all other delegations to feel free to bring up topics that you feel are appropriate. For today on this side, there have been many expressions of willingness to continue discussions, I want to encourage you to do that. I want then also to say that the Council should take note of all the statements that we have made today, that we should agree to revert to these matters at our next meeting, and I will, in presuming my role as elder statesman, try to chat with the TRIPS Chair, whoever that may be, and update him/her on the situation with whatever insight I might be able to provide for the future.

## **AGENDA ITEM 7: NON-VIOLATION AND SITUATION COMPLAINTS**

### **7.1 Brazil**

106. We welcome the addition of the Kyrgyz Republic to the list of co-sponsors of document IP/C/W/385/Rev.1. As provided in that document, concessions under the TRIPS Agreement cannot be characterized as "market access" under GATT or GATS. The TRIPS Agreement, unlike other WTO agreements, is a sui-generis agreement designed to establish minimum standards of intellectual property protection. Complaints regarding measures pertaining to market access should be filed under relevant provisions of the GATT and the GATS; applying the non-violation remedy to the TRIPS Agreement is unnecessary to address these cases.

107. For cases in which a Member believes that the obligations of the TRIPS Agreement are not being properly fulfilled by another Party, Article 64 unambiguously establishes a dispute settlement mechanism which was invoked and duly used in cases before the dispute settlement body. Claims that the availability of non-violation and situation complaints (NVSCs) would prevent Members from evading their TRIPS obligations are not supported by evidence.

108. NVSCs can also threaten the use of flexibilities by Members, in violation of Articles 1, 7 and 8 of the TRIPS Agreement. They could jeopardize the use of exceptions and limitations for the development of laws to protect public health and affect the delicate balance of rights and obligations reached by the Agreement.

109. Furthermore, the fact that no consensus on the matter was reached during the negotiations of the Uruguay Round underlines that the negotiating parties were not convinced these types of complaints would contribute to the attainment of the goals of the TRIPS Agreement. The continuous renewal of the moratorium since 1999 shows that Members remain unconvinced of any benefit that could be brought by the application of non-violation and situation complaints. In short, the application of NVSCs to intellectual property disputes would generate systemic imbalances and reduce the legal certainty of multilateral IP law.

110. Consequently, we propose that the TRIPS Council recommend to the Ministerial Conference scheduled to be held in Buenos Aires that complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under the TRIPS Agreement.

## 7.2 China

111. In 2015, the Nairobi Ministerial Conference decided to further extend the moratorium of the application of non-violation and situation complaints under TRIPS Agreement, however, till now, the divergence between members is still continues. China thanks the Chair and Secretariat for their efforts, and hopes that members could participate in the discussion constructively.

112. China reaffirms the position that non-violation and situation complaints are not applicable under the TRIPS Agreement, which has been elaborated in document IP/C/W/385/Rev.1 proposed by 16 members including China. China welcomes the discussion on this issue in accordance with the decision and mandate given by the Nairobi Ministerial Conference.

## 7.3 Chinese Taipei

113. The issue of non-violation and situation complaints has been debated in the TRIPS Council for many years now. I wish to underscore the following points:

- Document IP/C/W/349 was prepared by the Secretariat and is a very useful document in order to better understand the history and the current state of discussion on this matter.
- Since 2013, the United States of America, Peru, Brazil and other members have submitted proposals such as IP/C/W/385, IP/C/W/599 and IP/C/W/607 in order to facilitate detailed discussion on this issue among members, particularly with respect to the modalities applicable in the TRIPS Agreement context.

114. I wish to request the Secretariat to update and further develop the document IP/C/W/349 in order to make it more detailed and to reflect current reality.

## 7.4 Bangladesh on behalf of the LDC Group

115. Thank you Mr Chairman. Like all the developing countries and LDCs, we would like to express our concerns regarding the possible adverse fall outs of these complaints. We consider them to be unnecessary and evitable. We understand that the TRIPS Agreement provides a minimum level of protection of IP and much of the flexibility rests with the domestic laws of members. Drawing any simple parallelism in terms of non-violation and situation complaints with other WTO Agreements would be wrong, as TRIPS Agreement does not deal with market access and concessions. In addition, based on the nature and scope of protection of the TRIPS Agreement, the level of protection under domestic legal systems and practices is different from member to member. An introduction of such complaints would therefore result in much legal uncertainty to the entire system. So we do not support the application of this type of complaints under the TRIPS Agreement.

## 7.5 Argentina

116. In Argentina's view, non-violation and situation complaints do not apply to the TRIPS Agreement, as explained in document IP/C/W/385/Rev.1, of which my country is a co-sponsor together with a large number of other Members. In light of the foregoing, we consider that the forthcoming Ministerial Conference should adopt the decision proposed in document IP/C/W/607.

## 7.6 Switzerland

117. Mr. Chair, I will follow your call and abstain from repeating well-known positions. Let me just reiterate that while Switzerland believes that the DSU provides sufficient guidance for the application of NVNI in the TRIPS context, my delegation confirms our openness to examine and discuss any modalities' proposals other Members may wish to table in this respect. Also, my delegation is open to the proposal of the preceding Council Chair that the Secretariat produce a factual document on scope and modalities for NVNI complaints in the WTO to assist the Council's further discussion under this agenda item.

## 7.7 Russian Federation

118. The Russian Federation is of the view that the non-violation and situation complaints should not be applicable to the TRIPS Agreement. In order not to reiterate our position we would like to ask that the previous intervention should be reflected in the minutes of this Council. (See previous IP/C/M/83/Add.1 para 246).

The Russian Federation, once again, would like to reiterate its position that non-violation and situation complaints should not be applicable to the TRIPS Agreement. As it was mentioned earlier by numerous delegations there are several grounds that justify such approach of non-applicability of non-violation and situation complaints in the context of intellectual property. The TRIPS Agreement, unlike other WTO Agreements, is not designed to protect market access or the balance of tariff concessions, but rather to establish standards of IP protection, which, if abused, may even undermine market access. The application of non-violation complaints under the TRIPS Agreement could upset the delicate balance of rights and obligations in this Agreement, and could also limit the use of the flexibilities outlined in the Agreement to secure objectives relating to public health and other issues of public interest. Our position, as the position of the majority of WTO Members, was clearly pointed out in document IP/C/W/385/Rev.1. Like other delegations, we think this document should serve as a basis for discussions on this issue. Our delegation welcomes any constructive discussion on the issue and welcomes delegations to share any new views.

## 7.8 Egypt

119. The position of Egypt is well-known with regards to this agenda item. We continue to believe that complaints of the type identified in Article XXIII.1 (b) and (c) of GATT 1994 are not applicable to the TRIPS Agreement. We also believe that the best solution to this issue is that the document number IP/C/W/607 should be the basis of our future negotiations in this regard.

## 7.9 India

120. My delegation would like to thank the delegation of Kyrgyz Republic for joining as co-sponsor of document IP/C/W/385/Rev.1.

121. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged. It is worth noting that, in the run-up to the Ministerial Conference in Nairobi, there was a great confluence of interest on making such complaints inapplicable to TRIPS.

122. We are not convinced by the reasons provided by a couple of Members of their place in the TRIPS context. While the question whether the TRIPS Agreement is a market access agreement may or may not be relevant for their applicability, it is clear that the drafters did not unequivocally wish to apply NVCs to TRIPS. Article 64.1 of the TRIPS Agreement establishes that GATT Article XXIII applies to the TRIPS Agreement except as otherwise provided in Articles 64.2 and 64.3. Notwithstanding the expiry of the time-period under Article 64.2, non-violation and situation complaints only apply to the TRIPS Agreement in accordance with the procedure established under Article 64.3. Complying with this procedure, the importance of which Ministers reaffirmed through their adoption of the Decision on Implementation-Related Issues and Concerns, should be a matter of priority for the TRIPS Council. The Decision directed the TRIPS Council to "continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the Fifth Session of the Ministerial Conference." It also reflected the agreement that, in the meantime, members will not initiate such complaints under the TRIPS Agreement. Thus, the assertion that the expiry of the time-period under Article 64.2 makes non-violation and situation complaints automatically applicable to the TRIPS Agreement is, in our view, incorrect.

123. It is important to recognize that the TRIPS Agreement is a unique, sui generis agreement and is distinct from the GATT and GATS, contrary to the assertion made in the US communication. In the GATT/WTO legal framework, the establishment of the non-violation procedure aims primarily to prevent the tariff concessions or specific commitments on trade in services from being adversely distorted by the additional trade measures taken. With the gradual evolution of comprehensive trade agreements addressing a wide range of issues, it does not make any logical

sense to extend the same concern of circumvention/dilution of trade obligations in the context of agreements such as the TRIPS Agreement. When it comes to the GATT and the GATS as market access agreements, the non-violation complaint is an additional tool with which to balance the rights and obligations concerning market access in the GATT and GATS respectively. Fundamentally differing from the GATT and the GATS, the TRIPS Agreement is not "about reciprocal market access rights of governments". While IPRs might facilitate trade and investment, the obligations under the TRIPS Agreement cannot be characterized as market access concessions.

124. Serious concerns remain on the debilitating impact non-violation complaints in TRIPS can have on the regulatory policy space of members, on TRIPS flexibilities as well as increasing the complexity in interpreting the TRIPS provisions. It can not only have a chilling effect on Members' exercise of their IP regimes but could also severely restrain the ability of Members to achieve other public policy objectives.

125. The absence of non-violation complaints in the TRIPS context does not in any manner threaten or dilute the enforceability of TRIPS-related rights and obligations. On the contrary, the application of non-violation complaints in the TRIPS context could potentially present issues relating to rights of intellectual property right holders versus the legitimate exercise of regulatory policy choice by governments. Introducing non-violation and situation complaints into the TRIPS Agreement is unnecessary and inconsistent with the interests of the WTO members. Any benefits arising from the Agreement can be adequately protected by applying the text of the Agreement in accordance with accepted principles of international law, and without introducing the legally uncertain notion of non-violation and situation complaints.

126. We note that there is a moratorium on the applicability of such complaints until the next Ministerial Conference and we look forward to work with like-minded Members in making non-violation complaints inapplicable to TRIPS. We also wish to reiterate that until there is a consensus on the scope and modalities of the applicability of NVCs to TRIPS, NVCs will not apply to the TRIPS Agreement.

127. We do not support updating of the Secretariat's factual note on non-violation complaints as suggested by the delegation of United States. We would agree to that only if Ecuador's proposal of an update of three factual notes on the Triplets is agreed.

#### **7.10 United States**

128. For the reasons we have detailed in our previous interventions under this agenda item, we continue to believe that the drafters of the TRIPS Agreement envisioned that NVNI complaints should be available.

129. We also take this opportunity to confirm that while the moratorium on NVNI disputes under the TRIPS Agreement was extended in December 2015 for only an additional two years, the United States continues to maintain its long-held and firm position that NVNI disputes should be applicable to the TRIPS Agreement, that they are fully consistent with the TRIPS Agreement and that the application of such disputes in this context was the intent of the drafters of the TRIPS Agreement.

130. We believe that while valid questions have arisen, they are fully and adequately answered by the text of the TRIPS Agreement itself and further clarified through GATT and WTO adjudication, as we have enumerated in our communication to the TRIPS Council, which was circulated to Members as IP/C/W/599, as well as in our recent interventions.

131. The United States has provided detailed and extensive analysis in each of our statements under this item over the past several years and I would not propose to repeat now. We have explained the legal basis for such claims in the GATT and TRIPS Agreement texts, the panel and Appellate Body jurisprudence involving NVNI disputes, the extensive safeguards that exist to protect Members rights and obligations under the TRIPS Agreement, and concrete descriptions regarding how such disputes would work in practice.

132. As Switzerland indicated, we are open to discuss bilaterally, especially in the lead up to the Buenos Aires Ministerial.

### 7.11 Nigeria on behalf of the Africa Group

133. I am not going to re-state our position, since that is the guidance you gave us. We have listened to two sides: whether it should apply or whether it is not going to apply - and I don't see it being helpful to the whole process. I think we have two issues here: one is a question of a proposal in order to move the process forward. And there is a text on the table from those who believe that NVCs are not going to apply. Maybe I could suggest for the two delegations, who suggest that NVCs would apply and let the Panel and Appellate Body mechanism rule on this issue, to also make a proposal from their side. This might help the Chair in organising consultations to see how we could move forward. In the interim, since we are heading for MC11, I suggest we start discussing what to do with the moratorium. I believe that extending it until the time when we are able to resolve this issue would go a long way in facilitating the discussions. Every Ministerial we get a moratorium, and then at the end of one year, by the time you move into the second year, we are preparing another discussion on moratorium. So I think we should make it more permanent, not completely permanent, but pending until the time when we are able to agree or resolve this issue. I would encourage the two delegations at least to come up with a proposal so that we can look at two proposals on this matter.

### AGENDA ITEM 8: REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.1

No statements were made under this agenda item.

### AGENDA ITEM 9: REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2

#### 9.1 El Salvador

134. In November last year my delegation submitted responses to the list of question on the application of geographical indications. We are grateful to the Secretariat for having circulated the document IP/C/W/17/Add.34. We are also grateful for having giving us the opportunity to give a brief intervention relating to this notification. In El Salvador the protection of geographical indications is regulated by the law on trademarks and other distinctive signs, and this fully respects our commitments that we have taken on various treaties. Except for a so-called famous geographical indication, a registration is required in order to benefit from protection and the competent authority for granting this is the Intellectual Property Registry of the National Registry Centre. Geographical indication holders may opt for one of two systems of protection which co-exist in accordance with legislation. One can choose the trademark protection system, or the *sui generis* protection system. Under trademark protection one can request registration as an individual mark, as a collective mark or as a certification mark. The period of protection in this case is of 10 years and this period can be renewed indefinitely for periods of 10 years. The *sui generis* protection system includes two different types: geographical indications and denominations of origin. Geographical indications have a somewhat wider scope compared to denominations of origin, both with regard to the sign which is registered, as well as the link to the product which is identified by that geographical origin.

135. *Sui generis* protection cannot be applied to services, and the protection period is undefined, but lasts as long as the conditions required for the original granting of the registration persist. These protection regimes are applicable to all types of products, no matter whether these are wines, spirits, agricultural products or any other kind of products such textiles, manufactured goods in wood, earth ware or glass, to give a few examples. Protection systems are alternative or accumulative, and that means that at the discretion of the holder one can request only one type of registration, or request registration as a mark and as a geographical indication or denomination of origin, whether this be done simultaneously or consecutively, as long as in each case the formalities that are required are complied with for each type of mark.

136. The registration process for both systems of protection is initiated at the request of the holder. In the case of using both systems, if the protection of the mark lapses because there has not been a renewal, then *sui generis* protection will persist. In the case of foreign geographical indications, this is governed by the legislation of the country of origin and the procedure includes publication at the request of the requesting party as well as an opposition phase and a fee.

137. Finally the holder of a geographical indication, no matter what system of protection they have opted for, will enjoy the right of exclusivity of use and will have defensive tools enabling them to enforce this and they will have the ability to enter into administrative proceedings for other distinctive signs as well as to initiate legal proceedings for any infringement, or any unfair competition.

## **9.2 Switzerland**

138. Switzerland would like to commend El Salvador for submitting its responses to the checklist of questions and thank the delegate from El Salvador for the informative summary presentation of its answers and presentation of the national regime of El Salvador for the protection and enforcement of GI rights. My delegation welcomes your call, Mr. Chair, to Members who have not yet submitted their own responses to the checklist of questions to do so at their earliest convenience.

139. Further, my delegation would like to inform the Council that Switzerland is currently preparing an update to its responses to the Checklist of questions. Switzerland submitted its first set of responses in 1999 in Addendum 13 to document IP/C/W/117.

140. Since then, a fair number of changes have occurred in Switzerland's national and international regime for the protection of geographical indications. While we have notified relevant amendments in our national legislation in compliance with our obligations under Article 63 of the TRIPS Agreement, we believe it worthwhile to reflect those changes also in our responses to the checklist of questions. This for the sake of transparency and to facilitate WTO Members' review under Article 24.2 and better understanding of how Switzerland applies the provisions on the protection of geographical indications under Section 3 of the TRIPS Agreement in its national legal framework.

141. When the WTO and the TRIPS Agreement entered into force in 1995, geographical indications were a relatively new field of intellectual property for a number of WTO Members. This has changed over the last 20 years. In this period, geographical indications have seen dynamic developments at the national level of many Members and from all levels of development. Some of those have only introduced geographical indications as an IPR in their legislation on the occasion of their adherence to TRIPS Agreement, to better exploit the benefits of GIs for their economies. As is the case with many newly introduced laws and systems, they require regular review and overhaul to extend and fully reap the said benefits.

142. Switzerland believes, therefore, that it is high time that the Council resumes its substantive discussion under the built-in review of Art. 24.2 and that Members share their experiences for the mutual benefit of all WTO Members

143. Up-to-date responses to the checklist of questions from WTO Members provide a wealth of information and insights for our discussion here in the Council. For these reasons, we encourage all Members to submit their responses to the Checklist or update their earlier responses to reflect important developments that may have taken place in their national regime since the time of their earlier submissions of responses.

## **AGENDA ITEM 10: FOLLOW-UP TO THE FOURTEENTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT**

### **10.1 Bangladesh on behalf of the LDC Group**

144. We would like to thank the Members who have submitted their reports last year. We see that more and more Members are using the format suggested by the LDCs. For the LDCs technology and innovation are extremely important factors and sincere use of the provisions of Article 66.2 will meet urgent needs in the essential areas of life and development. As we all have adopted the SDGs and we have now the amendment of the TRIPS Agreement based on the Paragraph 6 system, we encourage the development partners to put into use the necessary incentives to their enterprises and institutes so that the equal transfer of technology may take place and the LDCs

can have viable technological base to achieve the SDGs and the opportunity provided by the recent amendment of the TRIPS Agreement.

## **AGENDA ITEM 11: TECHNICAL COOPERATION AND CAPACITY-BUILDING**

### **11.1 Secretariat**

145. Brazil had suggested at the TRIPS Council meeting on 30 January "that the next session of the TRIPS Council includes a presentation by the Secretariat on the notification system currently in place", as part of the suggested activities to raise awareness and address lack of knowledge, especially in procurement agencies. To address this proposal, the Secretariat has prepared a brief presentation on notifications that are required in order to use the Paragraph 6 System<sup>3</sup>. We have also made available hard copies of the Guide to Notifications which is based on the material that can be accessed on the WTO's dedicated webpage. To further simplify the submission of notifications, Members seeking to notify under the System can soon also opt to use the eTRIPS online submission webtool once it is finalized and operational.

146. The purpose of this presentation is to familiarize delegations with that material, including model forms for each of the three notifications that can be downloaded from the webpage. Obviously, the material has been prepared by the Secretariat on its own responsibility in order to assist Members who are considering using the System. The clear link with capacity building also explains the coverage under the item on technical cooperation activities at this meeting of the TRIPS Council.

147. We also wanted to introduce the webpage, because it is often very easy to say that 'all of this is available on our webpage'. We thought that, in order to introduce the item, we briefly run you through what is available on our webpage dedicated to issues related to TRIPS and public health.

148. As you see the gateway page on TRIPS and public health provides a brief general overview of matters related to TRIPS and public health, but currently focuses on the implementation and use of the Paragraph 6 System. The Secretariat is working on expanding the webpage to cover other relevant issues at the crossroad between IPRs and public health.

149. The first entry in the notifications box links to a webpage that recalls the context and legal basis for notifications by both importing and exporting Members and outlines the key elements of such notifications. In order to respond to the requirement on the WTO Secretariat to make available publicly the notifications by the importing and exporting Members (fn. 5 and 9 of the Annex to the amended TRIPS Agreement), this webpage also provides direct access to these notifications. By way of illustration, reference is made to the page addressing specifically importing Members and the link to documents online where specific notifications can be accessed.

150. On Slide 5 we have a second entry in the notifications box that links to the Guide to Notifications. This Guide is available online. A print out version of the Guide has also been made available for delegations in the back of the room.

151. Slide 6 on "How to notify" outlines formal requirements to submit a notification to the WTO. It briefly addresses the question of who signs the notification, i.e. any authorized government official. It also clarifies that there is no need to get approval by any WTO body, which is a common misunderstanding when I present on these issues, and that notifications are to be sent to the TRIPS Council through the Secretariat. In addition to communication by e-mail, fax and post, in the future we will also add the e-TRIPS online tool which we will soon make available.

152. These notifications are circulated in document series IP/N/8/.. (importing Member's intention to use), IP/N/9/.. (importing Member's specific needs) and IP/N/10/.. (exporting Member's grant of compulsory licence and conditions attached to it) and are available on our documents online webpage.

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<sup>3</sup> Document RD/IP/15



153. Slide 7 on "What to notify" lists three types of notifications required under the System. The first is by the importing Member or Members, that is the general notification of the intention to use the System. Least developed countries do not have to notify this intention. The second notification by the importing Member is about its specific needs – what are the pharmaceuticals that are needed and how much of these medicines are needed, we will get back to this when we get to the model form. And the third is by the exporting Member that has to notify the grant of the compulsory licence and the conditions attached to it.

154. In order to simplify the task of those who envisage to use this System, we have made available already for some time, model notifications for these types of notifications (Slide 8). We are operating at this stage on a dual legal basis, i.e. those that have accepted the TRIPS Amendment and that are therefore operating on the basis of Article 31bis of the amended TRIPS Agreement and the Annex and the Appendix to the Annex; and those that are yet to accept the TRIPS Amendment and that continue to operate on the basis of the 2003 waiver Decision.

155. This why we have now two sets of model notifications online which are otherwise in substance identical except for the legal basis, depending whether you operate on the basis of Article 31bis of course the legal basis would be different from those operating on the basis of the waiver Decision.

156. For illustrative purposes, the rest of this presentation will only refer to notifications that are made pursuant to Article 31bis of the amended TRIPS Agreement, it being understood that the same explanations would equally apply to notifications made under the 2003 waiver Decision.

157. Slide 9 on "First notification of importing Member's intention to use the System" summarizes the requirements for this notification. As you can see from the model notification, what is actually required is one sentence that signals a Member's intention to use the System. There is some optional language I will come to, but nothing more that needs to be notified as part of this first notification.

158. Least developed countries do not need to make this notification, and developed countries are, by definition, excluded from making this notification, because they have committed not to use this System as importers.

159. When to make the notification? It can be made at any time, either together with the details regarding the needed medicines (see second notification) or prior to such notification. There is no given time when this notification has to be made, it has to be notified once only, so once you have used the System for the first time there is no need to notify again the intention to use it.

160. It is important to note that the notification does not commit a Member to the actual use of the System. Making this notification does not mean that you have to follow up and also submit a specific notification about your needs in the pharmaceutical sector.

161. What needs to be notified? The optional language goes back to a provision in Para.1(b) of the Annex to the amended TRIPS Agreement which says that "a Member may notify at any time that it will use the System in whole or in a limited way, for example in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".

162. For Members who wish to make use of the System in such a limited way, we have suggested this optional language to provide assistance in case needed. I should also note that the Chairman's statement read out before the adoption of the Protocol in December 2005 noted several Members' confirmation to use the System only in circumstances of extreme urgency.

163. Here, a question for consideration: why has no such notification been made to date? That is a question to be asked when it comes to the functioning of the System.

164. Slide 10 deals with the second notification of the importing Member's specific needs (products, other details). Here again I would like to underline that the model forum for this notification can be downloaded from our webpages and is easily filled in, provided the importing Member is in a position to identify (i) exactly what and how much is needed to treat patients and

(ii) any existing patents for the needed medicines. If these prerequisites are given, it should be easy to fill in the notification.

165. Why is there a need to make this notification? From our perspective, this notification has an important and so far largely underutilized signalling function by which other Members and the public are informed about the concrete needs of an importing Member. As such, it can thus be used as a practical procurement tool to trigger the interest of potential suppliers, almost equivalent to a call for tenders. There is ultimately no obligation to procure the medicines under the System if other sources of supply can later be identified that can, for example, produce the products off patent or at an affordable price. This could reinforce consideration of the mere use of this notification as a procurement tool to flag a country's needs.

166. Who is obliged to make this notification? Notifications must be made by developing countries and LDCs that wish to import products under the System; it can be made by a regional organization on behalf of and with the consent of RTA members under the RTA mechanism (see fn 4 to the Annex of the TRIPS Agreement). Also, nothing prevents other Members from making joint notifications. This is supporting the objective of harnessing economies of scale and makes production under the System economically more viable for generic companies. Note that no (further) notification is required in case of imports from another RTA Member that is either manufacturing the needed products or imports them from third country suppliers.

167. What needs to be notified? The names and expected quantities of the needed medicines; but not, for example, the name of the potential supplier. It is actually preferable for a government not to do so, as this could limit potential competition among generic companies regarding the prices that could be offered for the needed medicines. So, it is important to note that there is no need to notify the name of the supplier, nor any time-frame for the supply and use of the imported medicines. None of this is mandatory for the importing country that notifies its needs.

168. Next, a Member that wishes to import medicines needs to notify that it has established that there are insufficient or no manufacturing capacities in its territory (see Appendix to the Annex), and how this has been established (see Chairman's statement read out prior to the adoption of the Protocol). This does not apply to least developed countries which are automatically assumed as not having sufficient manufacturing capacities.

169. The model notification also suggests some optional language. If there is no patent in force in the importing country, there is no obligation to notify anything in this regard. However, the very absence of patents in the importing country may be a useful piece of information for those who are intending to use the System, and hence the suggestion of optional language to also include this information in the notification.

170. Otherwise what needs to be notified when there are patents in force is the grant or the intention to grant a compulsory licence. In the case of least developed countries, as the example of Rwanda had shown in the past, it is also sufficient to refer to the extended transition period in the pharmaceutical sector instead of mentioning any grant or intention of granting compulsory licences.

171. Again, this notification raises a question for consideration to which we are yet to receive an answer. Why are such notifications not used more regularly by Members to flag their needs and thus to prepare the grounds for the actual procurement of the needed medicines, knowing that there is no obligation to run through the System to its end if you find different sources of supply.

172. The third and last notification concerns the exporting Member's compulsory licence and conditions attached to it. Again this should be easy to fill in for the exporting country. The Survey of WTO Members' implementing legislation which the Chair has mentioned in his introduction shows that legislation which has been put in place by WTO Members so far addresses these conditions in a flexible manner, such as the quantities covered by the compulsory licences and its duration. This includes, for example in some implementing laws, the possibility to augment authorized quantities through a simplified and accelerated procedure, or to renew the initial period of the compulsory licence or to review the duration by means of a simplified procedure.

173. Why is this notification needed? It is basically the response to the second notification by the importing country, so it is triggered by that importing country's notification of specific needs. Who is going to make this notification? Any exporting Member, for every compulsory licence that is used exclusively for production and export of medicines to an eligible importing Member.

174. Please note that there is no such notification required again in the context of regional trade agreements, so where that qualifies under the RTA mechanism, in case of exports from an RTA Member to other RTA Members under the regional mechanism. Also, there is no notification required when we operate under standard compulsory licence, in other words, when the predominant part of the production is used for the supply of the domestic market of the country that is also the host of the manufacturing company.

175. When to notify this third notification? Prior to the export, that is important, otherwise there is no specific rule in here.

176. What to notify? This is addressed by the set of bullet points in the model form which are required pursuant to Para.2(c) of the Annex to the TRIPS Agreement. Provided that these details are covered by the compulsory licence, this requirement could also be met by attaching a copy of the compulsory licence to the cover letter.

177. Other information, such as the number of the patent(s) covered by the compulsory licences, can be included on an optional basis. This would help to clarify the exact scope of the compulsory licences granted by the exporting country.

178. Finally, there is also a need to notify a link to the webpage where the licensee posts information regarding the quantities supplied to each destination under the System and the distinguishing features applied to the products. This can either be a webpage set up by the licensee (see the example of Apotex, which exported under compulsory licence from Canada to Rwanda) or a dedicated page on the WTO website (see fn.7 to the Annex).

179. The next slide is a summary of the resources which are available on the WTO webpage. On the final slide, and this is not related to notifications, I would like to give you the link to the document the Chair mentioned before, i.e. the Survey of WTO Members' implementing legislation, which is available online as well. Almost exclusively in table format, it provides an overview of how the key features of this System have been implemented in domestic law.

## **11.2 Brazil**

180. First of all I would like to thank the Secretariat for the very comprehensive presentation clarifying important aspects necessary to the operationalisation of Article 31*bis*. This is the first session following the meeting held in January regarding the entry into force of the Protocol. On that occasion, Brazil suggested three areas which the Organization could assist Members with activities and technical assistance related to the Protocol. In our view, the WTO and Members should work together towards full implementation, fulfilling expectations of society and stakeholders regarding the benefits of the multilateral trading system. We are confident that the expertise of the Organization would prove valuable to that task.

181. Regarding the Protocol itself, I would like to draw attention to the necessity of the extension or elimination of the deadline for acceptance of the Protocol currently limited to December 2017. The next session of this Council could initiate a discussion of the matter, in order to recommend a decision to the Ministerial Conference.

## **AGENDA ITEM 12: THE UNITED NATIONS SECRETARY-GENERAL'S HIGH LEVEL PANEL REPORT ON ACCESS TO MEDICINES**

### **12.1 India**

182. At the outset, I would like to thank the delegations of Brazil, China and South Africa who are also co-sponsors of this agenda item. In November 2015, the United Nations Secretary-General Ban Ki-moon convened a High-Level Panel (HLP) on Access to Medicines with an objective "to review and assess proposals and recommend solutions for remedying the policy incoherence

between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies." The United Nations Secretary-General's High-Level Panel on Access to Medicines released its Final Report on 14 September 2016.

183. The HLP Report referred to Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages" and reiterated that the State obligations include duties not only to respect, but to protect and fulfil the right to health.

184. The HLP Report highlighted that neglected tropical diseases (NTDs) continue to receive inadequate funding for R&D and access to health technologies, despite more than a billion people living with one or more NTD. The HLP Report also recognized that the costs of health technologies are rising globally and are being felt by individuals and by public and private insurance schemes in both wealthy and resource-constrained countries alike. In this context, it is pertinent to mention that recently, the President of a developed Member stated that pharmaceutical companies are "getting away with murder" in what they charge the government for medicines. To address this issue, the Panel Report recommended that governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to : (1) the costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and (2) any public funding received in the development of the health technology, including tax credits, subsidies and grants.

185. On innovation, the HLP Report stated that IPRs are "one policy tool among many for encouraging innovation and technological research and development". The Panel Report emphasized that limiting access to academic discoveries can obstruct follow-on innovation and force taxpayers to pay twice for the benefits of publicity-funded research. The Panel Report advocated for strong, enforceable policies on data sharing and data access should be a condition for public grants. The Panel Report also underscored that public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including use of non-exclusive licences, the donation of intellectual property rights, participation in public sector patent pools and other mechanisms that maximise innovation while promoting access. The Panel Report recommended that open access models of innovation can also lower entry hurdles and accelerate the pace of development of health technologies, including those needed to combat emerging infectious diseases.

186. In furtherance of the Objectives and Principles of TRIPS enshrined in Articles 7 and 8, a number of flexibilities have become an integral part of the TRIPS framework. These flexibilities have been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. It confirmed that WTO Members have the flexibility to interpret and implement the TRIPS provisions in a manner supportive of their right to protect public health.

187. The HLP Report recommended that WTO Members must make full use of the flexibilities in the TRIPS Agreement as confirmed by the Doha Declaration to promote access to health technologies when necessary. The following are some key recommendations of the Report, especially on TRIPS flexibilities and TRIPS-plus provisions:

- a. WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.
- b. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licences are left to the discretion of governments.
- c. WTO Members should revise the Paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license.
- d. Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.

- e. Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health.

188. At the side-event held today during the lunchbreak, we have also heard from the Co-Chair Ms. Ruth Dreifuss, former President of Switzerland, and other experts regarding proper implementation of the recommendations of the HLP Report for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.

189. At the last TRIPS Council meeting many Members stated that the HLP Report was still under consideration in their capitals. I would like to urge those Members to provide their comments on the HLP Report. At the subsequent sessions of the TRIPS Council, India would like to co-sponsor with like-minded Members sub-agenda items under the main agenda item "the United Nations Secretary-General's High Level Panel Report on Access to Medicines". Some sub-agenda items on which Members could share their experiences include specific recommendations of the HLP Report on patentability criteria, compulsory licenses, TRIPS-plus provisions in RTAs, etc.

### **12.2 Bangladesh on behalf of the LDC Group**

190. We just had a very good exchange during the last meeting on the Report and we are very happy to discuss the Report now. We consider that the Report of the High Level Panel is a significant and important step which has been long overdue, we admit that. Though we are now experiencing the highest level of scientific and technological development, this development is not even for everybody. For some this has even widened the existing divide. So it is a pity, that in spite of all these developments, we are yet to move forward to ensure the fundamental human right that is the right to health. LDCs have suffered most in the case of inequality, prejudice and unfairness in the multilateral system, and the issue of health was no different. Here the Report is very important for the LDCs, as observations and recommendations of the Report will be very useful for every country which considers the issue of access to medicines to be important.

191. The beauty of this Report is that it does not only deal with the existing multilateral agreements, rules and negotiations. It also sheds light on the current practices in international trade and commerce which in many cases may be contrary to the agreed international rules. The way the Report has been prepared, it cannot be said that the observations and recommendations are at variance with the current global IP regime. It calls for small rationalisation of IP regimes and its implementation, it examined all the possible causes for hindrances to access to medicines starting from policy making then the provisions of IP regime, profit motifs of the producers, determination of their cost of medicine and its development, strict provisions of some RTAs, transparency of the marketing of drugs, rewarding private funding and requirement of public funding for research and development. All these aspects were evaluated and considered when the public examined the issue of access to medicines. So it is not purely an IP issue, but many of the problems could be seen originating from or resulting ultimately into IP issues. We do not see the Report as an end in itself, as further discussion would clearly add to our comprehension and may make the recommendations even better.

192. Instead of just being critical about the Report we would be better off if we try to benefit from the useful elements of the Report, thus we may continue discussing the Report in the TRIPS Council in the future, for everybody's gain, as the Report has been prepared for the benefit of all in all countries, irrespective of the level of development.

### **12.3 Brazil**

193. As we all know, on 19 November 2015, the United Nations Secretary General Ban Ki-moon announced the creation of the High-Level Panel on Innovation and Access to Health Technologies. Responding to this invitation, two chairs were designated to the Panel, namely, Ms. Ruth Dreifuss, from Switzerland, and Mr Festus Mogae, from Botswana.

194. The Report of the UN Secretary-General's High-Level Panel was produced after extensive consultations. It builds on previous work in the field of health and has undergone a transparent, broad consultation process. Its expert advisory group comprised representatives from

governments and international organizations, as well as industry and civil society, promoting a comprehensive evaluation of the various aspects involved in this debate.

195. The document contains assessments and recommendations covering various aspects of access to medicines, an issue that must be examined from multiple perspectives. The complex interplay between the protection of intellectual property and the imperative of ensuring access to life-saving medicines is not a new issue. In the WTO, it dates back to at least 2001, when the Doha Declaration on TRIPS and Public Health was adopted by unanimous Decision; the Panel on the case "Canada – Pharmaceutical Patents", circulated in 2000, also addressed the topic. More recently, the United Nations' Sustainable Development Goals, unanimously adopted by all WTO Members' heads of state, also included the right to health as one of its priority, under Goal number 3.

196. The High-Level Panel was established to consider additional ways of providing incentives for both innovation and access. It is not a matter here of seeking the full endorsement of the Report itself, but of reviewing those individual recommendations related to the activities of the TRIPS Council. The inputs contained in the Report could provide further guidance for the discussion by WTO Members.

197. The High Level Panel states that WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening, thereby ensuring that only genuine innovations be awarded with patent rights.

198. The document further recommends the judicious use of the flexibilities contained in the TRIPS Agreement in order to ensure access to health technologies. In this regard, allow me to recall that exceptions and limitations to IP rights are intrinsic elements of the law of every Member. They are vital for striking a balance between the rights granted and the interests of society at large.

199. The Report also highlights that governments and private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Those types of strategies are against the spirit of the Doha Declaration and the TRIPS Agreement, in particular Articles 7 and 8. Nevertheless, this is something that has been observed in past years when WTO Members, including Brazil, initiated the procedures relevant for issuing a compulsory license in order to address urgent health needs.

200. Another TRIPS-related issue addressed by the Report is the recent entry into force of the Protocol of Amendment to the TRIPS Agreement. It demonstrates the need to have mechanisms that allow at the same time the adequate remuneration to intellectual property rights holders and the rights of governments to adopt measures necessary to protect public health, in line with the provisions of Article 8 of the TRIPS Agreement.

201. Brazil has a strong commitment to the improvement of public health and has been very active on guaranteeing access to medicines. In 2001, we were an active participant in the negotiations that resulted in the Doha Ministerial Declaration on TRIPs and Public Health.

202. Brazil believed then, as it believes now, that respect for intellectual property and efforts to ensure quality public health and access to medicines for all are not mutually exclusive. In our view, a balanced intellectual property system, with built-in flexibilities, as well as complementary policies and incentives, is the best way to promote innovation in all fields of technology, including the health sciences.

203. We encourage all WTO Members to join us in discussing the recommendations of the High Level Panel, as well as to share any other ideas that would bring us closer to our common goal of ensuring the highest health standards to the highest number of people.

204. Lastly, we would like to support continuing the discussion of the High Level Panel Report in the next session of the Council.

#### **12.4 South Africa**

205. South Africa is one of the co-sponsors of this agenda item, and I think in the last meeting we were quite encouraged by the number of delegations that took the floor and either indicated support for discussion of the topic, or indicated that they would revert to the next meeting to report back on feedback that they were awaiting from their capitals. It is rather disappointing to see that not many flags are up, but nonetheless I think in contextualising the topic that we have put on the table, we should not be paralysed by the fact that we refer to the United Nations High Level Panel on Access to Medicines. It frames a universal issue of access and equitability, it frames an issue of capacity, it also definitely impacts on the types of discussions that we have in this house. Given the fact that the Protocol has now come into effect, I believe that this discussion gives us an opportunity to put many of the issues on the table in respect of the efficacy of the System, in respect of many of the criticisms that have been expressed in respect of how the System specifically has been used.

206. Now of course, what we endeavour to do is to essentially create a platform to discuss a roundtable of many sub-issues as India has indicated, and this is also very closely linked to many of the other things that are happening in the Council. We had a short discussion this morning on Article 71.1, so practically from an implementation point of view, and from an assessment point of view, it is important for us to start talking about issues in this Council. The fact that things have been on the table for a long time and we get the standard responses we get in every meeting should be taken on and we believe that in revitalising our discussions in this Council we need to be able to discuss matters, even if they are difficult, in a constructive way and as a result of that we believe that further discussion of this particular topic is important. The context that we put in respect of this does not limit the discussion merely to some of the recommendations that have been made by the High Level Panel, but we necessarily may have to be more holistic and look at many of the other issues that we have not been able to discuss or where we have not been able to focus upon. Given this, we are happy to hear the views of other Members and we are also happy to support Brazil's proposal that we could continue this topic at the next meeting.

#### **12.5 China**

207. On 23 January 2017, the amended TRIPS Agreement entered into force. This is the very first amendment to WTO laws since the establishment of the WTO. China appreciates and welcomes it. China has always attached great attention to the issue of TRIPS and public health and believes that this amendment is helpful to secure a pathway to access to affordable medicines in the countries that lack medicine production capacity, and to overcome the public health difficulties in these countries.

208. Domestically, China has been using compulsory licensing, parallel imports and the Bolar exception which is permissible under TRIPS and the Doha Declaration on TRIPS and Public Health to promote access to medicines and secure public health. China's Patent Law and implementation regulation have specific provisions on compulsory licensing, which have been improved with the later amendments. In 2012, combining the related provisions, China issued the new detailed rules for compulsory licensing for easy operation.

209. The UN Secretary-General's High Level Panel Report on Access to Medicines gives various recommendations on promoting innovation, strengthening access to medicines, securing public health, which are of great value to the discussion on public health in the WTO. China notes that Members might have different views on the content and proposals in this Report, but still hopes that with this opportunity, Members could exchange views and experiences on how to take full advantage of the flexibilities in the TRIPS Agreement, and effectively address the public health issues.

#### **12.6 Indonesia**

210. Indonesia welcomes this agenda item and fully supports the ensuing discussion on IP laws and public health to take place in this Council. As a country with a population of 250 million people, the Indonesian Government sees the issue as a high priority and continues to work on policies that would help enhance pharmaceutical production, capacity to fulfil the need for affordable medicines and help technologies. IP protection is, indeed, an essential component for

fostering research and innovation needed in developing pharmaceutical products. However, for those products to effectively serve their purpose a balance must be maintained between the rights of IP holders and the rights of people to have access to affordable medicines.

211. In line with the TRIPS Agreement and the flexibilities contained therein, the Indonesian Government has enacted a number of policies and regulations to support the strengthening of Indonesia's capacity to provide medicines to its people. While providing protection to right holders, Indonesia is also attempting to provide more opportunities and to drive and facilitate research and innovation important for the development of pharmaceutical products. We believe that fostering innovation itself is equally important as providing IP protection and that the two concepts go hand-in-hand instead of subsequently. Indonesia supports that this agenda item be maintained for the next meeting of the TRIPS Council, especially with regard to the discussion on patent protection and the possible conflict with the right to health and how it relates to issue of encouraging new inventions and patent applications.

212. We would also support a discussion that addresses the issue of compulsory licensing and how it can be made effective, especially now that the Protocol amending the TRIPS Agreement is in effect. We are of the view that this discussion is important in order for us to serve better the legitimate rights of individual Members to adopt and implement flexibilities in the TRIPS Agreement and to enable every Member to draft and adopt national regulations that are effective.

### **12.7 Nigeria, on behalf of the African Group**

213. I did not have the intention to take the floor, but I am challenged by South Africa. I think it is clear when this Report came out, we were puzzled thinking about what really is going to be discussed in this Report. With the intervention by Brazil, things are becoming clearer. At least those issues or recommendations relating to the TRIPS Agreement can be discussed. We welcome, of course, the Report by High Level Panel and agree that those recommendations relating to the TRIPS Agreement be discussed in the TRIPS Council, in particular regarding the patentability criteria, that is the patent subject matter because it is good to share experience on that and what it entails. This concerns the issue of novelty, inventive steps, industrial application and disclosure of the patent. So we believe that the discussion would allow Members to appreciate each other's national law on these issues. Also, it would be good if we can look at the relevant provisions in bilateral agreements.

### **12.8 Egypt**

214. We would like to thank Brazil, India, China and South Africa for proposing this item on the agenda of our meeting today. As raised by the four countries, the Report of the UN Secretary General High Level Panel on Access to Medicines contains very important recommendations for both developing and least developed countries. Therefore, we urge the TRIPS Council to start studying the way to implement these recommendations, especially the one regarding the proposed cooperation between UNCTAD, UNDP, WTO, WIPO and other relevant organizations in order to support governments to apply public health patentability criteria.

### **12.9 United States**

215. Let me begin by reiterating that the United States is absolutely committed to working on and identifying practical ways to increase access to safe, effective, and affordable medicines around the world, and to support policies that drive development of new medicines. As we have made clear in our past statements and interventions on the United Nations Secretary-General's High-Level Panel on Access to Medicines, "the narrowly focused mandate of the Panel was flawed" and led to outcomes that fail to "adequately address this complex issue. The result includes conclusions that further this narrow perspective, raising fundamental questions regarding the legitimacy of those conclusions."

216. When this topic was discussed at the November 2016 TRIPS Council, there was lack of consensus and widely divergent views over the Report amongst WTO Members. Outside of the TRIPS Council, there has been no dearth of events held, articles written, and a wide variety of views and positions expressed. Similarly, parties have not found common ground on any of these issues. We further note that the Panel itself was unable to come to consensus on its key



recommendations, with two of the panellists — the two who had the most extensive experience in managing R&D portfolios — warning that the Report's recommendations could result in serious negative unintended consequences for research and development.

217. These concerns have also been expressed by a large group of stakeholders, including from the research-based biopharmaceutical industry, patients, research universities, and inventors.

218. We have, of course, listened to the interventions today, and do note that the Panel's work has been concluded. However, we have heard a wide range of proposals today. Before we end this discussion we would like to seek clarity as to what is being proposed. There has been at least three different pieces of proposals that have been voiced, and I think that we would definitely like to discuss that before we end this agenda item.

### **12.10 Japan**

219. The delegation of Japan shares the view that access to medicines is an important issue. From our experience, we have found that various factors, besides intellectual property, have a strong correlation with this issue.

220. We believe that financial incentives for the development of new drugs promote R&D and bring benefits to people around the world. Therefore, the appropriate protection of intellectual property rights plays a critical role in providing incentives to find innovative tools to save millions of lives in the world as has been the case. Although discussions on the issue of access to medicines have been conducted at several organizations of the United Nations including the World Health Organization (WHO), it seems that the results of these discussions have not been sufficiently reflected in the High Level Panel Report. For example, the joint report made by the WHO, WIPO, and WTO in 2013 reported that "the WHO framework for access to medicines recognizes that lack of access to medical technologies is rarely due to a single isolated factor and thus includes rational selection and use of medicines".

221. Japan shares the view of the importance of dealing with the issue of access to medicines for orphan diseases, neglected tropical diseases, and other diseases lacking market incentives as raised in the Report. However, the scope of the Report is rather limited, focusing only on "policy incoherencies between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies". We believe that access to medicines is affected by a variety of other factors such as health systems governance, the quality and quantity of human resources for health, access to medical facilities, and supply systems of medicines in the country. Furthermore, Japan would like to point out that the recommendation of this Report neither reflects the opinions of, nor has been endorsed by, UN Members working to solve the issue by supporting global health.

222. While this delegation does not intend an in-depth substantive discussion, we believe that this issue could be dealt with more effectively by taking a more comprehensive approach towards the multiple factors already discovered in the existing work, rather than focusing on the narrow issues considered in the High Level Panel Report.

### **12.11 Canada**

223. The Government of Canada considers access to medicines to be a key priority in our ongoing efforts to promote global health and prosperity, and welcomes the attention that the Report of the UN Secretary General's High-Level Panel on Access to Medicines has drawn to this important issue.

224. The Government of Canada continues to review the detailed Report of the High-Level Panel and its various recommendations. For Canada, these recommendations touch upon a variety of complex domestic policies, laws, and regulations, not only in respect of IP, but also areas such as pricing, public funding for research and development, governance, accountability, and transparency, and which fall under the responsibility of a variety of Federal Government departments and agencies.

225. While there are a number of recommendations that are not in line with our current practice, there are also other recommendations that may be consistent with the Government of Canada's

approach to the promotion of access to medicines and which we continue to reflect upon. The Government of Canada will therefore require further time to consider the Report's recommendations in more detail. At the same time, Canada is pleased to participate in discussions on this issue today.

226. Canada recognizes that improving access to medicines needs to be achieved through the promotion of health equity, stronger health systems, and universal health coverage. Indeed, Canada's international development priorities and significant investments in strengthening health systems and the health and rights of women and children are contributing to improved access in this regard.

227. Canada is a global leader in supporting partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Drug Facility; and Gavi, The Vaccine Alliance, which strengthens health systems and provides targeted programming to increase access to medicines and vaccines. In September 2016, Canada hosted the Fifth Replenishment Conference of the Global Fund, and pledged CAD \$804 million (or roughly USD \$613 million) for 2017 to 2019. Canada is also the sixth largest donor to Gavi, having pledged CAD \$520 million (or USD \$396 million) for the 2016-2020 period.

228. Once again, Canada is pleased to be part of the discussion on this important issue, and to have the opportunity to share our own experiences on the promotion of access to medicines. Along these lines, Canada looks forward to learning more about the views of other Members as they continue to reflect on the various recommendations made in the Report of the High-Level Panel.

#### **12.12 Korea, Republic of**

229. Korea is open-minded to any discussion for promoting innovation and public health which are essential elements for sustainable development. So Korea once again welcomes the entry into force of the TRIPS Amendment which is a significant achievement for the WTO and public health.

230. Regarding the proposal, Korea is still reviewing the elements raised in the High Level Report and at this Council meeting. At this stage, Korea believes that our work should focus on the implementation of the TRIPS Amendment while encouraging the Members which have not yet ratified the Protocol to do so.

#### **12.13 Norway**

231. Norway attaches great importance to tackling global health challenges, including providing access to affordable medicines for all. There are various and complex reasons behind the problem that many people around the world, especially in least developed and low-income countries, do not have access to the medicines and vaccines they need. This access depends, among other factors, on regulatory frameworks, prices, procurement systems, systems for distribution of medicines to the clinics, and the presence of qualified health personnel. This complexity requires a balanced discussion.

232. The UNSG's High-Level Panel Report focuses mainly on intellectual property rights, which is only one of several elements that influence the prices of medicines and vaccines. Moreover, it seems to us that the Report does not give a fully representative picture regarding the role of patents and related intellectual property rights in providing access to medicines. The Report seems to focus too narrowly on negative aspects. However, the system is also contributing to bringing new medicines to the market.

233. A narrow focus on negative aspects of the system is not conducive. We need in our view to take a broader perspective – which includes other important elements that influence access to medicines, and I mentioned some of them at the beginning of my intervention. Norway supports several international initiatives which work to improve these challenges – for instance: UNITAID, Medicines Patent Pool, and WAMBO.org within The Global Fund to Fight AIDS, Tuberculosis and Malaria.

234. As for the continued discussion on the interface between IPRs and health here in the WTO, it is Norway's opinion that it would be more fruitful to take as point of departure the joint study by

the WTO, the WHO and WIPO from 2013: *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*.

#### **12.14 European Union**

235. In the interest of time, and since our statement is actually the same as in the last TRIPS Council, I would simply like to refer to it. It can also be downloaded free of any copyright issues from our EU delegation website, and at the request of Members we can also make it available to the Secretariat for circulation.

#### **12.15 Switzerland**

236. My delegation also refers to its intervention on this ad hoc agenda item at the last TRIPS Council meeting. Let me recall today just two points: the access to medicines discussion is an important one. Switzerland has been fully supportive, committed and actively participating in all mandated work that this Council has done on IP and access to medicines in the WTO and TRIPS context. I refer, in particular, to the negotiations leading to the Paragraph 6 System and its introduction into the TRIPS Agreement through Article 31*bis*. Obviously, Switzerland's commitment applies similarly to the relevant work on access to medicines at the WHO, which Switzerland considers to be the core competent international organization for access to medicines issues, and it also extends to WIPO, when IP aspects have been primarily concerned.

237. Concerning the HLP Report on Access to Medicines, we recall that it was not mandated by WTO Members or commissioned by UN Member States. The Report has no formal status in this Organization. Other reports on IP and access to medicines have been commissioned and published by dedicated panels and groups over the years. The TRIPS Council did not consider these reports or their recommendations and conclusions as instructing the Council's discussion.

#### **12.16 Australia**

238. Australia welcomes the opportunity to discuss issues relating to access to medicines and health technologies for developing and least developed countries. The challenges faced by least developed countries in tackling disease and illness are vast and ongoing and access to medicines and health technologies is critical to helping to address those challenges.

239. Australia's commitment to access to medicines at home and abroad is reflected by its positive contributions in this area. These include Australia's AUD\$30 million funding to support Product Development Partnerships, in particular partnerships which are in the later stages of product development and that have prospects of bringing new diagnostic tests and drugs to market to address tuberculosis and malaria; Australia's award in 2016 of a further AUD\$2 million in funding for the Tropical Disease Research Regional Collaboration Initiative; and Australia's support of the WIPO Re:Search Project, which promotes research and development to address neglected tropical diseases, malaria and tuberculosis in developing and least developed countries.

240. Underlying many of these contributions, and critical to improving health outcomes, is health and medical research and innovation and a key part of this is having in place effective and balanced intellectual property systems. Australia notes existing TRIPS flexibilities and welcomes, in particular, the recent entry into force of the TRIPS Protocol. Australia supports utilisation of TRIPS flexibilities to the extent possible and we are open to hearing Members' experiences of utilising the TRIPS flexibilities.

241. More broadly, Australia's view is that IP is only one factor of many that can affect access to medicines and a narrow focus on intellectual property can only be of limited value where it does not take into account the interplay of many other factors. As the High Level Panel acknowledges, there are a range of factors that can affect access to medicines, including under-resourced healthcare systems, workers and education, and regulatory barriers and insurance issues. In this regard, we note the cooperative efforts between the WTO, WIPO and the WHO, including their trilateral report on Promoting Access to Medical Technologies and Innovation.

242. In Australia's view, the response to the access to medicines issue requires a holistic approach cognisant of all relevant issues – not just intellectual property. We look forward to hearing other Members' views on this agenda item.

#### **12.17 Chinese Taipei**

243. Public health problems afflict many developing and least developed countries. We would like to highlight the need for the TRIPS Agreement to be part of the wider national and international action to address these problems. We would also like to emphasize that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health and, in particular, to promote access to medicines for all.

244. My delegation supports the Paragraph 6 System and attaches great importance to improving access to medicines, particularly in low-income countries.

#### **12.18 Chile**

245. Access to medicines is a very important issue for our delegation. We note that the High Level Panel Report, regardless of its legal quality or validity, contains valuable elements for discussion within the WTO framework. Our delegation therefore stands ready to address and discuss the elements of the Report in an open and non-binding manner, with, for instance, WTO Members sharing their experiences of these elements.

#### **12.19 Brazil**

246. I would like to quickly respond to some aspects raised by delegations on this agenda item. The first one is that IP is one of many factors affecting access to medicines. As we have mentioned in our statement we do not dispute this fact, however, this is the Council for TRIPS. Under its mandate, it is intellectual property and that is why we should discuss, in our view, the IP-related aspects of the Report.

247. Another point mentions the other documents and reports circulated on the matter and the lack of discussion in this Council. Brazil would very much welcome delegations to propose discussion of those reports. However, that is not what we have seen during the last years. The last aspect I would like to raise is the lack of consensus and divergent views on the Report. In our view this underlines the complexity of the issue and the need to further continue the discussion on the matter.

#### **12.20 WHO Secretariat**

248. We very much welcome the opportunity to continue the discussions on the High Level Panel Report. Since the last discussions, WHO Member States seized the opportunity to discuss the HLP Report at the WHO Executive Board meeting in January. The Executive Board also decided that the HLP Report should be discussed again by the World Health Assembly in May 2017.

249. We will not repeat our statement on the different recommendations of the High-Level Panel Report, but would like to refer to our statement as reproduced in the minutes of the last meeting. We would like to seize the opportunity to welcome, in particular, the call of the Panel Report for more transparency on prices. One of the High Level Panel recommendations to WHO is to set up a global pricing database. This recommendation ties very well with activities already ongoing at WHO. Indeed, the WHO Global Price Reporting Mechanism provides pricing and procurement data for HIV; TB and malaria treatment and has recently been expanded to include the new hepatitis C treatments.

250. WHO has set up a comprehensive web platform that provides information on vaccine product, price and procurement data with the goal of increasing price transparency and informing decisions around vaccine introduction and implementation.

251. In the framework of our new initiative on Fair Pricing, we are assessing the production costs of essential medicines. This will allow procurement agencies to better evaluate their performance

and will contribute to the overall objective of transparency. The Fair Pricing Forum will be co-hosted by WHO and the Government of the Netherlands on 10-11 May in the Netherlands.

252. One of the main themes of the HLP is the call for more policy coherence. As a response to this call, WHO took the initiative in December 2016 to call for an "all agency meeting" with UNDP, UNAIDS, UNCTAD, WTO, WIPO; High Commissioner for Human Rights and UNITAID to discuss the different activities and plan for the future, including how to best follow up on the HLP Report.

253. Access to medicines is a complex issue. The WHO Secretariat commits to pursue its efforts to ensure access for all to needed medicines, including through providing assistance to its Member States on using all possible means to achieve access to essential medicines. Without this, there shall be no Universal Health Coverage.

#### **12.21 Chair**

254. Now that we are coming back to the discussion of the various statements that we have heard, obviously we have divergent opinions; some delegations feel that it would be useful to have greater discussion on this issue, others feel that more time is needed. Various delegations would like to revert to the issue, but we do have a request from the United States to clarify some of the proposals and suggestions that have been made.

#### **12.22 South Africa**

255. In terms of the agenda item, as one of the co-sponsors, we had requested a continuation of discussion, given the fact that many delegations had indicated that they were still in contact with their capitals and would revert at the next meeting, so we expected that such delegations would have come back during this meeting. Also given the fact that this is an ad hoc item, an item which has been described in respect of the procedural rules, the question arises whether or not, it would be clear that a further continuation would be appropriate. Given your comments, and also some of the other comments, we have two possibilities: should such delegations still wish to revert back to this particular item, we could inscribe a continuation of discussion of this topic on the agenda of our next meeting. If this is not the case, of course, the other option, as India had indicated, would be that proponents of this item use the High Level Panel Report as an appropriate peg to highlight many of the issues that are relevant to the TRIPS Council; many delegations have also indicated that some of the recommendations are specifically directed at the work that we deliberate on.

256. Given this fact, if there is no continuation of this particular topic, I think it would be incumbent on the proponents for the next meeting, once again, to place an item on the agenda that proposes to look at aspects of access to medicines and of course this proposal would be elucidated and described within an appropriate context, perhaps with another document outlining some of the topics that we would like to discuss, and to cover not only the next meeting, but the following meeting. I think those are the two possibilities, and we would be happy to hear what other Members think of this.

#### **12.23 United States**

257. It is really up to the proponents of the item to determine which way they would like to proceed. Our only perspective that we can offer is that we follow the agreed-upon rules of procedure which details how ad hoc items are to be placed on the agenda. Like for many Members who have inscribed items, there is usually a process before the notification is sent out by the Secretariat of providing a paper and providing the details about the proposal for discussion, to allow all interested delegations to prepare back in capital. So our view is that if this is to be placed on the agenda again, then we follow the rules of procedure, and there be again more detail about what is proposed to be discussed.

#### **12.24 European Union**

258. Just to say that we support the United States on that topic.

### **12.25 Chair**

259. The Council takes notes of the comments that have been made. It would not be appropriate for me to decide what Members want to do with respect to the continuation of this discussion that we have been looking at today. I do understand that there are various options. Last time the Council agreed to include the ad hoc item on today's agenda. South Africa has mentioned a couple of options, and in order not to take on board the prerogatives of Members, I would like to suggest to the sponsors, the proponents that they may have some suggestion on how we should move forward in the future, on the future agenda. If not, all I can do is to say that we will have to discuss this to see how we can proceed. This could be included as an ad hoc issue on a future agenda, if that is what Members want.

### **12.26 Switzerland**

260. We have understood from the discussion today that a number of delegations have raised questions with regard to the Report being the basis for the Council discussions. We have also heard various proposals what could be discussed in the future under an ad hoc agenda item, and I believe that it would therefore be the most straightforward way if proponents wish to table an ad hoc agenda item at the future Council meeting again, they are obviously free to do so. But we suggest that this be done according to the normal procedures for an ad hoc agenda item, and not by a Council decision today.

### **12.27 South Africa**

261. Having heard all the relevant opinions and in the interest of time and efficiency, I think the proponents will in due course circulate a new communication on the scope of the discussion that we would like to enter into, and so from that perspective we believe that a continuation of this topic may not be entirely necessary.

## **AGENDA ITEM 13: WORK PROGRAMME ON ELECTRONIC COMMERCE**

### **13.1 Brazil**

262. Thank you for introducing this item requested by Brazil. I think you gave a very good historical background on the issue of the work programme, which is why we are asking for this agenda item. We have two co-sponsored documents: The first, on copyright, is co-sponsored by Argentina and the second is co-sponsored by Argentina, Paraguay and Brazil. The two topics have been identified under the dedicated discussion of the General Council as topics related to the issue of e-commerce, and both documents here are being submitted to the TRIPS Council in order to give the opportunity to Members to get acquainted with the message we want to convey and to give us the opportunity to clarify and to answer questions. We are going to present both documents, and will be more than happy to respond to questions or requests for clarifications. I will ask my colleague to introduce the document on copyright and I will myself introduce the second one afterwards.

263. Thank you for this opportunity to present our document on electronic commerce and copyright. It responds to the invitation of the work programme on electronic commerce to examine and debate trade-related issues of global e-commerce. We wish to launch a comprehensive discussion of copyright management in the digital environment and we invite delegations to express their views on this important subject.

264. Recent advances in technology have enabled the creation of business models based on the use of copyrighted works in digital platforms. Unlike the physical environment, access to such works is gained without transfer of ownership or possession of the work by the final user. Those innovative business models create new forms of rights management, generating opportunities and challenges for all participants in the creative process. The success of these new models was underlined in 2015, when the digital market surpassed sales of physical formats and became the primary source of revenue for recorded music.

265. Legitimate concerns are being raised at national and international level regarding the remuneration of copyrighted works. Digital platforms affirm that most of their revenue is being

distributed as royalties, but authors and performers complain about lack of remuneration. Likewise, producers and the cultural industry highlight a "value gap" in the amount due for the rights.

266. The modern music business involves a huge number of micro-transactions, in which stakeholders receive fractions of the revenue generated. New technologies would normally be associated to more transparency, but actually we are seeing the opposite: opaque contractual frameworks create an obstacle for the due diligence of creators and artists when considering the commercialization of their work.

267. Brazil argues that a first possible decision on copyright management for fair payments could stress the importance of transparency in the remuneration of copyright and related works in the digital environment. This would allow creators and artists to properly understand the payments and accounts they receive.

268. Copyright laws recognize certain limitations on economic rights of protected works. Those limitations have the character of public interest, in that they strike a balance between the interest of rightholders and the users of such works. For this reason, they are present in the legislations of all Members.

269. In the business model of digital platforms, technological protection measures (TPMs) are widely used, offering an almost absolute control of digital intellectual goods. However, TPMs in the physical environment were already considered an obstacle to the exercise of some legitimate uses defined as limitations or exceptions to copyright by national legislations. This is magnified in the digital environment and may halt even the simplest operations, such as the interoperability and portability of digital goods.

270. There is a growing concern that obligations related to the inviolability of TPMs might exclude the possibility of enjoying exceptions and limitations in the digital environment. These technologies are essential for the normal exploitation of the work in e-trade and its circumvention could be understood as a breach of international obligations (step 2 of the three step test). Therefore, the second collective initiative suggested in our document to improve management of copyright in the digital environment is to clearly assert that exceptions and limitations available in physical formats should also be available in the digital environment.

271. Finally, the last aspect of the document relates to the territoriality of copyright. The digital environment is borderless by its nature while the copyright system is based on national laws. These different characteristics make more challenging the task of implementing the shared objective of protecting authors, performers and other copyright holders in the digital environment. Payments to digital platforms, for instance, can be made through international credit cards, bypassing the law in the country of access to the creative content.

272. It is thus suggested that Members reaffirm the territoriality of copyright as a principle of the international trading system, making their national copyright legislation applicable to trade relations where content is accessed from within their national borders.

273. The three areas highlighted should be considered building blocks of a sound business environment for the international trade of intellectual goods. They should continue to be explored in order to find common understanding among Members and to provide the General Council with the information necessary to consider the way forward on the matter.

274. Let me now turn to document JOB/IP/20, co-sponsored by Argentina, Paraguay and Brazil. It is based on the resolution adopted by MERCOSUR in 2006, which means that this text has been negotiated among developing countries. This is a proposal on how a technical issue can be handled from a trade-related perspective. Although technical, this issue is of great importance not only to e-commerce, but to the digital economy in general, because electronic signatures ensure the digital identity of whoever is using the Internet or doing electronic transactions. Needless to say, in order to have legally valid effects, the certainty of the recipient on the other side of the internet that this is the person it is claiming to be, is very important in the digital environment. The insurance of the digital identity of a person therefore has cross-cutting utility.

275. One common and very important application of this digital identity is in e-government solutions. For instance, if we take the communication from India suggesting a trade facilitation agreement for services, in one of the sections, Paragraph 10.3 of the proposal, there is the suggestion of electronic application of documents. If that submission of electronic documents is backed by a digital identity, via an advanced electronic certificate, this would increase certainty of the system and would make it more reliable, both to the government and to the users. I do not intend to go through to the paragraphs or the articles of the proposal, but I am more than happy to clarify any questions that Members might have in this regard.

### **13.2 Argentina**

276. Argentina is grateful to Brazil for including this item in the agenda as it provides an opportunity to continue discussions on this important issue. Progress in technology and communications makes electronic commerce increasingly important for all countries. Argentina is not immune to this phenomenon. Our country attaches great importance to this issue, having played an active role, in MERCOSUR in particular, in putting forward proposals and measures to promote the development of electronic commerce in the region.

277. Document JOB/IP/19 identifies three areas of possible convergence concerning copyright in a digital environment: transparency of payment for copyright and related rights; balance of rights and obligations; and territoriality of copyright. Argentina shares the views expressed by Brazil in this document and has asked to be included as a co-sponsor.

278. Document JOB/IP/20, co-sponsored by Argentina, Brazil and Paraguay, introduces a pertinent question in relation to the discussions on the work programme on electronic commerce, namely electronic signatures. Argentina was one of the first countries in the region to adopt national standards on electronic signatures and protection of personal data. Digital signatures are governed by Law No. 25.506, approved and enacted in 2001. The Law determines various concepts, differentiating between digital signatures and electronic signatures. A digital signature is comparable to a handwritten signature as a result of the use of digital certificates, which contain data identifying the owner of the signature. Digital certificates, issued by registered certifiers authorized for this purpose, enable a third party to establish the authenticity of a signatory and detect any alterations to electronic documents signed digitally. By circulating Resolution GMC 37/06, which deals with the question of digital signatures within MERCOSUR, we hope to contribute towards the discussions on this issue.

279. Lastly, we should like to emphasize that, being a member of the Group of Friends for E-Commerce for Development, Argentina is ready to make a constructive contribution in order to move ahead on this issue.

### **13.3 Paraguay**

280. Paraguay welcomes the contribution on electronic commerce and copyright (JOB/IP/19), which describes three areas of possible convergence in the WTO as regards existing links between electronic commerce and copyright. As stated in the aforementioned document, new technologies continue to transform business models and copyright management, for right-holders, businessmen, users and regulatory bodies. Paraguay therefore supports the idea of making this system more transparent through the voluntary notification of national and regional legislation, regulations or systems relating to the management of copyright in the digital environment.

281. Moving on to the communication on electronic signatures (JOB/IP/20), the delegation of Paraguay endorses and supports Brazil's statements, this being a matter of interest identified by various WTO Members.

282. For instance, document JOB/IP/21, entitled "Trade Policy, the WTO, and the Digital Economy", refers to the recognition of e-signatures and authentication in its "Regulatory Frameworks" box. The recognition of e-signatures could serve as a trade facilitation tool, as it seeks to ensure the authenticity, integrity and privacy of online cross-border transactions and communications, thereby providing greater security and predictability for users. Notifying this Council of similar regulations will facilitate comparisons and discussion regarding the use of



e-signatures, and we therefore encourage further analysis of this issue on the basis of contributions from other Members.

283. Lastly, another interesting aspect of document JOB/IP/21, which Paraguay co-sponsors, is the idea of increasing dialogue with other international bodies engaged in work on the digital economy. Within the framework of the Work Programme on Electronic Commerce, and given its importance in the discussion in this Council, we consider it important to listen to any initiatives and comments from the WIPO Secretariat in respect of the digital economy and existing links between intellectual property and electronic commerce, both in terms of international agreements and cooperation projects.

#### **13.4 Bangladesh on behalf of the LDC Group**

284. I thank all the proponents for their very informative submissions which draw our attention to the fact that E-commerce will soon be a key factor in our lives. Better preparation will enable us to better benefit from e-commerce in the future. Global e-commerce is still a fledging issue and the participation of LDCs is rather limited because of capacity constraints. However, while we chart our route for a future negotiation based on the proposals and information submitted by the proponents, LDCs would like to recall that universally agreed special and differential treatment for LDCs must be applied, especially in the case of technological protection measures that have been mentioned by Brazil. We also support the application of national copyright legislation if the content is accessed within the national borders, as mentioned in one of the documents.

#### **13.5 Switzerland**

285. We have studied the national and regional experiences and practices contained in the different submissions with great interest. We consider each of the topics treated as relevant in the context of international trade, and thank the delegations and co-sponsors for their communications.

286. I am going to comment in particular on the three Communications on E-Commerce and Copyright (JOB/IP/19), E-Commerce and Electronic Signatures (JOB/IP/20), as well as on E-Commerce and Development (JOB/IP/22).

287. On E-Commerce and Copyright: We recall that the WIPO Standing Committee on Copyright and Related Rights (SCCR) has already taken up specific questions related to copyright, the applicable law and the *lex fori*. Obviously, duplication of the discussion in the WIPO, *vis-à-vis* more trade-related aspects here in the WTO, needs to be avoided. It has become clear that the topics addressed in JOB/IP/19 are quite complex and broad, considering the wide array of different *national approaches* and conflict-of-law regimes. From a regional perspective, for Switzerland and most European countries the Lugano or the Brussels Convention on the jurisdiction and enforcement of judgments in civil and commercial matters of 1988 apply in this context. We will follow the discussions in the WIPO and also here in this Council closely and with interest.

288. On E-commerce and Electronic Signatures: Switzerland has a new federal law on certification services in electronic signatures and other digital certificates that has come into force this year, on 1 January 2017. The new law assigns, under certain conditions, equal status to the electronic signature and a handwritten signature. To promote digital trade in Switzerland, the legislator allows Certification Service Providers to be recognized by an accredited federal government agency. The Certification Service Providers verify electronic data and issue digital certificates. There are a number of other aspects to our national regime and some may be relevant in the wider IP context. Our delegation is interested to hear about other regimes, and about how they may interlink with aspects of intellectual property and the work of the TRIPS Council.

289. It is also with particular interest that we have studied communication JOB/IP/22 on E-Commerce and Development, which outlines the potential that e-commerce may offer for MSMEs in middle and low-income countries. In the past, the TRIPS Council in its discussion on IP and Innovation already touched on a number of aspects which have been raised in the present communication, e.g. the potential that mobile apps bear, and the opportunity which e-commerce tools presents for small business operators to more easily enter the market at low cost.

290. Switzerland agrees that the topic of e-commerce is relevant for MSMEs in particular. The WTO and the TRIPS Council should take into account this interest of MSMEs. It is noteworthy that MSMEs are the backbone of any economy, also of the Swiss economy. Our delegation stands ready to enter into more substantive discussion and to further explore related aspects at the intersection of IP and digital trade. Aspects which the TRIPS Council deems to be important and which lie within its mandate.

### **13.6 United States**

291. The United States is encouraged by the energy WTO Members have devoted to the Work Programme on Electronic Commerce in advance of MC11. We also note that there is a wealth of work going on regarding this very important issue in other institutions, indeed as the delegation of Switzerland just noted, at WIPO, for example.

292. The United States places a strong importance on e-commerce issues and on ensuring that e-commerce and digital trade realize their promise as an engine of economic growth while fully respecting intellectual property rights. Intellectual property, including copyrights, patents, trademarks, and trade secrets, have contributed to vibrant marketplaces of ideas, creative content, and the delivery of a diverse range of products. With the explosive growth of the Internet, there are more global opportunities and challenges for providing legitimate content to users through electronic and physical means.

293. The United States supports the work of the E-Commerce Work Programme to identify possible new approaches to these issues while consulting closely with this Council to ensure that our consensus views are taken into account.

294. With respect to two of the papers that were presented for this meeting, we would like to make two brief remarks. First, with respect to the delegation of Brazil's E-commerce and copyright proposal, we sincerely appreciate the communication that was prepared by the delegation of Brazil to share their views and put forward suggestions relating to e-commerce and copyright. We continue to study the paper and some of the concepts noted, and may revert back to the delegation inter-sessionally to request clarification on certain concepts contained in the proposal.

295. With respect to the Communication from Argentina, Brazil and Paraguay on Electronic Signatures, we also welcome the information shared with this Council on electronic signature issues and very much appreciate the input. While we take note of the important role electronic signatures already plays in facilitating trade and commerce on the internet, we recognize that our colleagues in other WTO bodies may well be best suited to consider the issues raised in this paper. The general approach of the United States is to accept the legal validity of electronic signatures, provided that both parties to a transaction have mutually agreed upon its acceptability. With respect to IP, I would like to share that the US Patent and Trademark Office has for ten years accepted electronic signatures. The United States is happy to share further details on this issue inter-sessionally for any delegation that is interested.

### **13.7 Norway**

296. Norway would like to thank the delegations for the Communications they have submitted. The delegation of Norway would like to state that we should aim to find elements of commonality in the proposals, elements of importance for both trade in goods and services, for e-commerce to work to the benefit of all, especially developing countries and LDCs.

297. We should also seek to find areas where WTO rules and guidelines can make a difference, a difference in the sense that it pushes Members to put in place the necessary domestic rules that will help enhance each Member's capacity for international trade through e-commerce. If we can agree on just a few such elements in the coming year, this would be real progress.

### **13.8 European Union**

298. The EU considers e-commerce as one of the important topics of future WTO work. This is the area where achieving progress could benefit the membership at large, and provide tangible results for our economies and citizens, both in developed countries as well as in developing countries. The

digital economy has developed remarkably in the past decades, our trade practices have evolved accordingly to capture those developments, but only limited progress has been achieved in the WTO. The major gaps in the multilateral rulebook have been acknowledged by many in the post-Nairobi discussions, with Members indicating their interest and readiness to look into this issue in the WTO context more thoroughly than in the past. This interest has been demonstrated by numerous submissions in the context of the E-Commerce Work Programme last year.

299. To facilitate the discussions on the potential WTO work in this area, the EU and other co-sponsors of the communication JOB/IP/21 attempted mapping trade policy-related issues that impact e-commerce. This communication was originally submitted in the context of the E-Commerce Work Programme in July 2016. However, since a number of Members considered it useful to have technical discussions on e-commerce in regular committees we have submitted our communication to the GC, CTS, CTG and CTD. We consider it also useful in the TRIPS Council context.

300. Turning to the substance of our submission, it includes a list of elements of trade policy that are relevant for e-commerce including the rule making, liberalization commitments as well as facilitation measures. The development dimension cuts across the entire list of issues. As indicated in the paper, the submission does not present an exhaustive list of issues, it is not a negotiating proposal, and is without prejudice to what elements the co-sponsors would seek to pursue.

301. This paper is meant to be a starting point of a conversation. For the sake of discussion we have tentatively grouped all the elements we have identified around four clusters:

- a. All that pertains to rules that enhance transparency and promote the confidence of consumers, i.e. consumer protection, privacy, spam etc., or that facilitate trade by ensuring that regulatory barriers are addressed, such as for electronic payments or access to the internet.
- b. Open markets, which covers liberalization measures, both in the form of bindings for goods and services, and of measures addressing trade barriers in relation to data flow, localisation requirements or source code.
- c. Initiatives facilitating the development of e-commerce beyond rules and liberalization measures; e.g. many initiatives contribute to enhancing e-commerce, regulatory cooperation, customs facilitation measures or technical assistance.
- d. Enhanced transparency at the WTO where we have identified a series of ideas on how the WTO can continue to play an important role in enhancing transparency of Members' policies that relate to e-commerce.

302. Against this backdrop, the co-sponsors invite WTO Members to consider a series of questions, notably with respect to this mapping exercise, and to come forward with more ideas as well as comments and questions in order to continue a focused technical work. We particularly invite Members to reflect if there are additional e-commerce-related elements of trade policy which should be included in the mapping, and on what elements would Members wish to have focused technical discussions in the Council for Trade-Related Aspects of Intellectual Property Rights.

303. Many will agree that e-commerce is an area where the WTO could demonstrate its continued relevance in the modern economy and we suggest that WTO Members actively engage in defining the longer term priorities and potential short term deliverables to be considered for negotiations in the respective negotiating bodies.

### **13.9 Singapore**

304. We are introducing document JOB/IP/22 on behalf of 13 developing country Members: Colombia, Costa Rica, Hong Kong, Israel, Malaysia, Mexico, Nigeria, Qatar, Singapore, Brunei, Seychelles, Pakistan and Turkey.

305. This paper was first circulated at the Dedicated Discussion last July, and has now been re-circulated at the TRIPS Council, CTD, CTS, and CTG. Our motivation in tabling this paper

remains the same – to help spur further discussion and reflection on e-commerce, especially on the nexus between development and e-commerce. In this regard, we had sought to identify a few potential areas of interest relevant to developing countries in the e-commerce space.

306. E-commerce has opened up opportunities for businesses, especially MSMEs, and allowed them to reduce their cost of doing business and to reach beyond their own backyards. This has happened not just in the developed countries, but also in developing countries. That said, the conduct of e-commerce in developing countries has certain unique characteristics. For instance, cash-on-delivery is still prevalent in the conduct of e-commerce in many developing countries. Connectivity and access to reliable communication networks have posed particular challenges, but have also provided innovative opportunities for businesses.

307. We therefore urge members to use the opportunity of the re-circulation of this paper to engage substantively at the technical level, to share on areas/elements of interests, as well as the challenges they face in leveraging e-commerce. Enhanced information and experience sharing will help us all better understand and identify where the WTO can help us achieve our trade policy objectives in e-commerce.

308. The co-sponsors of this paper stand ready to work with other interested delegations to take forward work in this area.

### **13.10 Chinese Taipei**

309. My delegation joins others in thanking all the proponents for the proposals on the Work Programme on Electronic Commerce. Today, we have some comments on Brazil's proposal, JOB/IP/19.

310. We consider that "value gap" occurs when a platform operator makes profit by using works of a right holder via a certain business model, but refuses to pay royalties that are generally the result of negotiation. We look forward to more discussions among Members on how to deal with the tension between value gap and safe harbour.

311. Regarding copyright remuneration in the digital environment, we also consider that more efforts are needed to establish a fair remuneration mechanism to be in line with the principle of free market. We still have some comments on the balance of rights and obligations, and territoriality of copyright in regard to this proposal.

312. We look forward to exchanging points of view with Brazil and other proponents on the proposals. We will continue our engagement with you and fellow-Members on all aspects of this most important topic of e-commerce, and endeavor to contribute as constructively as possible.

### **13.11 Canada**

313. Canada remains encouraged by the positive discussion and exchange of national experiences on IP and e-commerce issues under this item. On that note, Canada would like to thank Brazil for circulating its communication on "E-commerce and Copyright" (JOB/IP/19), and for sharing its own national experiences on a number of emerging copyright issues in the digital environment. Canada would also like to thank the co-sponsors of the papers on "Electronic Signatures" (JOB/IP/20) and "E-Commerce and Development" (JOB/IP/22), which serve to highlight the broad range of issues addressed by electronic commerce and digital trade.

314. As co-sponsors of our re-circulated General Council paper on "Trade Policy, the WTO and the Digital Economy" (JOB/IP/21), Canada aligns itself with the EU intervention. As expressed by the EU, we are mindful of the views expressed by a number of delegations that e-commerce discussions should be managed in a bottom-up fashion with relevant bodies taking up specific topics, and we have re-circulated our paper accordingly to stimulate substantive discussion in those bodies. Canada remains of the view that the TRIPS Council can usefully contribute to the objectives of the 1998 WTO Work Programme on Electronic Commerce, by way of sharing national experiences and practices on IP and e-commerce, with a view to informing and enriching Members' policy development. To be clear, and further to some of the interventions made by Members in recent meetings of the TRIPS Council, Canada remains of the view that sharing national

experiences and practices on IP and e-commerce would be undertaken on a non-prejudicial basis and in a non-negotiating manner. Along these lines, Canada also remains mindful that discussions on issues such as copyright in the digital environment are underway in other international institutional fora elsewhere, such as the WIPO Standing Committee on Copyright and Related Rights.

315. Members will recall that the Nairobi Ministerial Decision of 19 December 2015 decided to continue the Work Programme "based on the existing mandate and guidelines and on the basis of proposals submitted by Members in the relevant WTO bodies as set out in paragraphs 2 to 5 of the Work Programme" (WT/MIN(15)/42). With respect to IP, the Work Programme tasks the TRIPS Council with "examin[ing] and report[ing] on: protection and enforcement of copyright and related rights; protection and enforcement of trademarks; [and] new technologies and access to technology". Canada's view remains that these topics remain sufficiently broad to foster discussion across a range of IP and e-commerce issues, drawing from Members' national experiences and practices in these areas.

316. Canada remains open to the views of other Members as to how discussions on e-commerce and IP might be structured, with a view to fulfilling the Ministerial guidance on this issue. We would like to thank Members once again for their constructive interventions on this issue so far, and look forward to hearing views on e-commerce and IP topics for consideration in future sessions of the TRIPS Council.

### **13.12 Moldova, Republic of**

317. The Moldovan delegation would like to join the proposal and the Communication JOB/IP/21 regarding the Work Programme on Electronic Commerce, co-sponsored by Canada, Chile, Colombia, Côte d'Ivoire, the European Union, the Republic of Korea, Mexico, Montenegro, Paraguay, Singapore and Turkey. The Republic of Moldova further looks forward to explore in more detail the proposals presented by the Brazilian delegation, Argentina and Paraguay in JOB/IP/19 and JOB/IP/20, and also by the delegation of Singapore on behalf of co-sponsors of document JOB/IP/22. The Republic of Moldova shares the view of the communication presented by the European Union on behalf of all co-sponsors of document JOB/IP/21, as well as of the majority of Members considering that electronic commerce is essential in our digital era of human development. E-commerce and investment are the main priorities for the Moldovan Government, and we do believe that the WTO has a role to play to help leverage the digital economy for inclusive economic growth and encourage closer economic integration among participating Members.

318. In the case of the Republic of Moldova, the current developments in this field, as well as the creation of e-government centre with the assistance and support the certain Member states of the European Union, especially Estonia, helped us to achieve a much more open government and data of public interest by means of capitalisation of the value of information and technologies and advanced competitiveness policy. All these actions have led to the improvement of trading services, the national agenda being focused on the line of ensuring digitalisations of all public services until 2020. Efforts of the Moldovan authorities will be continuing as well in the direction of capitalising the opportunities with a view to create market stake holders platform approach to internet governance processes by ensuring the meaningful and accountable participation of all stakeholders, including governments, the private sector, SMEs, civil society, the technical community, the academic community and users, taking into consideration the Trade Facilitation Agreement provisions.

319. Many Eastern European countries are known for their IT specialists. In this sense, I am pleased to note that Moldova has the sixth fastest Internet speed in the world by download data capacity. Regarding the proposal made in the Communication JOB/IP/21, by the European Union and the Members co-sponsoring this Communication, we would like to answer certain questions raised by the authors of this Communication and to offer some additional ideas and elements for the trade policy and guidelines for an interactive debate under electronic services in the WTO committees. We look forward and we would like to engage in a constructive and technical discussion under electronic services supply for businesses, as solutions for e-commerce buyers in general and particularly in the framework of the implementation of the Trade Facilitation Agreement. A list of electronic services should be included into this communication, in order to share national expertise and the regulation regarding electronic services. In this context, I would

like to underline the importance of certain e-commerce services such as e-invoice services, single window system, state register of inspection which can offer a common online platform allowing authorised control bodies to automatize the process of planning controls and the registering of planned and unplanned checks as well as publishing them on a public portal. The public procurement reporting services offer the possibility for the economic agents to present and report to the online portal. The licensing services provide the full range of specialised functions to optimise submission and review of licence applications from the licensing chamber.

320. The electronic fiscal record service can strengthen the fiscal capacity. It is an electronic statement which offers an automated method for completing and submitting fiscal reports, including the latest barcode coding technology. Many more electronic services should be taken into consideration for a technical discussion if we really want to have it in the WTO Committees and Councils. All these objectives mentioned in the communications regarding the open markets require frameworks and enhanced transparency of the multilateral trading system, especially to identify measures and initiatives to be taken in order to facilitate the development of e-commerce. All of them are first of all about services. Since we are talking about electronic services we should have an interactive debate at the E-commerce Committee of the Council for Trade and Services and of course the TRIPS Council as well.

321. The Republic of Moldova strongly believes that our efforts in the WTO negotiations can produce a common result in the area of trade in services, e-commerce and competition of trade policies in the digital economy which will be stipulated in the next WTO Ministerial Declaration. E-commerce will always remain the fundamental pillar of services trade policies. Moldova looks forward to having an interactive debate and is ready to deliver concrete results for MC11.

### **13.13 Mexico**

322. As co-sponsor of the document entitled "Trade Policy, the WTO and the Digital Economy" (JOB/IP/21), Mexico endorses the statements made by the European Union and Canada. We believe that the TRIPS Council can make a constructive contribution to the discussions on electronic commerce under the 1998 Work Programme on Electronic Commerce.

323. Sharing of Members' experience of intellectual property rights protection and enforcement issues in relation to electronic commerce, as proposed by Canada, could contribute positively to discussions falling within the scope of the Work Programme.

324. Mexico is willing to participate in this dialogue with an open mind and is confident that this exercise will help to outline more clearly what the role of the WTO should be in spurring electronic commerce and the digital economy.

325. Turning to the proposal "Electronic Commerce and Development" (JOB/IP/22), Mexico endorses Singapore's statement and highlights the potential importance of electronic commerce for economic development, chiefly in boosting the export capacity of small and medium-sized enterprises and in lowering the costs of doing business.

326. We are also prepared to work in this Council to determine how the rules protecting intellectual property rights can impact the growth of electronic commerce. We encourage Members to exchange information on their experiences in this area in order to identify linkages in the WTO that can strengthen the relationship between electronic commerce and economic development.

327. Lastly, we welcome the Communication from Brazil and Argentina (JOB/IP/19) on Electronic Commerce and Copyright and the communication from Argentina, Brazil and Paraguay on Electronic Signatures (JOB/IP/20). We hope to contribute to discussions on these documents at forthcoming Council meetings.

### **13.14 Australia**

328. Australia welcomes the discussion today on electronic commerce and the papers circulated for this meeting. Australia recognises the value and importance of e-commerce for trade. We also recognise that electronic commerce is a gateway for greater participation in the global marketplace, in particular for micro, and small- and medium-sized enterprises. We consider that

the entire WTO Membership will benefit from outcomes that enable growth in e-commerce. We also recognise the fundamental importance of balanced and effective intellectual property frameworks. These frameworks are essential for businesses trading in the digital environment as they provide protection and confidence for businesses, as well as consumers.

329. We have appreciated hearing more from the proponents of the papers as we continue to consider them. We also look forward to hearing Members' ideas for issues to discuss on intellectual property and e-commerce.

#### **13.15 Turkey**

330. As co-sponsor of the re-circulated General Council paper on trade policy in the WTO and the digital economy, JOB/IP/21, Turkey aligns itself with the EU intervention. Turkey believes that the TRIPS Council can usefully contribute to the objectives of the 1998 WTO Work Programme on Electronic Commerce by sharing national experiences and practices on IP and e-commerce. Turkey defines IP as one of the pillars of its industrialisation and development. Turkey is of the opinion that sharing national experiences and practices will be undertaken on a non-prejudicial basis and in a non-negotiating manner. Turkey is open to the views of other Members with a view to fulfilling the Ministerial guidance on e-commerce, we would like to thank Members once again for their constructive interventions on this issue and look forward to hearing views on e-commerce and IP topics for consideration in future sessions of the TRIPS Council.

#### **13.16 Colombia**

331. As co-sponsors of the documents JOB/IP/21 and JOB/IP/22 we wish to endorse the statements by EU, Canada, Mexico and Singapore and others, and wish to continue substantive discussions on e-commerce. We also would like to highlight the importance of this topic for our economy. E-commerce is seen as an opportunity for growth, particularly for SMEs. According to a study by the Electronic Chamber of Commerce of Colombia this area grew by 64% in 2015 and is expected to have a similar growth for 2016. In the same way there is a total of 40million USD of transactions exceeding more than 16million USD, approximately 4% of GDP for 2015, and accounted for 2.6% of GDP for 2014. I would also like to highlight the importance of IP in the development of e-commerce, stressing particularly two aspects.

332. First of all, this trade includes services and products that are based on intellectual property such as informatics computer programmes, designs, music, training systems etc., and the granting of necessary licences thereto. For these products the value is based on production of intellectual property and defence against possible infringement. Here, trademark protection is very important with respect to development of knowledge and good reputation which are very important on the internet and which needs trademark protection and protection from unfair competition.

333. At the same time and as a second important aspect, intellectual property protects those electronic systems which enable online trade itself. Computer programmes, networks, integrated circuits, interfaces, etc., are all elements of intellectual property which must be protected under intellectual property rights. I would also like to underscore how these elements are dealt with in the documents that are under discussion and it is important to bear them in mind for a future development of programmes on electronic commerce.

#### **13.17 Russian Federation**

334. We welcome Members' ambitions to share experienced and views on how to foster discussion on IP issues related to e-commerce. The Russian digital distribution market is growing every year. Digital content presents additional opportunities for copyright holders, but at the same time leads to the possible infringement of copyright and related rights due to the borderless nature of the Internet. We have on the table several submissions from Members and we would like to express our support for constructive engagement on the following suggestions as well as additional issues: Intellectual property right protection especially in light of illegal practices and the formation of new IP markets in the Internet; copyright and related rights protection in the digital environment; protection of trademarks and other means of individualisation; protection and access to technologies especially during technology transfer or use of new technologies including ICT and 3D printers. While sharing the general interest in discussing particular IPR issues related to

e-commerce, we should bear in mind the cross-cutting nature of e-commerce and the interrelation that exists between goods, services, IPRs and development.

### **13.18 Chile**

335. We welcome the proposals in documents JOB/IP/19, 20, 21 and 22, which were circulated by various Members. These proposals contain ideas on how to move forward in the discussions on electronic commerce, and, in our view, many of these ideas are similar. One of the documents we would like to highlight is JOB/IP/21, "Trade policy, the WTO, and the digital economy", which is co-sponsored by Chile. This document, like those indicated by the European Union and other Members, is a useful tool, as it provides a starting point for discussion in the form of a tentative, extensive and open-ended list of trade policy elements that are important to electronic commerce.

336. At the request of one group of Members, the document has been submitted at the level of the Councils and the Committee on Trade and Development, where we hope it will generate substantive and productive discussion on this issue, one that is vital to all WTO Members, regardless of their level of development.

337. As we stated at the last meeting, Chile notes with interest the proposal on exchanging views on different experiences in the area of intellectual property and electronic commerce.

338. There are a number of intellectual property issues relating to electronic commerce, and we realize that they are important for discussions on the digital economy. We therefore feel that the questions set out therein are relevant, in particular those concerning the elements Members feel should be included in an exercise of this type in the area of intellectual property.

339. Furthermore, within the framework of this Council, Chile is interested not only in engaging Members in a substantive discussion on relevant issues in respect of the elements common to intellectual property and electronic commerce, but in exploring avenues to continue this discussion in the TRIPS Council.

340. To this end, Chile believes that a starting point for the discussions in this Council could be requesting the Secretariat to update document IP/C/W/128 – the factual background note examining the provisions of the TRIPS Agreement relevant to paragraph 4.1 of the Work Programme on Electronic Commerce. Since many of these issues are being examined in other intergovernmental organizations, the Secretariat should include in its update information on the relevant activities of these organizations.

341. We hope to work with the other delegations concerned to find the best way to resume productive and substantive dialogue on this important matter.

### **13.19 Korea, Republic of**

342. Korea supports the discussions on e-commerce, including in this Council. E-commerce has a great potential for innovation and trade expansion, which are badly needed in this time of sluggish growth. In this regard, Korea appreciated the efforts of Argentina, Brazil and Paraguay to share their thoughts and experience on specific issues related to e-commerce, and Korea is pleased to join the initiative led by the European Union and Canada. Korea will continue to participate in this discussion.

### **13.20 India**

343. I would like to thank the co-sponsors of documents JOB/IP/19, JOB/IP/20, JOB/IP/21 and JOB/IP/22. According to the co-sponsors of the document JOB/IP/21, "Intellectual property rights protection and enforcement issues are an important component of e-commerce and digital economy discussions, and are addressed in a number of international fora, including the World Intellectual Property Organization (WIPO) and at the WTO TRIPS Council."

344. We understand that in WIPO some work has already been done with regard to resolution of e-commerce disputes. According to WIPO's website, WIPO's Arbitration and Mediation Centre specializes in international dispute settlement and is well suited to solving international IP



problems arising in E-Commerce. The Centre has also focused significant resources on establishing an operational and legal framework for the administration of disputes relating to the Internet and electronic commerce, including disputes arising out of the abusive registration and use of Internet domain names. Some Members have already stated that there shall not be duplication of work at WIPO and WTO.

345. According to the Work Programme on Electronic Commerce, the Council for TRIPS shall examine and report on the intellectual property issues arising in connection with electronic commerce. The issues to be examined shall include: protection and enforcement of copyright and related rights; protection and enforcement of trademarks and new technologies and access to technology.

346. Discussions in this Council must take place in accordance with the Work Programme. As the mandate is exploratory, I would like to request the proponents of job-documents to clarify what specific intellectual property issues they would like to discuss in this Council on an exploratory basis. We look forward to engaging constructively in the discussions on e-commerce in this Council as per the Work Programme.

### **13.21 New Zealand**

347. New Zealand welcomes these proposals from various Members and recognises both the value and potential of e-commerce and trade for the entire WTO membership. New Zealand is especially interested in the benefits and potential for MSMEs as some Members have outlined here. We greatly appreciated today hearing more from the proponents on these papers, as we continue to consider each of these.

### **13.22 Brazil**

348. I will be very quick, it is just a reaction to some comments regarding our proposal JOB/IP/19 on copyright. There were at least a couple of references of avoiding duplication of work, of regarding work that is being carried out in other fora. We do not necessarily see this as a duplication, since what we are discussing here under the Work Programme is not necessarily the same, just as the TRIPS Agreement is not a duplication of the Berne Convention. The fact that you had the Berne Convention and later the TRIPS Agreement was not seen as a duplication. Just to make clear the importance of this issue for us, in e-commerce it seems that we have a number of very sensitive issues that at some point would have to be discussed, and I am talking about privacy protection, data flow, localisation, and for us it would be very difficult to approach those issues without having a more holistic approach to sensitive issues coming from all quarters, just to highlight the importance of keeping this discussion of copyright together with the other core issues of the e-commerce discussion.

### **13.23 United States**

349. With respect to Chile's request regarding the updating of the Secretariat note on E-Commerce, IP/C/W/128, we would like some time to think about that. We prefer to work at that inter-sessionally, and we can of course also talk to our colleagues from Chile inter-sessionally.

## **AGENDA ITEM 14: INTELLECTUAL PROPERTY AND INNOVATION: INCLUSIVE INNOVATION AND MSME COLLABORATION**

### **14.1 Australia**

350. Australia welcomes the opportunity to introduce the discussion on intellectual property, inclusive innovation and micro, small and medium sized enterprises (MSMEs). Australia acknowledges our fellow co-sponsors: the European Union, Switzerland, Japan, the United States and Chinese Taipei.

351. This overarching topic recognises the positive role MSMEs play in the global economy and the wider contributions they make to trade, growth, investment and competition; as well as social and economic development. As foreshadowed in document IP/C/W/622, it is proposed to consider three elements of this important topic, Inclusive Innovation and MSMEs, at each of the TRIPS

Council Meetings to take place this year; firstly, MSME collaboration; secondly, MSME growth; and, thirdly, MSME trade. Australia extends an invitation to all Members to share national experiences, policies and practices under each of these themes, with a focus on intellectual property and innovation.

352. Australia is pleased to introduce the first theme: Innovation and MSME Collaboration, as set out in document IP/C/W/625 for discussion today. Australia acknowledges that MSME collaboration has many benefits for developed, developing and least developed countries. Through collaboration, MSMEs can share information, ideas and research and can establish themselves in global value chains. Collaboration models can take shape in many forms: from public-private and inter-firm partnerships, research and development opportunities, start up or accelerator hubs and entrepreneurial ventures.

353. Intellectual property rights play a key role in MSME collaboration. Intellectual property frameworks encourage creative endeavour, incentivise investment, and promote the sharing of ideas and knowledge. Australia has established a number of IP and innovation initiatives to encourage MSME collaboration. Australia will take the opportunity today to outline some of these initiatives.

354. **National Innovation and Science Agenda – Global Connections Fund:** Under the National Innovation and Science Agenda, Australia introduced the Global Connections Fund ( GCF) to support SME collaboration. As part of the GCF's Bridging Grants Programme, a researcher from the Royal Melbourne Institute of Technology University (RMIT), was awarded AUD50,000 to collaborate with an Indian research and biotech business to develop an eco-friendly solution to control powdery mildew and downy mildew, two diseases that devastate grapes in both countries. Both partners to this collaboration have created a framework under which intellectual property rights are shared. The expected outcome of the collaboration is a product that can be marketed globally.

355. **National Innovation and Science Agenda - Global Innovation Linkages:** Australia recently introduced the Global Innovation Linkages programme. It provides funding to assist Australian researchers and businesses, including SMEs, to collaborate with global partners on strategically focused, leading-edge research and development projects. It will advance Australia's international collaboration and encourage Australian businesses, including SMEs, to leverage entrepreneurial expertise found in key locations overseas. Collaborations are encouraged in a range of economies including Brazil, United States, Singapore, Viet Nam, Israel, China, India, the EU and others.

356. **National Innovation and Science Agenda – Landing Pads:** At the November 2016 TRIPS Council meeting, Australia introduced the Landing Pads Program which is an initiative set up by the Australian Government to connect export ready Australian start-ups with access to some of world's most renowned innovation and start up ecosystems in Berlin, San Francisco, Shanghai, Singapore and Tel Aviv. This Program has already produced some excellent results. For example, Event Workforce Group, a small, Australian-based technology start-up that develops apps to assist large businesses connect with talented staff members, has benefitted from the San Francisco Landing Pad. Through the collaboration established through the Landing Pad, Event Workforce Group has been able to develop its technology and services. Agreements relating to the protection of intellectual property have fostered this successful collaboration. Event Workforce Group has recently signed a contract to assist staff the 2018 Super Bowl in Minnesota, and the 2017 Alpine Skiing World Cup in Aspen.

357. **IP Toolkit for Collaboration:** IP Australia has developed an IP Toolkit for Collaboration, designed to simplify the management of IP in collaborations between researchers and businesses, including SMEs. It provides collaborations with checklists of key matters to consider when establishing a partnership and includes template contracts, confidentiality agreements and term sheets, as well as guides on developing partnerships and advice on the management of IP. This toolkit is specifically designed to assist small and medium-sized businesses and researchers to develop and build effective collaborations. The Toolkit reduces the need for legal advice, freeing up resources to focus on building the partnership and attracting funding. A Mini IP-Toolkit is also available for lower value or less complex collaborations.

358. Today, I have provided some examples of Australian IP and innovation initiatives that have promoted MSME collaboration within Australia and abroad. We encourage other Members to join us in sharing national practices today and under future discussions on MSME Growth and MSME Trade.

## 14.2 United States

359. The United States welcomes this opportunity to share views and experiences on the important issue of inclusive innovation and MSME collaboration. I would also like to express thanks to Australia, the European Union, Japan, Switzerland, and Chinese Taipei for co-sponsoring this item.

360. This morning we will share our experiences in fostering inclusive innovation with a focus on MSME and explore several different ways that MSMEs contribute to the innovation ecosystem through collaborative efforts. In my remarks, I will describe the vibrant U.S. MSME landscape, demonstrate the critical role that intellectual property protection and enforcement play for MSMEs, highlight several U.S. policies and programmes that serve to help MSMEs make use of IPR systems and provide case study examples of innovative US MSMEs that depend upon US intellectual property policies.

361. I'd first like to share with you some data to paint a picture of the US small business landscape derived from the latest statistics from the Small Business Administration (SBA). According to the SBA's data<sup>4</sup>, in 2013, there were 28.8 million small businesses in the United States which comprised 99.9% of all firms and employed 48% of private sector employees. These small businesses also represented 97.7% of exporting firms with 33.6% of known export value.

362. Small businesses have played a critical role in the development of the US technology sectors. In 2012, there were 244,243 small employer firms in high-tech industries, representing 98.5% of all employer firms in these industries. The Department of Commerce's inaugural Annual Survey of Entrepreneurs released in 2016, which looked at the 5.4 million US firms with paid employees, revealed that "most firms had fewer than 10 employees (4.3 million, or 78.5 percent)"<sup>5</sup>.

363. In the United States, MSMEs play a critical role in driving inclusive innovation. They are engines for economic growth, employment and technological progress. This is particularly true for women and minority-owned businesses, where innovation has made critical contributions to economic empowerment, gender parity and social inclusion and equality.

364. I would now like to describe how intellectual property contributes to MSME development. For MSMEs, IPR protection and enforcement is not a luxury, but is an existential determinant for whether or not the firm can survive or fail. For example, trade secrets play a critical role in the development of MSME innovation and are among the primary forms of intellectual property that MSMEs use to protect their innovations, as smaller firms "tend to have fewer resources and limited expertise and capacity for managing intellectual assets using formal IPRs"<sup>6</sup>.

365. Patent protection also plays a critical role for the development of MSMEs in several notable ways. MSMEs, as compared to larger firms, may factor into their growth strategies, considerations such the marketing advantages that ensue from being able to claim patent protection. MSMEs also may use the presence of a patent to potentially boost their attractiveness to investors and increase their valuation<sup>7</sup>.

366. Prudently registering and maintaining relevant trademarks can also help ensure that the firms' investment in creating a distinctive brand will not be undermined by a competitor. Without this legal protection, an innovative MSME can miss out on the goodwill associated with a brand that has been made possible by an innovative creation.

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<sup>4</sup> [https://www.sba.gov/sites/default/files/advocacy/SB-FAQ-2016\\_WEB.pdf](https://www.sba.gov/sites/default/files/advocacy/SB-FAQ-2016_WEB.pdf)

<sup>5</sup> <https://www.census.gov/newsroom/press-releases/2016/cb16-148.html>

<sup>6</sup> Brant, Jennifer; Lohse, Sebastian; *Trade Secrets: Tools for Innovation and Collaboration*; International Chamber of Commerce: Innovation and Intellectual Property Series, 2014; Page 10.

<sup>7</sup> Hughes, Alan; Mina, Andrea; *The Impact of the Patent System on SMEs*; A Report to the Strategic Advisory Board for Intellectual Property (SABIP); Pages 27-28.

367. Copyright protection also plays a key role in a large number of MSMEs, not only those engaged in content creation and distribution. In fact, copyrighted materials factor into MSMEs in all sectors by virtue of their importance in protecting websites, logos, brochures, advertisements, and jingles<sup>8</sup>. Copyright licensing is a critical source of revenue for many MSMEs, that helps supports much needed jobs and capital for further growth and investment of creativity-powered entrepreneurs. From application developers, to the music community, and the film and TV industries, copyright helps fuel the MSME creative economy in developed, developing and least developed countries.

368. Recognizing both the important role that MSMEs play in the United States and the value that they derive from intellectual property, the United States Government has enacted policies and programs to promote MSME IPR protection.

369. Despite the relevance of one or more types of intellectual property to small businesses of all types and sectors, many MSMEs unfortunately lack an understanding of how to protect their intangible assets or register for IPR protection, when needed, and the processes for doing so. The US Patent and Trademark Office (PTO) and Department of Commerce International Trade Administration (DOC/ITA) play key roles in helping to educate MSMEs through extensive trainings and educational initiatives.

370. For example, ITA launched the STOPfakes.gov Road Shows - an innovative IPR outreach initiative that has reached over 1,000 SMEs to date. For these events, ITA's Office of Intellectual Property Rights (OIPR) partners with USPTO and the US National IPR Coordination Center to increase SMEs' awareness of IPR issues from both perspective: law enforcement and a trade.

371. ITA also maintains a website that broadcasts on-demand webinars and hosts other materials to help MSMEs and other business protect and enforce their IPRs. STOPfakes.gov was launched to serve as a one-stop shop for U.S. government tools and resources on IPR. The federal agencies behind STOPfakes.gov have developed a number of resources to educate and assist businesses, particularly MSMEs, as well as consumers, government officials, and the general public.

372. Moreover in 2015, DOC/ITA travelled to various US cities through the Start-up Global Initiative to help more start-up firms to think globally from the earliest stages. ITA participated in half day educational seminars in partnership with local incubators and accelerators to educate on protecting intellectual property among other things.

373. In September 2016, the US Customs and Border Protection (CBP) launched the "E-Commerce and Small Business Branch" to help educate small business importers on CBP compliance requirements. This initiative, along with CBP's longstanding priority focus on IPR enforcement, helps protect US MSMEs and all firms against the harm caused by imports of infringing goods.

374. CBP also provides information on how rights holders, including MSMEs, may utilize CBP enforcement tools, including by providing detailed information, product training sessions, and legal counsel.

375. The USPTO has several free or reduced fee programs to assist independent inventors and small businesses in securing patent protection for their inventions: the Patent Pro Bono Program, Pro Se Assistance Program, and Certified Law School Clinic Program.

376. Through the Patent Pro Bono Program, the USPTO partners with non-profit organizations and law schools to establish regional programs throughout the country. By working with their regional patent pro-bono program, under-resourced independent inventors and small businesses may secure free legal representation to help them file and prosecute patent applications.

377. PTO's Pro Se Assistance Program provides tools to assist MSMEs and others who file patent applications without the assistance of a registered patent attorney or agent. PTO's partnerships with laws schools also match law students to interested applicants—often MSMEs-- to help them

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<sup>8</sup> World Intellectual Property Organization; *How can Your SME Benefit From Copyright?*  
[http://www.wipo.int/sme/en/ip\\_business/copyright/copyright.htm](http://www.wipo.int/sme/en/ip_business/copyright/copyright.htm)

draft and file patent and trademark applications. Finally, PTO's Global IP Academy (GIPA), which many in this room may have visited for bilateral meetings or programs in the past, also offers assistance tailored to MSMEs. In Fiscal Year 2015, GIPA provided training to 2,701 people associated with MSMEs.

378. The US Copyright Office also provides a variety of tools, including FAQs, podcasts, and reports, to help business better understand how to register a copyright and understand their rights.

379. Before concluding this intervention, I would like describe examples from the United States of inclusive innovation and MSME collaboration using examples of US MSMEs. At a macro level, an MSME's level of confidence in its ability to protect its intellectual property can fuel collaboration and spur new ideas, products, and innovation through these partnerships.

380. For example, if an MSME has confidence that its trade secrets can be protected through trade secrets laws, it may be more willing to rely upon non-disclosure agreements, non-competes, and other types of contracts that give it confidence to share this valuable information with others. Absent such protection, a company may not be willing to share its crown jewels outside of a family or close associates.

381. With respect to patents, an MSME with patent protection may find that it increases its valuation in the eyes of an investor; and, is, therefore, able to attract critical early stage capital infusions and enter into licensing agreements to bring their new ideas to market.

382. Moving to the micro level, one way to understand inclusive innovation and MSME collaboration is by looking at the diverse set of relationships and partnerships that comprise an innovation. For example, an inspired inventor or small team of researchers may envision a way to transform an existing, popular product of a larger company or industry by incorporating exciting technological innovation.

383. In the case of the founding team of Skydio, who originally met as graduate students at MIT, this has led to exciting advances in "intelligent navigation" technologies for unmanned aerial vehicles that provide quality cinematography and enable businesses with new ways to monitor the functioning of their infrastructure. The company has the goal of "making the power of flight a trusted and useful part of people's everyday lives"<sup>9</sup>. In this case, an enterprising set of innovators have identified a way to improve an existing idea that is marketed by a larger global manufacturer.

384. Another exciting type of innovation stands out for providing a standalone creative solution to longstanding challenges. A good example of this is from the products that have emerged from Ecovative Design, a growing firm that began as a collaborative class project between two classmates at Rensselaer Polytechnic Institute in New York, who discovered a novel way of producing biodegradable insulation using agricultural waste.

385. According to a story published about their origins, the professor of an Inventor's Studio class they both attended saw promise in their discoveries and convinced them to take another semester of the class so that they could work on their idea and start a business. He even put them in touch with a patent attorney seeing early promise in the budding invention.<sup>10</sup> In 2011, Ecovative announced that a group that included 3M, Rensselaer Polytechnic Institute, and DOEN Foundation had invested in the company to scale Ecovative's manufacturing operations and accelerate the development its polymeric materials.

386. Today, the company produces safe and sustainable biomaterials used in a variety of ways, including in furniture, an engineered wood alternative, and packaging materials using mycelium, which is the vegetative growth stage of fungi. Customers can even purchase Grow it Yourself Mushroom Material and create their own new applications of the technology. One of Ecovative's products, the Mushroom Packaging, has led to mutually-beneficial international connections. For

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<sup>9</sup> <https://www.skydio.com/blog/2016/01/series-a/>

<sup>10</sup> <http://www.newyorker.com/magazine/2013/05/20/form-and-fungus>

example, a UK precision testing equipment manufacturer uses Ecovative's packaging material as a way to help meet its own sustainability goals.

387. In conclusion, I want to underscore the important role that intellectual property and IPR protection plays in fostering MSMEs growth in the United States. The US Government has recognized this linkage and developed policies, programs, and materials to help address the unique needs that MSMEs face in fully harnessing our IPR systems to help them protect their innovations, grow, and partner with others. As innovation seldom happens in isolation, the contributions of inventors, MSMEs, and their partnerships with established firms have played a critical role in collaborative innovation.

388. In surveying the landscape, it has been clear that while there may be needs and challenges specific to MSMEs in fully utilizing the IPR systems, the protections provided are relevant to firms large and small. The same incentives that continue to drive the growth of large, international firms, are also responsible for creating the opportunities that bring MSME inventions to market.

389. We look forward to continuing to engage in an active dialogue to find ways to further bring MSMEs into the global innovative ecosystem and look forward to hearing from other Members on this important topic today.

### **14.3 Chinese Taipei**

390. This delegation is pleased to join Australia, EU, Japan, Switzerland and the United States in co-sponsoring this Agenda item. We are very pleased to have the opportunity of sharing our own experiences with fellow-Members, and of being able to learn from the best practices of other Members at the same time.

391. We fully identify ourselves with the observation made by the delegates of the United States and other co-sponsors, that IPRs help micro, small, and medium-sized enterprises (MSMEs) to channel the potentially boundless contributions of a wide array of innovators and creators in different economies. IPRs also enable MSMEs to spur innovation and creativity, to structure partnerships, and to join global value chains.

392. I would like to point out one of the priorities of my Government's industrial policy is to assist MSMEs, which account for nearly 98% of all local companies, to participate in domestic and international markets. To further develop a better environment for new business, we endeavour to build an ecosystem to provide for creation, innovation and start-ups. Thus, we are devoted to implementing programmes via the entrepreneurship consultation mechanism and MSMEs innovation incubation.

393. My Government launched the Entrepreneurship Consultation Service for potential entrepreneurs by means of free counselling service, single online portal, and international community linkage.

394. Meanwhile, the Entrepreneurship Incubation Education Programme offered education and training opportunities for start-up owners by organizing a series of training courses. It helps entrepreneurs enhance their competence and keep abreast with new trends and information on business management.

395. Secondly, the Entrepreneurship Dream Building Plan was launched to help MSMEs which set up for less than 5 years. In this plan, we provide layered counselling for start-ups, help them obtain professional certificates and government's support, hold exchange and matching activities, and offer the entrepreneurship awards to honour outstanding creative products, technologies, process or services of start-ups. This plan has successfully assisted 500 start-ups and created 3,000 jobs last year.

396. Thirdly, with respect to SMEs innovation incubation, we have set up several new incubation centres since 1997. These centres provide office space, equipment, R&D technology, resources of fund-raising, HR development, and opportunities to involve in international business. Around 100 incubatees from incubation centres have been listed on the stock market. My Government also

introduced the Entrepreneur Work Visa to attract talented entrepreneurs from all over the world. The entrepreneurs from overseas are eligible for residence, if they meet certain requirements

397. Fourthly, since 2013, the Emerging Industries Accelerator Program has been launched to establish international incubation cooperation platforms across Europe, America, Asia and the emerging market. The programme aims to facilitate global business portfolio by leading MSMEs to develop the local market. It also aims to encourage large enterprises' contribution in intensified consultation to help MSMEs quickly incorporate into supply chains. We expect to increase the survival rate of MSMEs through this "large and small cooperation" and stimulate the speed of innovation for the traditional companies. Now, we focus on the six major fields of technology, which are: cloud computing, Internet of Things, biotechnology, green energy, digital content and precision machinery.

398. In terms of IP, the MSMEs face many different challenges when it comes to creating, protecting, circulating, and applying their intellectual properties. That is why the "IP SME Corner" of the Intellectual Property Office (TIPO) is the newest one-stop search and information platform that helps MSMEs to quickly access information on all the available and latest government resources

399. In conclusion, we acknowledge MSMEs demonstrate the power and importance of inclusive innovation. MSMEs also play an essential role in diffusing economic growth and innovation throughout our societies, including their contributions to innovation and creativity, and their reliance on IPR protection. We believe that business start-up and incubation are the most important factors in the world striving for innovation and sustainable development.

400. We looks forward to hearing from other delegations about their existing policies in this regard and discussing topics which were proposed in document IP/C/W/622, which can offer the opportunity to demonstrate how IPRs can promote inclusive innovation through MSMEs.

#### **14.4 Japan**

401. Today, the delegation of Japan will share our experiences on MSME-university collaboration based on IP.<sup>11</sup>

##### **Slide 1**

402. There are various ways MSMEs can collaborate with other entities. Especially, MSMEs collaborating with universities have the potential to create new businesses and promote innovation. So, today, we would like to focus on IP-based Collaboration between MSMEs and Universities; and talk about some of our initiatives to improve such collaboration in Japan.

403. The left half of the first slide describes our 20-year history of initiatives, starting in 1995. It starts with the enactment of the "Basic Law for Science and Technology", which was designed to improve the collaboration between MSMEs and universities.

404. These initiatives were designed to advance and implement three key factors that promote collaboration, namely: "tech-transfer one-stop services" to give advice to and match researchers and companies; "IP management offices" to find seeds of technology and handle IP; and, funding such as venture capital that grows the seeds into goods and launches them into the market. The synergy of the three factors can promote IP-based collaboration, where technology is transferred in a "briefcase" called IP, in order to promote innovation.

##### **Slide 2**

405. A major method of collaboration between existing MSMEs and universities includes joint research and sponsored research.

406. Of the three key factors mentioned in the previous slide, the "tech-transfer one-stop service" and the "IP management office" mainly contribute to increased access to university technology. The figure on the left shows the increase in the number and amount of funding for joint research between universities and all private companies.

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<sup>11</sup> The representative of Japan made a PowerPoint presentation, available in Room Document RD/IP/16.

407. The figure on the right shows the number of joint research projects in green, and the number of sponsored research projects in red. From this figure, we can see that private companies, such as MSMEs favor joint research, which has increased approximately three times since 2001. One explanation for this might be that joint research allows MSMEs and other companies to learn how to carry forward research from their experiences with universities.

### **Slide 3**

408. Another type of collaboration between MSMEs and universities is a start-up. In this slide, we would like to show you the recent developments and the current state of our university start-ups. The figure on the left indicates the number of new Japanese university start-ups each year. The figure on the right indicates the changes in the total number of Japanese start-ups in operation.

409. As you can see in the figures, there was a rapid increase in the number of university start-ups around 2000. But the rate has been slowing since 2006. According to a recent survey on start-ups, there seems to be a further need to support MSMEs in creating business, IP, and marketing plans; setting up exit strategies, and also finding foreign business partners.

### **Slide 4**

410. The final slide shows our recent initiatives for further promoting collaboration between MSMEs and universities. In addition to the needs found in the survey, experience has taught us that many start-ups face difficulties, especially at the initial start-up phase and early growth stage. This is sometimes called the "Valley of Death" because no product has yet been developed to generate revenue, but the start-up begins running short of funding.

411. Thus, from both from the financial and management perspectives, we needed new venture capitals to complement existing ones in helping start-ups develop their technology and find products that sell well in the market. Considering this situation, Japan launched the "Public-Private Partnership Innovation Program" in 2013. In this program, four major national universities in Japan were granted funds to establish and invest in venture funds that could offer "hands-on" support, especially in the early stages of the start-ups' development. In addition to the Program, Japan also supports grass-root initiatives to promote MSME-university collaboration in local communities. We hope that these efforts will boost new MSME-university collaborations.

## **14.5 European Union**

412. Intellectual Property Rights (IPRs) play a crucial role in: catalysing innovation and creativity; promoting economic growth and development; creating and growing jobs; improving the quality and enjoyment of our lives; and, combating the manifold challenges we face as individuals as nation and as a global community.

413. Among this multitude of positive contributions IPRs provide a critical conduit for inclusiveness in local and global trade. In particular, IPRs help micro, small and medium-sized enterprises (MSMEs) to channel the potentially boundless contributions of a wide array of innovations and creators in different economic sectors and from diverse communities. IPRs also enable MSMEs to spur innovation and creativity to structure partnerships and to join global value change. The key role of intellectual property in the success of start-ups and innovative SMEs has been recognised. It allows innovative businesses to profit from the result of their creativity, inventiveness and R&D investments and creates an incentive for further investment in innovation.

414. Recent data from the EU Intellectual Property Office (EU IPO), show that businesses using IPRs perform better; and, that this is particularly true in the case of micro, small and medium-sized enterprises. MSMEs owning IPRs have almost 32% higher revenue per employee than MSMEs that do not. They also expand their workforce faster and pay higher salaries. IP is, therefore, essential for smart and sustainable growth. Given that knowledge-based parts of the economy in developing and developed countries with strong innovative performance is made up of business whose most valuable assets are intangible, innovative and creative start-ups and MSMEs need to be aware of the advantages of using IP and the dangers of neglecting it. To better assist MSME the European Commission set up the Executive Agency for Small and Medium-Sized Enterprises which manages the vast majority of the EU Programmes designed for MSMEs to help them innovate and do research.



415. The Commission announced in 2015, that it would come forward with EU level measures to support the use of IP by SMEs, in the framework of the Single Market Strategy. As delivery of that commitment, the Commission has put into place a package of IP support measures for start-ups and SMEs aiming to improve coordination and consistency in addressing sub-optimal use of IP by them across the EU.

416. This package was recently presented in a new communication utting intellectual property at the service of SMEs to foster innovation and growth and another communication entitled "Europe's Next Leaders: The Start-up and Scale-Up Initiative". The communication shows that the European Commission has now a coordinated approach across EU policies to be delivered through a set of pragmatic measures in order to boost innovation and research with the involvement of micro, small and medium-sized enterprises. The new measures include: the streamlining European IP Awareness Schemes for SMEs and providing a cooperation platform for EU Member States; developing an EU IP Mediation and Arbitration Network for SMEs; encouraging the creation of European-level insurance schemes for litigation and IP theft; building on a common IP valuation method; and, improving coordination of IP support funding schemes, including by means of a possible guidance to Member States and by developing monitoring methods for their impact.

417. Working in partnership with all levels of government, in EU Member States, regions and cities and all stakeholders, including start-ups and scale-ups themselves, is necessary for the efficient and successful implementation of initiatives intended to help SMEs and allow them to cooperate better. The EU and Member States are working on further simplifying the life of start-ups by supporting them in the following areas: connecting them with the right partners, i.e., investors, business partners, universities, research centres etc.; assessing commercial opportunities, especially procurement contracts; recruiting employees with the right skills including from outside the EU; and, in recent years, the European Commission and EU member States have supported the creation of communities to help start-ups connect with potential partners.

418. At EU-level, the "Europe's Next Leaders: The Start-up and Scale-Up Initiative" has emerged as a recognised brand for creating links between ecosystems, focusing on connecting people, international outreach and providing information, a one-stop shop for start-ups. "Europe's Next Leaders: The Start-up and Scale-Up Initiative" also helps SMEs through in particular match-making between investors, corporates and entrepreneurs as well as networking of regional decision-makers. "Europe's Next Leaders: The Start-up and Scale-Up Initiative" objectives are to reinforce the links between people, businesses and associations who build and scale-up the start-up ecosystem, linking them also to information on IP, but other measures are web-investor forums, the accelerator assembly and the crowd-funding network. These are meant to inspire entrepreneurs and provide role models for others to follow. They also celebrate a new and innovative start-ups, help them to expand their business and give them access to funding on the Horizon 2020 which is the main research and innovation framework programme of the EU.

419. The Web Investors Forum brings together the investors and accelerators from all over Europe with a goal to foster a more scale-up friendly ecosystem. The Web Investors Forum acts as an international channel of conversation for the European Investment Fund and European Commission with European and international investors. Specifically, the Web Investors Forum bridges investors to corporate development heads like the Start Up Europe Partnership (SEP), European Matching Funds and the European Commission. In addition, the European Institute of Innovation and Technology (EIT) has set up a number of knowledge and innovation communities in the thematic areas of ICT, energy, climate change, health and raw materials with 25% of public financing, the rest being private investments.

420. The European Institute of Innovation and Technology is helping on a number of fronts, for example: on entrepreneurship skills, mentoring, start-up accelerators and information about IP. The EU has also established thematic smart specialization platforms, linking up regions and businesses and supporting the European Structural and Investment Fund (ESIF) for scale-ups promoted by regional networks and European strategic classic partnerships. Together with the targeted support they receive, these projects help create opportunities for scale-ups.

421. The European Commission has provided increased support to SMEs through the Horizon 2020 Research and Innovation Framework Programme, either as partners in collaborative projects with research organizations and other firms, or as single beneficiaries. It has also boosted support for innovation including through more demonstration projects, facilitated access to

experimentation and pilot facilities, actions on innovative procurement and reinforced financial instruments. As a consequence, SME participation has increased and is currently above 20% of the target level. From 2018, the Horizon 2020 Research and Innovation Framework Programme will adopt a fully bottom-up approach, so innovative projects that cut across sectors and technologies become eligible for support, making it easier for start-ups to access financial and technical support, targeting market-creating breaks through innovations with a scale-up potential.

422. Another instrument is the European Cluster Collaboration Platform which is an online platform created by the European Commission providing information and network support for clusters aiming to improve and increase their competitiveness through transnational and international cooperation. The aim of the Platform is to facilitate cluster cooperation between organisations and members, i.e. companies, R&D institutions among others, not only by providing relevant information, but also by organising match-making missions across the EU focused on specific topics. This service facility aims to: provide cluster organisations with modern tools which allow to make efficient use of networking instruments; search and find potential partners and opportunities; develop collaboration transnationally within Europe and beyond and support the emergence of new value chains through cross-sectorial cooperation; access the latest quality information on cluster development; and, improve their performance and increase as well as their Members competitiveness.

423. To conclude, we would like to underline that transparent and predictable intellectual property rules assist MSMEs to engage confidently in international trade. Successful collaborations between entities often involve transfer, sharing and creation of knowledge, ideas or technology. Intellectual property rights provide a framework for the ownership, protection and use of ideas and information created through partnership in Europe and beyond.

#### **14.6 Switzerland**

424. Let me thank Australia for introducing this agenda item today, and the earlier delegations that introduced their presentations. Switzerland is pleased to co-sponsor agenda item 14 and to co-sponsor also the two Communications on the topic, in IP/C/W/622 and IP/C/W/625. The purpose of document IP/C/W/622 is to take a look ahead and to suggest topics in relation to IP innovation and MSMEs that the Council could discuss. That should give Members more time to prepare to look into their own national situations and gather information. We believe that MSMEs are a common denominator of all WTO Members and could allow a discussion as inclusive as possible.

425. My delegation welcomes the opportunity for Council Members to exchange such experiences and views on how cooperation among companies and companies' interaction with public agencies may contribute to innovation and on the role IP protection can play in facilitating such collaborations. My delegation will illustrate its own national experience by presenting two case studies of private-private and private-public collaborative innovation ventures.

426. "Innovation is a team sport." A corporate culture of cooperation is a prerequisite for a company to produce a sustainable innovation process. A culture of curiosity, the exchange of ideas, asking challenging questions, and working on answers from different angles are key for innovation to happen in a company.

427. What is true about fostering a culture within a company is similarly true of collaboration between two or more separate entities. Let me illustrate the importance of cooperation in R&D with two practical case examples.

428. The first case concerns an electronic system called Flokk<sup>12</sup>. The Flokk system provides new and interactive illumination solutions for designers and architects. It is the result of a multiple-player R&D-project that involved a Swiss University of Applied Science and three different companies who contributed their know-how, resources, and material at varying stages of the project.

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<sup>12</sup> <https://iart.ch/de/-/flokkeineoffeneplattformfurinteraktivelichtlosungen>.

429. The inventor of Flokk acted as the project's driving force. To further develop and test his concept, he reached out to partners in the manufacturing sector. There, interest for his ideas proved to be high. A Swiss SME called *iArt* (45 employees) managing innovative projects for museums, international events, brands, architects and media artists, became the main partner for the further process engineering and the launch of the product. After establishing the project's major guidelines and cornerstones, as well as clarifying all IP aspects, the two parties were able to get support from the Federal Commission for Technology and Innovation. Furthermore, the project got support and input from the Swiss SME Inventron and the international electronics manufacturer Philips. It was thanks to the interaction and collaborative effort between all those players that Flokk took many of the hurdles that need to be overcome from the stage of an idea to introducing an innovative product, which is commercially successful in the market.

430. Flokk luminaires can interact with each other, with their environment and with digital data to display information in the form of light effects, such as patterns of clouds for example. The Flokk technology makes also use of an algorithm to keep luminance in the room at a constant level. If one luminaire is dimmed, another will shine brighter. This allows for an even and pleasant lighting. Flokk's technology attracted commercial attention from an early stage of its development and gained a design award in Switzerland in 2016.

431. The initiators of the project are currently moving ahead by transforming this technology into serially-produced consumer products. An important enabler in the Flokk technology was intellectual property. It brought the parties together with their different backgrounds, knowledge and experience. It helped manage their partnership. A contractual agreement on who would own which IP rights and how future commercial benefits would be shared, contributed to the well-functioning of the partnership, and therefore worked as an enabler for the successful project.

432. Our second example concerns an invention consisting of a technical solution that increases precision in robotic systems. Such systems are used and are often indispensable in scientific laboratories or in hospitals, where precision is key. The invention is called CASCAD. This innovative technology allows for example to prepare medical samples for analyses with a particularly high accuracy. Apart from scientific and medical applications, the technology also offers considerable potential in other field of technology, such as the semiconductor or the solar industry.

433. Like Flokk, CASCAD is the result of collaboration between private companies and a Swiss University of Applied Science. The initial project-idea came from two private companies. The University of Applied Science contributed technical input at the later stage of the project. Combining the expertise from different parties proved to be a success-story for the project. It is a perfect example of the potential benefits of R&D-collaboration.

434. Even in a political and economic environment conducive to innovation, novel ideas and innovative ventures include trial and error, success and failure. In case an innovation has the potential for a commercial success, the innovator should early pay attention to how to protect his or her innovation against illegitimate free riders. In many cases, this includes securing the relevant intellectual property rights in order to secure a return on the investment made in the R&D process, to procure financing, reinvest in improving an existing innovation or innovate in a new field. If securing intellectual property rights is neglected or attempted too late, innovators risk losing their competitive advantage and loss of their assets. What could have been a commercial success may thus turn out to be an economic failure.

435. Nowadays, ideas and knowledge are no longer developed in the same place as where they are transformed into product innovations. The case examples presented are illustrative: in this respect: The Flokk illumination system was based on a researcher's ideas which were eventually transformed with several players from the private sector into a commercially viable product. In the case of the CASCAD robotic system, the idea originated in a private company and was then developed and pushed towards market introduction also thanks to the input from another company and from institutions, both private and public, proficient in basic and applied research and product development.

436. R&D cooperation can be particularly useful for SMEs to diversify risks, share R&D costs, and tap financial resources and specific knowledge. Additionally, SMEs can generate new revenue streams by licensing out their IP.

437. At the same time, SMEs often fear that their specific know-how could be misappropriated or be unintentionally revealed through innovation collaborations. Therefore, an early and well thought through IP strategy addressing these concerns and challenges becomes important to support innovation collaboration.

438. The government, providing the legal framework, has an important role to play here. With reliable IPR protection in place and efficient enforcement in the case of IPR infringement available, companies will more readily engage in innovation collaborations and thereby contribute to the growth and competitiveness of a national economy.

439. "Innovation is a team sport", as I mentioned earlier. As in any team sport, rules are needed so the players know what their task is in the game and how they should interact with the other players, what is fair and what is foul play and what they need to accomplish to become a successful team. In the field of collaborative innovation, intellectual property is one chapter of the rulebook that MSMEs should read carefully.

#### **14.7 India**

440. My delegation would like to thank the delegations of Australia, the European Union, Japan, Switzerland, the United States and Chinese Taipei for tabling an agenda item on "IP and Innovation: Inclusive Innovation and MSME Collaboration". The submission by Co-sponsors refers to "inclusive innovation". The term is not defined. It would be important for a common understanding to clarify what is meant by use of this term.

441. In para 5 of the document (IP/C/W/622), the co-sponsors have selectively quoted from the study about the Informal Economy, Innovation and Intellectual Property, by de Beer, Fu & Wunsch-Vincent (2013, page 39) to support their position that IP must be considered as a relevant aspect for innovative micro-sized enterprises. However, the important observation by de Beer, Fu & Wunsch-Vincent in their study is that formal IP-based exclusions and proprietary knowledge are not compatible with the knowledge diffusion and learning processes of the informal economy which are based on communities, clusters and the exchange of information.

442. I quote from same page 39 of the study

"the absence of formal appropriation and the work in clusters make up the strengths of the Informal Economy(IE)'s innovation system. In this view, the innovation system in the IE largely rests on "collective learning experiences" based on low entry barriers and free flows of knowledge. The dynamics among similar enterprises in collective geospatial clusters determine rates of innovation, economic successes and the value of the cluster. Individual firms or economic units are not the key determinants of innovation and efficiency.

Appropriation efforts must also be considered in light of the social systems -- specifically family structures, community networks and commercial clusters -- within which the Informal Economy operates. Knowledge flows are characterized by trust, reputation, reliability, social and cultural signalling, and the willingness to pool resources and collaborate. This facilitates access to information, and critically reduces transaction costs.

Clearly, in this context, the notion of formal appropriation of ideas can be considered alien and inadequate in this Informal Economy context. As one study suggests, actors believe that formal IP based on exclusions and proprietary knowledge is not compatible with the knowledge diffusion and learning processes of the Informal Economy which are based on communities, clusters and the exchange of information."

443. The co-sponsors of the agenda item on "IP and Innovation" have argued that increasing patent monopolies would drive greater innovation. However, the evidence does not support this assertion. On the contrary, the view gaining ground is that increasing patent monopolies would actually stifle innovation.

444. Joseph Stiglitz, the Nobel laureate, in his 2016 paper on "Industrial Policy, Learning, and Development", questioned the benefits of IP and stated that IPRs, especially if poorly designed, can impede innovation and learning.

"There are significant static costs of intellectual property. It impedes the use of information and gives rise to monopoly power. Increasingly, the alleged dynamic benefits have come to be questioned. IPR, especially if poorly designed, can impede innovation and learning. Knowledge is the most important ingredient to production of knowledge, and IPR reduces access to knowledge. Moreover, the patent system intervenes with the open system that is essential for the advancement of science. In addition, the patent thicket and patent trolls have provided further impediments to research. The patent system even distorts the pattern of research, encouraging more research directed at extending market power.

These adverse effects are especially significant for developing countries. Successful development entails closing the knowledge gap and necessitating access to knowledge. It is even more important in areas of health—access to life saving medicines has implications that go beyond the budget."

445. Intellectual Property is only one element in a larger innovation ecosystem and IP laws alone do not promote technology development. According to the Trilateral study by WTO, WHO and WIPO on "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (2013)", Page 126,

"Patent law is not a stand-alone innovation system. It is only one element of the innovation process, and one which can be deployed differently in diverse innovation scenarios. Patent law has little bearing on many other factors that lead to the successful development of technologies, e.g. the nature and extent of demand, commercial advantages gained by marketing and ancillary services and support, commercial and technical viability of production processes, and compliance with regulatory requirements, including through effective management of clinical trials data."

446. India declared the decade of 2011-2020 as the Decade of Innovation. The spirit of innovation has to permeate all sectors of economy from universities, business and government to people at all levels.

447. The MSME sector in India consists of 36 million units and provides employment to over 80 million persons. The sector, through more than 6,000 products, contributes about 8% to GDP, besides 45% to the total manufacturing output and 40% to the exports from the country. The MSME sector has the potential to spread industrial growth across the country and can be a major partner in the process of inclusive growth.

448. To enhance awareness of MSMEs about Intellectual Property Rights (IPRs), the Government of India launched a scheme titled "Building Awareness on Intellectual Property Rights (IPR)" for the MSMEs, in August 2008. The scheme enhances awareness of MSMEs about IPRs to take measures for protecting their ideas and business strategies, which would also assist them in technology upgradation and enhancing competitiveness.

449. A national innovation survey had been conducted during 2011-12, in India, by the Department of Science and Technology (DST), of the Government of India. A national report entitled "Understanding Innovation: Indian National Innovation Survey" with special focus on MSMEs has been brought out by DST. The report is based on the analysis of sample survey of 9001 firms, largely MSMEs, spread across 26 states and five Union Territories across various industrial sectors in the country.

450. The survey identified many barriers to innovation with regard to MSMEs. Some important barriers to innovation include availability of finance and in general the cost of innovation, availability of skilled manpower, access to market information and availability of information technology, infrastructure, domination of established player in the market, regulatory requirements etc. IPR-related issues are not found to be of any concern for the innovation activities of the firms.

451. I conclude by quoting from our Prime Minister Narendra Modi's statement during the launch of the Mission Innovation in Paris in November 2015.

"Our innovation initiative should be driven by public purpose, not just market incentives, including on intellectual property. That also means strong public commitment by suppliers to developing countries. ... Innovation must be backed by means to make it affordable and ensure adoption."

#### **14.8 Colombia**

452. We would like to thank those who have presented this document, which seems to establish the link between intellectual property and innovation and the relation with MSMEs. Colombia recognises intellectual property as one of the priorities for supporting the generation of companies. For this reason, the National Government, in February 2012, established the Business Growth Management Unit which seeks to promote entrepreneurship, innovation and productivity as pillars for business development and competitiveness in the country. This entity also includes among its lines of action, skills training for companies to use tools to protect their innovative developments and innovations working together with the Ministry of Trade, Industry and Tourism and the Observatory for Science, Technology and Innovation.

453. Under the National Strategy to Promote Investment Protection, which seeks to promote a culture of industrial property in regions of the country where there are low levels of patent applications. One of the main outcomes of this Initiative was the launch of two meetings, one in December 2016 and one in February 2017, seeking to provide technical and financial support for the registration of MSMEs to develop innovations that are patentable. These companies reached the necessary technical level to submit several patent applications to the competent authority. This is a continuous effort, and we hope that we can continue to strengthen the programme given its positive impact on the development of these regions.

#### **14.9 Canada**

454. Canada is pleased to present some of its national experiences on MSME collaboration, as part of the broader discussion on "Inclusive innovation and MSME collaboration". We would like to thank the co-sponsors for their Communications on this issue, as well as the delegations that have provided insights on their national experiences and practices so far.

455. One of the key challenges facing MSMEs is that innovation is constrained by the availability of resources for research and development (R&D). Indeed, a key irony for small businesses is that, while the fastest way to boost productivity and economic growth is often innovation, the resources available for R&D are also tied to a firm's size. In Canada, for instance, MSMEs make up the largest proportion of Canadian firms (and similar to the proportions reported by a few other delegations, this accounts for roughly 97% of domestic firms). Individually however, MSMEs account for proportionally less R&D spending than large businesses. Collaboration between MSMEs, as well as with other types of firms, educational and other institutions, can therefore play a crucial role in supporting innovation in a competitive global economy. For MSMEs, global collaboration has become a competitive necessity. Indeed, as global trade becomes increasingly organized along global and regional value chains, innovation is also correspondingly designed around research networks and clusters, enabling MSMEs to enter into cross-border research arrangements and seek new market access opportunities.

456. In view of the economic constraints faced by MSMEs in innovating, growing and seeking new markets, the Government of Canada has undertaken a range of initiatives and programs aimed at facilitating their collaboration. For instance, Canada's Trade Commissioner Service (TCS) and the National Research Council Industrial Research Assistance Program (NRC-IRAP) manage several bilateral programs aimed at fostering collaboration between small Canadian businesses in partnership with foreign market players. For instance, the Trade Commissioner Service Going Global Innovation program supports Canadian researchers from SMEs, universities and non-governmental research centres aiming to commercialize technology through collaborative R&D partnerships in foreign markets. This program provides financial assistance to Canadian researchers, including for international travel, legal fees to support formalized partnerships, and other costs related to international collaboration.

457. Similarly, the Canadian International Innovation Program (CIIP), managed by the TCS and NRC-IRAP, is a bilateral funding program that fosters collaborative R&D projects for the

commercialization of research between researchers in Canada and partners in Brazil, China, India, and Korea, as well as with Israel through the Canada-Israel Industrial Research and Development Foundation. For instance, in March 2016, the CIIP launched a request for proposals from Canadian SMEs and innovators in India on collaborative R&D projects. This collaboration, undertaken in partnership with India's Global Innovation Technology Alliance, will provide R&D funding in priority areas such as: clean and green technology; energy efficiency; affordable healthcare; information and communications technologies (ICTs); electronic system design and manufacturing; advanced manufacturing; and, water technology.

458. More recently, in September 2016, the NRC-IRAP and Germany's Ministry for Economic Affairs and Energy signed a declaration of intent to stimulate and fund innovation-driven collaboration among German and Canadian SMEs. The arrangement will foster collaborative scientific and industrial R&D projects aimed at accelerating the development of new technologies with high potential for commercialization. In the fall of 2016, a call for proposals was launched in which eligible SMEs may receive funding through Canada's NRC-IRAP, as well as through Germany's Central Innovation Programmes for SMEs.

459. Canada has also developed formal science and technology relationships and partnerships with established and emerging innovation networks around the world. For instance, Canada has developed a framework for international collaboration through science and technology (S&T) agreements with a number of bilateral partners, including in the Asia-Pacific, Europe, Latin America and the Caribbean. These S&T agreements serve as guidelines for Canadians to effectively work with partner countries to increase international science and technology capacity. A related initiative, the Canadian Technology Accelerator (CTA) provides high-growth, market-ready Canadian companies support to access global markets and entrepreneurship services within the ICT, life sciences, and clean technologies. Managed by the TCS, the CTA provides support for Canadian technology SMEs to access global market opportunities in nine cities, including key ICT, life sciences, and clean technology markets in the United States.

460. Canada is also an associate country of EUREKA, an international network for market-driven industrial R&D. EUREKA includes over 40 economies from the EU, Europe, Israel, and Korea, and serves as an international network to coordinate national funding sources between international project partners, to accelerate innovation in new technologies, products and services for commercialization. Since joining EUREKA in 2012, Canada's associate membership has provided close to 50 Canadian innovators, most of which are SMEs, with the opportunity to pursue projects with international partners with a combined value of over CAD\$50 million (or approximately USD\$38 million). As well, as part of this program, participants retain complete IP ownership and negotiate IP arrangements amongst themselves on a project-by-project basis.

461. With respect to collaboration among MSMEs relating to IP more specifically, the Government of Canada's framework laws on IP are designed for general applicability to all businesses, while also being mindful of not creating barriers to MSMEs. For instance, the Canadian Intellectual Property Office (CIPO) provides IP frameworks and innovation programmes that assist MSMEs to build and maintain collaborations. In particular, CIPO provides online guidance for businesses on licensing or assigning part or all of a business' IP rights to third party collaborators or purchasers; business intelligence on how to use IP data to learn about innovations in a particular field, including with respect to potential partnerships, competitors, and changes in market conditions; and financing resources for IP. CIPO is also modernizing its services to help businesses in Canada better access the Canadian IP system and leverage their IP rights for collaborative purposes, including through licensing and other arrangements. Furthermore, Canada's efforts to align with international IP standards and filing systems creates an environment that facilitates global MSME collaboration, for instance, by harmonizing filing procedures available to businesses collaborating in networks across jurisdictions.

462. Once again, Canada would like to thank the co-sponsors for proposing this topic for discussion. Given the role that collaborative arrangements play in innovation, not only nationally but also in the form of regional research networks and international partnerships across jurisdictions, we remain very interested in hearing about the experiences and practices of other delegations. Canada will also be pleased to continue discussions on topics of "MSME growth" and "MSME trade" at upcoming meetings of the TRIPS Council, and looks forward to sharing more of its experiences on these issues.

#### 14.10 Argentina

463. Argentina thanks Australia, Chinese Taipei, the European Union, Japan, Switzerland and the United States for the proposal contained in documents IP/C/W/622 and 625 on "Inclusive Innovation and MSME Collaboration" and for their presentations.

464. We view this proposal with great interest. In Argentina, as in other countries, MSMEs play a key role in the economy by reason of their contribution to GDP, employment and economic development. In addition, they possess enormous innovative capacity. Intellectual property rights are an important aspect of innovation. Patents, trademarks, industrial designs, copyright and utility models are tools that can be used to protect innovation.

465. Argentina's domestic production plan focuses on MSMEs and helps to protect their development through trademarks, industrial designs or patents. We await with interest the exchange of experience regarding the three aspects of innovation cited by the co-sponsors (collaboration, growth and trade) and their relationship to MSMEs.

#### 14.11 Guatemala

466. We thank the delegations that have proposed this agenda item, as it underlines the importance of the link between the intellectual property system in innovative agencies and enterprises.

467. Guatemala points out that, in its National Intellectual Property Strategy, intellectual property has emerged as a key tool for countries' innovation, transfer of technology and competitiveness, as it has resulted in creations and knowledge that become intangible wealth-generating assets of commercial value. A good intellectual property system strikes a balance between the interests of the right holder and the general interest, encouraging creation and innovation and facilitating economic and social development.

468. Currently, the ability to compete on a global scale conditions a country's prosperity; to be able to compete at the international level, a country's economic actors need to stand out and to do so they must incorporate the intangible assets aspect into their business strategies, particularly intellectual property.

469. Intellectual property does not only enhance the value of companies but also of the economy as a whole. In the knowledge economy in which we live, the bases of competitive advantage lie in the processes and characteristics that make products or services unique. Innovation is essential in achieving this differentiation or value added, meaning innovation in the broad sense, not only as regards technology but also the product of business models, procedures, market positions or other elements which make something unique or different.

470. A broader vision of innovation can help a country to attract more resources. A vision which can be applied in the following sectors:

- (a) technological improvements;
- (b) improved processes;
- (c) different products;
- (d) new marketing approaches;
- (e) new forms of distribution;
- (f) green innovation or eco-innovation.

471. Together with the foregoing, innovative capacity will depend on an interrelated ensemble of investment, business policies and allocation of resources to support innovation that is "new for the world". The following are needed to achieve this:

- promotion of all types of innovation;



- education to improve creativity and entrepreneurship;
- fostering the mobility of researchers;
- greater exploitation of the domestic market;
- particular attention to be paid to the services sector which offers under-exploited opportunities, notably through synergy with the industrial sector;
- standardization and guarantee of quality;
- international bilateral and multilateral cooperation;
- promotion of groups or clusters from which knowledge reaches the market more rapidly;
- increased productivity;
- attracting investment;
- promoting research;
- strengthening the entrepreneurial basis.
- developing special products or services and capacities.

472. On this basis, as part of its 2016/2021 Economic Policy, the Government of Guatemala has established support for MSMEs as a strategic focus in order to enable and promote action for productivity, competitiveness and internationalization, determining the use of intellectual property systems as one of the tools to achieve this.

#### **14.12 Mexico**

473. We are pleased to be able to contribute to this agenda item of the TRIPS Council. The public policy of the Government of Mexico considers the use of intellectual property to be a key factor in the development of small and medium-sized enterprises, particularly for start-ups, whose business model is dependent on innovation. Intellectual property in a start-up is, therefore, a critical factor in protecting the company's intangible assets.

474. The importance of intellectual property also extends to socially-oriented businesses, which, with intellectual property protection, can make profits in a shorter period of time. We will accordingly go on to briefly illustrate the cooperation of the Mexican Industrial Property Institute in the Entrepreneur Support Network (Red de Apoyo al Emprendedor) programme, which is implemented by the National Entrepreneurship Institute (INADEM), the Mexican Government agency specializing in small and medium-sized businesses.

475. Through the Entrepreneur Support Network, users have access to an Internet portal, whose main purpose is to ensure that anyone with a good business idea has access to the support they need to enter the market.

476. In the case of the Mexican Industrial Property Institute, cooperation via the portal involves offering advice and support to entrepreneurs in obtaining intellectual property rights, as well as providing general information on the subject and raising awareness of its benefits.

477. Between July 2014 and August 2016, advice was provided to 9,823 entrepreneurs via the Network, which the Mexican Industrial Property Institute also used to actively participate in various national events, including the National Entrepreneurship Week (Semana Nacional del Emprendedor) and the National Entrepreneurship Award (Premio Nacional del Emprendedor), designed to encourage and promote innovation among entrepreneurs, particularly among micro, small and medium-sized businesses.

478. Additionally, every year the Mexican Industrial Property Institute holds the "Jornadas Expo Ingenio", which are mobile events with discussion panels, workshops and personalized advice aiming to bring together those who create and promote industrial property with industrial property users and applicants. Participants in these events include representatives of the intellectual property ecosystem, entrepreneurs as well as micro, small and medium-sized enterprises.

479. Last but not least, in the framework of international forums, particularly in the Intellectual Property Rights Experts Group (IPEG) of the Asia-Pacific Economic Cooperation forum (APEC), the Mexican Industrial Property Institute has advanced initiatives in the field to support entrepreneurs and micro, small and medium-sized businesses.

480. Within the IPEG, Mexico was part of a joint initiative which also involved Korea, Russia and the Philippines, in which the countries joined forces and discussed actions to assess and strengthen the industrial property-related capacities of SMEs.

481. In 2016, the IPEG approved an intellectual property project submitted by Mexico, called "SMEs Innovation: Capacity Building on IP Strategy". One of the objectives is to create links between SMEs and the academic and scientific sector, so that entrepreneurs become focused on constant innovation and researchers acquire a business-oriented outlook to place their inventions on the market. The event will last two days in Mexico City and will take place in September 2017.

#### **14.13 Israel**

482. When talking about Israel, we have to talk about innovation, technology and start-ups. As many of you probably know, Israel is a start-up nation. We refer to start-ups, because in Israel the term is widely used and recognized. Although the term may be broader than the term micro, small and medium-sized enterprises or MSMEs, we believe that the term encapsulates many of the so-called MSMEs. Defining a start-up is more difficult than it seems, but there are a common few traits: solutions, innovations and lack of resources. These are traits shared by MSMEs. It is true that some start-ups graduate to the next level, but it is also true that the bulk of them remain as MSMEs.

483. In 1993, a Government initiative aimed to increase the number of companies using Israel Inventor funds. As a result of this effort, Israel's annual venture capital outlays rose nearly 60-fold, from 58 million to 3.3 billion, in the first ten years, and the growth tendency continues. The number of companies launched using Israeli venture funds rose from 100 to 800. Israel's information technology revenue rose from 1.6 billion to 12.5 billion. With a population of 8.5 million people, Israel has over 6,000 start-ups, and attracts more venture capital per person than any other country in the world.

484. The Israeli start-up scene extends from the tech hub of Tel Aviv to Jerusalem, and all the way to the southern district city of Beersheba. In Israel the start-up scene is a way of life and innovation permeates our society and culture. This is reflected in Israel's R&D expenditure as a percentage of the GDP which in 2014 was the highest within OECD members at 4.2% of GDP, while the average at OECD stands at 2.4%.

485. This all leads to a highly innovative country which was ranked fifth place, according to Bloomberg's Innovation Index in 2015. In Israel, we have had many programmes and policies to foster this innovation environment, but one of the ones worth highlighting are those under the Israel Innovation Authority. The Israel Innovation Authority, formally known as the Office of the Chief Scientists of the Ministry of Economy, is responsible for the country's innovation policy and is an independent and impartial public entity that cooperates for the benefit of the Israeli innovation ecosystem and the Israeli economy as a whole. Its role is to nurture and develop Israel innovation resources, while creating and strengthening the infrastructure and framework needed to support the entire knowledge industry.

486. For the benefit of entrepreneurs and stakeholders in the high-tech industry, the Israeli Innovation Authority has set up a vast array of active innovation divisions that concentrate on providing optimal solutions to a variety of changing needs. One of these divisions is the Start-Up Division, which offers unique tools to support the early development stages of technological initiatives. These tools assist entrepreneurs in the start-up companies in developing their innovative technological concepts at the planning or initial R&D stages. Transforming ideas into reality can reach significant fundable milestones. The Start-Up Division incentive programmes are designed for the following target audiences: entrepreneurs with an innovative technological idea, and early stage start-up companies.

487. Another programme worth highlighting is known as "Tnufa Incentive Programme", which is designed for fledgling entrepreneurs who are interested in formulating and validating an innovative technological concept and in reaching the R&D stage, where they can raise funding for further development and commercialisation. The main objective of this programme is to assist the project in building an initial prototype, intellectual protection and initial business development.

488. Although Israel focuses heavily on technology, non-technology and innovations can benefit from some of these programmes as well. This is just a very brief description of some policies Israel aims at fostering innovation in MSMEs which as I mentioned before share many traits with what we call in Israel start-ups.

#### **14.14 Dominican Republic**

489. We would like to thank the proponents for including this item on the agenda of this Council meeting and we would like to share with Members the experience of the Dominican Republic in the area of intellectual property and innovation: inclusive innovation and collaboration with SMEs.

490. In The National Intellectual Property Strategy of the Dominican Republic, innovation has been established as a priority, and it is through the National Office of Industrial Property that a priority plan was launched for the promotion of invention and the use of a patent database as a tool which does give added economic value to national production.

491. In the course of the last two years our country has already witnessed the changes of this new focus which has led to a boosting of technological innovation. We also must highlight the excellent results of the first Appropriate Technology Competition which was carried out in the Dominican Republic in 2016, and thanks to motivation of our country, in the first trimester of 2017 four nations of the Central American sub-region will carry out competitions that promote innovation and emphasize the role of the innovator in problem-solving and wealth creation. The competition is sponsored by the Korean Invention Promotion Association (KIPA), the Korea Intellectual Property Office (KIPO) and the World Intellectual Property Organization (WIPO). It is in this way that the Dominican Republic carried out the Appropriate Technology Competition, entitled "Innovative Solutions for Everyday Life". Appropriate technology is designed with particular attention given to environmental, ethical, cultural, social and economic aspects of the targeted community. Given these considerations, appropriate technology comes from the local environment and normally requires fewer resources, it is easier to maintain such technology and is less costly and has a lesser impact on the environment as compared to other equivalent technologies, they do also generate innovate solutions and completely aimed at resolving local problems.

492. One of the aims of the competition is to raise awareness of the use of patent databases and the importance for Dominicans to become more familiar with seeking of solutions which already exist and adapting them to the socio-economic reality of the country. For the promotion of the competition, 30 nationwide local workshops were organized, along with advertisement in the national media, resulting in 56 participants presenting 83 innovative projects. From those projects, 10 were selected as finalists according to the terms established by WIPO and KIPO, and later 3 were selected as winners. The competition was a success and it did achieve the result, that is, to use information of patents to generate Appropriate Technology, providing solutions to everyday problems in a community. With this type of initiative the Dominican Republic aims at fomenting invention in the new generations and to promote the industrial property rights system. We would like here to quote a few examples:

493. The programme "Formalize Yourself" which is a legal formalization programme for enterprises, increased by 82% in 2015 with a total of 1,215 of trade names registrations granted by 15 December 2016.

494. In the area of innovation, The Centre for Support to Technology and Innovation (CATI) was created by the National Office of Industrial Property of the Dominican Republic, on an initiative of WIPO with the purpose of facilitating access to information on industrial property for innovators and researchers, entrepreneurs, universities, SMEs in the country through information technology services, distinctive signs and other related high quality services. The CATI of Dominican Republic was set up in 2011 and since then different activities have been carried out so as to promote the use of patent information and public domain. It has the following objectives: advice to inventors,

researchers, students and the general public on industrial property and particularly on patents; search for technological information to know prior art for a given product or an invented procedure; advice on the presentation of applications for patents or industrial designs, forms, drafting of documents, fees, terms, international applications and support to meet the different requirements, both on a formal and substantial examination; approach universities and research centres so as to disseminate the objectives of CATI and promote the setting up of local CATI, along with SMEs, industries and clusters, with the objective to promote the services of CATI; and train the focal points of universities and research centres through on-line and classroom classes.

495. Other initiatives that we have successfully carried out in our country is the Innovator Summer Camp. This came as a solution to respond to the need to train innovators and motivate teenagers to choose STEM careers (Science, Technology, Engineering and Mathematics). The methodology of this camp is based both on theory and practice. Over a period of 4 weeks in July, 50 meritorious students are chosen specifically with a high level of knowledge in the natural sciences and mathematics, from the third grade of the middle school both in public and private schools in the four mentioned areas. The idea is always to focus searches on the basis of patent databases which then can be applied at the end of the summer as a prototype or oral project.

496. Training is provided to SMEs in creation of trademarks for which we have trained 153 SMEs at national level. Workshops have been organized on trademark and packaging so as to strengthen the export capacity of national MSMEs.

497. Finally different cycles of talks have been organized on "Industrial Property and Development of Fashion Trademarks" by the Dominican Republic Institute of Fashion (INMODA RD) with the objective to increase the training culture in fashion in the country.

#### **14.15 Russian Federation**

498. We would like to thank Australia, the European Union, Japan, Switzerland, the United States and Chinese Taipei for their initiative and the tabled documents. We are glad to share today the Russian experience relevant to fostering collaboration and innovation among MSMEs.

499. In order to increase MSME's inclusion in innovation the Government of the Russian Federation created a non-profit Assistance Fund for Innovation, which provides help to small enterprises in R&D domain. The Fund is represented in more than 70 regions of the country. Its main activities cover the following:

- enhancement of inclusiveness of young population in innovation activities,
- support of start-ups,
- support of commercialization of R&D results,
- development of hi-tech sectors of economy.

500. One of the regional offices is located in the Academic City of Novosibirsk, which is a complex with a unique technological infrastructure, creating extremely favourable environment for innovative activities by MSMEs. Its experience of inspiring collaboration between its residents has been recognized as one of the most effective among all Russian technological clusters. Academic City focuses its activities in four directions:

- information technologies,
- instrument engineering,
- nanotechnology
- biotechnology.

501. The Academic City provides special infrastructure for each of these activities. In particular, specialized business-incubators help young companies by providing cheaper facilities, equipment and access to laboratories.

502. This project became a leader in the number of participants, created work places and volumes of return of its participants, among 12 technological clusters created in Russia. Moreover, it

became highly commercialized with the share of state investment amounting to only 21% of all investments attracted to the Academic City.

503. International collaboration is enhanced by its membership in the European Business and Innovation Centre Network, as well as in the International Association of Science Parks and Areas of Innovation.

504. We thank the Membership for their attention and hope that our short presentation has provided certain understanding of the Russian experience in creating favourable environment for fostering MSMEs collaboration and innovation.

#### **14.16 Brazil**

505. We thank the delegations of Australia, EU, Japan, United States and Switzerland for the documents circulated for this session. The interrelation between intellectual property and innovation is a topic of interest to our delegation, since the encouragement of innovation and knowledge is one of the major justifications for the intellectual property system. The TRIPS Council, by addressing these issues in a coherent way, could provide valuable contributions to the design of effective national innovation policies.

506. The document IP/C/W/625 continues to be analyzed by relevant Brazilian authorities. We will be glad to report back to our capital the discussions held in this session. The improvement of the productivity and competitiveness of MSMEs is a continuous goal of the Brazilian government.

507. Regarding the document IP/C/W/622, while we favorably view the discussion contained in it, our understanding is that adopting a work programme would depart from the ordinary practice of this Council.

#### **14.17 New Zealand**

508. Thank you to the co-sponsors of this item for putting it on our agenda and also for their comprehensive presentations. Also thanks to those who have since taken the floor to add their experiences. MSMEs play an extremely important role in New Zealand's economy and New Zealand recognises the importance of promoting inclusive innovation and business collaboration and building capability. In the interest of information sharing we would like to briefly outline New Zealand's two government agencies which support innovative businesses.

509. The Callaghan Innovation has a domestic focus and offers a range of services and tailored programmes to businesses involving innovation and IP. This includes access to experts, technology and product development, innovation skills, business collaborations and research and development grants.

510. New Zealand Trade and Enterprise is an international business development agency whose purpose is to help New Zealand businesses grow internationally. It offers a range of similar services and tailored programmes to assist businesses to expand into new markets. It also promotes New Zealand to foreign businesses and investor as well as helping businesses and investors in innovation as well as making international connections and mutually collaboration across international borders.

#### **14.18 Bangladesh - on behalf of the LDC Group**

511. I thank the proponents Australia, the European Union, Japan, Switzerland, the United States and Chinese Taipei for submitting such an important issue for discussion. I thank them for sharing with us their good and exciting experiences with MSMEs in their countries. It is true that micro, small and medium-sized enterprises are the real pivotal force for the national and global trade and commerce and this could not be more factual and relevant for LDCs because as mentioned in the submission, we also see the importance for employment, production of goods for daily necessities, agriculture, poverty reduction, empowering of women, savings, export and other social development. All these factors are particularly dependent on the activities of MSMEs in LDCs.

512. However, if we examine the status and investment of MSMEs in the LDCs, we see that establishment and securing an IP regime may or may not play a role for their development. A prerequisite for the development of MSMEs in LDCs is the creation and promotion of an ambience for innovation first rather than enforcement of an IP regime.

513. In Bangladesh, the number of MSMEs are around 1.6million. MSMEs constitute 99% of private industrial establishments and provide 70-80% employment of the non-agriculture labour force. We have the two largest end-users in the world, one is Brac Bank and the other is Grameen Bank and they principally deal with employing the SMEs. In addition the Government also disperses huge amount of micro-credit for MSMEs. Our experience shows that if the MSMEs are provided with an enabling environment for innovation, they are better. We have seen that MSMEs usually use the local genetic resources, traditional knowledge and traditional cultural expressions to the advantage of their business and development.

514. So, if we have to protect anything, then we will have to protect the genetic resources, traditional knowledge and traditional cultural expression of the different countries locally and globally. The agenda items 4, 5 and 6 or the IGC can also be important in this regard. This national and global protection will create a beneficial and supporting environment for innovation. Going for protection of IP without promoting and securing these elements will be like putting the car before the horse. We also have to remember that the nature and orientation and the very differentiation of MSMEs in developing countries and LDCs are starkly different from those in developed countries. So, local realities in developing countries and LDCs must be considered when we look for ways and means for development of MSMEs. A simple combination of two different environments would be erroneous. I, again, thank all the proponents for introducing such an important issue to the Council.

#### **14.19 Nigeria - on behalf of the Africa Group**

515. Let me thank the proponents of this agenda item and, of course those who have shared their experiences. In particular, the presentation by Japan was a very good one, because at least there is involvement of the young ones. Because in Nigeria we say "you catch them young", so at least when you start with universities it is a welcome development. This item is coming at an important period when the Government of Nigeria is increasing its effort to diversify Nigeria's economy. In this context, the Government of Nigeria has launched a nationwide project code named "MSME Clinics" to address the challenges faced by the MSMEs in Nigeria. The project will serve as a one-stop shop to address the challenges faced by small business owners. According to the Nigerian National Bureau of Statistics, over 37 million MSMEs operated in Nigeria between 2010 and 2013. To encourage MSMEs in Nigeria to use intellectual property, there are a number of programmes that are on course at the moment, like the one on national awareness programme on intellectual property rights and technology information in patent documentation; and, also other collaborative efforts are under way between the Office of the National Office for Technology Acquisition and Promotion of Nigeria and then the Small and Medium Enterprises Development Agency of Nigeria.

### **AGENDA ITEM 15: INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO**

#### **15.1 WTO Secretariat**

516. Many thanks for giving the Secretariat an opportunity to provide a further update of IPR-related issues as they have come up in the most recent Trade Policy Reviews.

517. Since the meeting in November, the Trade Policy Reviews of Guatemala, Solomon Islands, the United States and Sierra Leone have taken place. I am pleased to report that developed country, as well as developing country and LDC Members have substantively contributed to the discussions on TRIPS-related issues during these reviews.

518. In particular, Members continued to engage in a constructive exchange views on a wide range of trade-related IP issues, including: copyrights and related rights; royalty fees for satellite transmissions; statutory copyright licences; trademarks; geographical indications; plant variety protection; patent quality; preferential patent fees; benefit sharing agreements; data exclusivity; marketing approval for new drugs; protection of trade secrets; enforcement measures, online and

at the border; adjudication procedures; judicial review of administrative decisions; and the operation of Articles 66.2 and 67 of the TRIPS Agreement. Members also touched upon the ratification of WIPO Treaties including the Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired, or otherwise Print Disabled; Beijing Treaty on Audio-visual Performances; and the Trademark Law Treaty; the implementation of national IP strategies, as well as on Technology and Innovation Support Centres.

## **AGENDA ITEM 16: OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS**

### **16.1 United States**

519. Just in the interest of reiterating our long-standing position, we can agree to permanent observer status for ARIPO, OAPI, GCC and EFTA. As for the other pending requests, we are unable to support those at this time.

### **16.2 Nigeria on behalf of the Africa Group**

520. Let me start by thanking the United States for their statement, in particular for supporting our two regional bodies that are responsible for IP implementation in Africa. With this statement perhaps if there could be consensus, of course, last time we heard an intervention from Brazil trying to at least justify the position that they took. The Africa Group deliberated on that and we are still not convinced, because our belief is this: we know it is beyond the competence of the Africa Group to force consensus on the CBD Secretariat. We are members of the CBD, we will continue to push for CBD Secretariat's observer status whether it is ad hoc or permanent, but at least for the ARIPO and OAPI who are responsible for IP in Africa, I think it is important that they should be allowed to come in as permanent observers in the TRIPS Council.

### **16.3 India**

521. India supports granting of permanent observer status to three intergovernmental organizations - South Centre, the CBD Secretariat and the International Vaccine Institute. They fulfill the requisite criteria laid down by the General Council with regard to observer status.

522. South Centre is an intergovernmental organization with 53 developing country Members coming from the three developing country regions of Africa, Asia, and Latin America and the Caribbean. The South Centre undertakes research and analysis oriented on various international policy areas that are relevant to the protection and promotion of the development interests of developing countries, including on IPR issues. They have contributed to the discussions in the TRIPS Council like sponsoring a side-event yesterday at the WTO on the report of the High Level Panel Report on Access to Medicines. South Centre already has observer status in WIPO, WHO, CBD and many other UN bodies.

523. The Convention on Biological Diversity (CBD) fulfills all the required parameters for observer ship of the WTO. The WTO Secretariat has observer status at the CBD and regularly participates in the CBD meetings. So as a matter of reciprocity, the CBD Secretariat shall be granted observer status.

524. We would also like to support the request from the International Vaccine Institute (IVI) for observer status in the Council for TRIPS. The International Vaccine Institute, which was created initially as an initiative of the United Nations Development Programme (UNDP), is the world's only international organization devoted exclusively to developing and introducing new and improved vaccines to protect the world's poorest people, especially children in developing countries.

525. India requests Members opposing the three organizations to provide a valid reason for their stand given that all the three organizations fulfill the requisite criteria laid down by the General Council with regard to observer status.

526. On the request of Nigeria, India is in a position to support only the two African Intellectual Property Organizations, ARIPO and OAPI.

#### **16.4 Bangladesh on behalf of the LDC Group**

527. I take the floor just to reiterate our position that we support the three pending requests from the International Vaccine Institute, South Centre and CBD Secretariat. We think that they would positively contribute to our discussion and they would add value to whatever we discuss here, especially South Centre is already a permanent observer in other WTO Committees and we can draw reference from them and we can see that there is nothing to fear. So again we ask all the Members to support their request.

#### **16.5 Brazil**

528. Brazil supports the approval of the request from South Centre and CBD as permanent observers at the TRIPS Council as a matter of priority. As stated by our colleague from India, South Centre is the intergovernmental organization of developed countries that helps them combine their efforts and expertise to promote the common interests in the international arena. It has observer status in several international organizations. In the WTO, it is an observer to the Committee on Trade and Development, its first request for observer status in the TRIPS Council dates back to 1999. It would contribute to a more meaningful participation of developing countries in the TRIPS Council discussions without in any way harming the interest of other Members.

529. The CBD is an agreement ratified by as many as 196 parties. It represents a dramatic step forward in the conservation of biological diversity, fostering the sustainable use and the fair and equitable share of benefit arising from the use of genetic resources. Unlike other permanent observers, the CBD is directly implicated in a number of items of the TRIPS Council's permanent agenda. A specific item regarding the relationship between the TRIPS Agreement and the CBD is part of the agenda of every TRIPS Council meeting, and those discussions could greatly benefit from the participation of the CBD Secretariat as a permanent observer.

530. Brazil reiterates its view that the decision should be taken with respect to South Centre and CBD as a matter of priority. We invite delegations to share their concerns regarding their observer status, something we have not heard up to this moment.

531. Regarding the other four requests, namely ARIPO, OAPI, GCC and EFTA, we support the ad-hoc status. We are looking for a holistic solution for the outstanding requests of all organizations.

#### **16.6 European Union**

532. We can also reiterate our long-standing position. We can go along with the proposal to invite the Convention on Biological Diversity Secretariat on an ad-hoc basis whenever the relationship between the Convention on Biological Diversity and the TRIPS Agreement is on the agenda of the TRIPS Council, given the relevance of the debate for some of the provisions of the Convention of Biological Diversity and Nagoya Protocol.

533. We also support to grant observer status to ARIPO, OAPI, the GCC and EFTA.

#### **16.7 South Africa**

534. Our delegation would align itself with the statement made by Nigeria on behalf of the Africa Group. We support the call to have ARIPO and OAPI inscribed as permanent observers. Furthermore, in respect of South Centre and the CBD Secretariat, we have reiterated in the past that we would also support observer status of these organizations.

#### **16.8 Egypt**

535. We would like to associate ourselves with the statements made by both Brazil and India with regard to granting observer status to both the CBD Secretariat and South Centre. We also support the requests from Nigeria regarding granting observer status to both ARIPO and OAPI.



### **16.9 China**

536. China supports that the CBD Secretariat and South Centre be granted permanent observer status, at least on an ad hoc basis.

### **16.10 Plurinational State of Bolivia**

537. We also join India, Brazil, Bangladesh, China and others who have spoken before us in order to support the request to grant permanent observer status in this Council to South Centre, the CBD Secretariat and also to the International Vaccine Institute. We support this and we hope that we can find a solution to this problem.

### **16.11 Cuba**

538. Cuba would also like to support the granting of observer status to South Centre and to the CBD Secretariat.

### **16.12 Bolivarian Republic of Venezuela**

539. We also support the statements made by India, Brazil and Cuba in terms of granting the South Centre observer status.

### **16.13 Indonesia**

540. Indonesia would like to reiterate its position to support South Centre and the CBD Secretariat to be granted observer status.

### **16.14 Nigeria on behalf of the Africa Group**

541. Now that we have no consensus for the permanent observer status of these institutions, I would encourage the Chair between now and the next TRIPS Council to hold consultations to see if we could arrive at consensus.

## **AGENDA ITEM 17: OTHER BUSINESS**

No statements were made under this item.

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