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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 13 JUNE 2017

Chairperson: Ms Irene Young (Hong Kong, China)

Revision[a,b]

The present document contains the statements made during the Council for TRIPS meeting held on 13 June 2017.

[a] In English only.
[b] This Revision is being distributed to communicate a corrected index on page 2.

INDEX OF THE STATEMENTS MADE
AT THE MEETING OF COUNCIL FOR TRIPS 13 June 2017*

***** 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.

AGENDA ITEM 1: ELECTION OF CHAIRPERSON

1. No statements were made under this agenda item.

AGENDA ITEM 2: NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

2.1 WTO Secretariat

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

- From Hong Kong, China, Patents and Ordinance Order 2017, the Registered Designs Ordinance Regulation, the Trademarks Ordinance Regulation 2017 and the Layout-Design (Topography) of Integrated Circuits Regulation 2017;

- From Switzerland, a number of notifications which include among others consolidated versions of the Federal Law and Ordinance covering the following areas: copyright and neighbouring rights; trademarks and indications of source; patterns, designs and topographies of semi-conductor products; a number of GI–related ordinances as well as the consolidated version of the Federal Law on Agriculture and the Federal Law on the Statute and Tasks of the Federal Institute of Intellectual Property as well as the Fees Charged by the Institute. Some of these laws and regulations notified also include provisions related to IP enforcement;

- From the European Union, the 2006 Directive on the term of protection of copyright and certain related rights; certain Commission Regulations in the field of trademarks; the 2013 Regulation establishing a Common Organization of the Markets in Agricultural Products, the 2014 Regulation on the Definition, Description, Presentation, Labelling and the Protection of Geographical Indications of Aromatised Wine Products, as well as a number of Commission Regulations in the field of geographical indications; the E-Commerce Directive adopted in 2000; as well as the 2012 Regulation entrusting the Office for Harmonization in the Internal Market with tasks related to the enforcement of intellectual property rights; and

- From Norway, the Industrial Property Office Act which entered into force on 1 April 2013.

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

4. Furthermore, Kazakhstan has notified its responses to the Checklist of Issues on Enforcement shortly before this meeting which have been circulated in the IP/N/6–series of documents. No other initial responses or updates to earlier responses have been submitted since our last meeting.

5. To conclude, as regards contact points, we have received information from Myanmar under Article 69 for the exchange of information and cooperation on trade in infringing goods. Also, Botswana has updated its Article 69 contact points. And again the information on the Members' transparency toolkit page has been updated accordingly.

2.2 European Union

6. We did a bit of house-cleaning in our legislation and we went out to look back for any pieces of legislation that are intellectual property relevant. We found a number that we had not notified in due time. Since there are around 15 pieces of legislation, I will introduce two of them as an example: Regulation 251/2014 on Geographical Indications for Aromatized Wine Products, this is a Regulation that stipulates the specifications of aromatized wine products, and protection of their geographical indications. It seeks to ensure high levels of consumer protection, product authenticity, market transparency and fair competition. It applies to all aromatized wine products placed on the market in the European Union whether they are produced in the EU or in non-EU countries, and also products produced in the European Union for export. The preceding Regulations dating from 1991, and from 1994, regulating aromatized wine products, proved

successful and, while independent of these Regulations, markets considerably expanded and there was a growth in this area. However, due to technological innovation, market development and evolving consumer expectations, it was necessary to update the rules on the definition, description, presentation, labelling and protection of geographical indications for these products.

7. Regulation 386/2012 on the Establishment of the European Observatory on Counterfeiting and Piracy created an institution that is producing remarkable work since then. This Observatory had already been established de facto in 2009 as an EU-wide network of representatives to support the protection of intellectual property rights and help combat the growing threat of IP infringement and also as a centre of excellence on information and data relating to the value of intellectual property rights and the negative consequences of infringement thereof. The Observatory was at the time intrusive to OHIM which in the meantime became the European Union Intellectual Property Office, our agency in charge of registration of trademarks and designs in June 2012 by this Regulation. The Regulation covers the responsibility for a wide range of tasks relating to research, communication, and spread of best practices and enforcement of all types of intellectual property rights, thus not limited to the ones that are attached to the EUIPO. In order to carry out these assigned tasks, an Observatory department was formed in late 2012 consisting of three main areas: (i) the Observatory operations and projects (ii) the Academy and (iii) the Chief Economist. Thus the Observatory has become fully integrative into the EU IP Office and benefits from all the capabilities and resources of this Office. Aligned with the EU IPO Strategic Plan, there is an Observatory multi-annual plan which identifies several key initiatives designed to enable it to become the centre of excellence and the central resource for gathering information that will facilitate and support the activities of national authorities, EU institutions and the private sector. Here in the broader sense of the term it is not only about right holders but also other civil society sectors and organizations.

8. These key initiatives will be executed by the Observatory and/or several resources as appropriate, taking full advantage of the synergies created by putting in place representatives of all these different interests. European Union policy makers see innovation and creativity as a corner stone of economic development. In this context and considering the mission and the range of activities defined in Regulation 386/2012 the EU has set three main goals for the Observatory: provide facts and evidence for use in formulation of effective IP policies by policy makers; to create tools and resources to sharpen the fight against IP infringement; and to raise awareness of intellectual property and of the negative effects of counterfeiting and piracy. The approach to achieve these proposed goals is based on two complementary pillars. The first pillar aims at strengthening the efficiency and efficacy of the public-private network that makes up the core of the Observatory's function. The second pillar aims at facilitating and promoting the process of cooperation with third countries in order to advance knowledge and enhance protection of intellectual property.

9. The three goals of the Observatory will be achieved by executing five key initiatives grouped in the following lines of action: 1) evidence based contributions and data to enable EU and national policy makers to shape effective IP enforcement policies and to support innovation and creativity; 2) data, tools and databases to support EU and national authorities in the fight against IP infringement; 3) knowledge building and learning programmes for enforcement authorities as well as for businesses especially small and medium-sized enterprises and on that I will be discussing more later in the Agenda; 4) campaigns to raise overall awareness of IP value and the negative effects of IP infringement; and 5) initiatives to help right holders protect their IP rights both within and outside of the European Union. In pursuing these programmes the Observatory has already published a considerable number of studies on intellectual property, on methodology, and on economic value. Therefore, remarkable work has already been done in the last five to six years. I believe this is useful because there is an international dimension to the work of the Observatory and there is of interest in value to all Members of this Council.

2.3 Hong Kong, China

10. We have recently updated the list of qualifying countries, territories or areas for meeting the international obligations under the Paris Convention and/or the TRIPS Agreement of affording the same level of intellectual property protection under four respective legislations concerning Patents, Register Design, Trademarks and Layout-Design (Topography).

2.4 Switzerland

11. Switzerland introduced its updates of notifications according to Article 63.2 of the TRIPS Agreement at the last Council meeting. The update which has been circulated concerns amendments made to the Swiss IP legislation between 2012 and January 2017.

12. We are referring to our intervention at the last meeting and the summary of the most significant developments which have been provided.

2.5 Norway

13. The notification from Norway relates to the Act on the Norwegian Industrial Property Office and the Board of Appeal for Industrial Property Rights. The Act was passed by the Norwegian Parliament on 6 June 2012 and repeals the Act on the Norwegian Industrial Property Office from 1910. From the entry into force on 1 April 2013 new and updated provisions on the purpose and tasks of the Norwegian Industrial Property Office and the Board of Appeal and general provisions on case handling were modified, however without affecting the exclusive rights governed by the Patents Act, the Trademarks Act and the Designs Act. The Act was translated into English and the unofficial translation was published on the homepage of the Norwegian Industrial Property Office shortly after the entry into force in 2013. Due to an error that translation was only now notified to the Secretariat.

2.6 WTO Secretariat

14. This brief interim report supplements the series of briefings the Council has received over recent sessions on this elaborate project, which represents a once-in-a-generation overhaul of how we manage TRIPS documentation and how we serve Members in making this information accessible and practicably workable. The project, I am glad to report, is in its late stages, having been assisted and guided by the feedback provided by interested delegations, whom we thank, and who took part in informal briefing and demonstration sessions and gave us very helpful feedback and suggestions.

15. While this is a brief interim report, we expect to have a significant advance to report at the next meeting of the Council. At this stage, the e-TRIPS project has almost completed the full digitisation of the entire range of TRIPS-related notification and review materials. We are currently in the process of validating and closely checking the thousands of individual records concerned and intensively testing the prototype on-line notification tool. We are also preparing a draft web gateway that will greatly facilitate access to and use of all TRIPS-related materials by WTO Members. We have just secured the necessary ad hoc resources to take forward the final stages of implementation both of data validation and upload of the data onto the information management system, on the input side, and for the development and elaboration of an accessible gateway, for the effective use of these data. We are therefore reasonably confident of reaching the final stages of the project in the course of this year, and we will be again reaching out to interested delegations to consult with us both for demonstrations of the current advanced prototypes and for feedback on how to ensure this new facility best meets the practical needs and requirements of Members, both Geneva-based delegates and officials in capital. We certainly welcome the interest and involvement of any interested delegations.

AGENDA ITEM 3: REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

3.1 Kazakhstan

16. We have already transmitted the responses to the US questions and hope that these will be sufficient for them.

3.2 United States

17. With respect to the review of Kazakhstan's national implementing legislation, we deeply appreciate the efforts made by Kazakhstan to respond to our copyright-related follow-up questions and we are further pleased that Kazakhstan has also responded to the Council's Checklist of Issues on Enforcement.

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 India

18. 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.

19. India has been a major victim of bio-piracy. Pursuant to the 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 bio-piracy can be prevented. India has signed TKDL Access Agreements 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 was only one part of the solution. Further, the TKDL represented a subset of the universe of available traditional knowledge. The realm of traditional knowledge in areas other than herbal cures and genetic resources was not covered by the digital library.

20. 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 is contained in document 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 amendment of 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 bio-piracy, further strengthen the credibility of the patent system by facilitating assessment of the novelty and inventiveness criteria.

21. The Nagoya Protocol of the Convention on Biodiversity (CBD) entered into force on 12 October 2014. So far 100 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 Clearing-House 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, five countries (Guatemala, India, Mexico, Spain and South Africa) have published 52 internationally recognized certificates of compliance (IRCC) with details of prior informed consent for access to genetic resources and benefit sharing on mutually agreed terms.

22. 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. This demonstrates that ABS and the Nagoya Protocol are making an important contribution to the conservation of biodiversity and sustainable economic development for all.

23. It would be quite useful to the delegates of the TRIPS Council, if the CBD Secretariat is requested to brief the TRIPS Council in October session on the latest developments in the implementation of the Nagoya Protocol, including the decisions that were taken

at the December 2016 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.

24. 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.

6.2 South Africa

25. In respect of the triplets, we note that Paragraph 19 of the Doha Ministerial Declaration instructs the TRIPS Council to pursue its work programme under Article 27.3b, Article 71.1, and paragraph 12 of the Ministerial Declaration, *inter alia*, "to examine the relationship with the Convention of Biological Diversity and the protection of traditional knowledge..." A large group of developing countries proposed an amendment to the TRIPS Agreement to introduce a mandatory disclosure requirement in patent applications and have sought clear guidance on this matter as part of the modalities decision. The basis of this amendment is contained in TNC/W/59 which requires access and benefit sharing, prior informed consent and disclosure of the source of material when a patent is applied for.

26. South Africa is rich with natural resources, being the 3rd most biologically diverse country after Indonesia and Brazil. It represents 2% of the world's landmass, has 10% of the world's plants, 7% of all mammals, birds and reptiles, and 15% of all known marine species. South Africa is also a Contracting Party to the CBD and has ratified the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in 2013 which came into effect in October 2014.

27. The ABS legal regime for South Africa, is contained in Chapter 6 of the National Environmental Management: Biodiversity Act No 3 of 2003 which governs bioprospecting and the use of indigenous biological resources. This Act regulates *inter alia*: bioprospecting involving indigenous genetic and biological resources; the exportation of indigenous genetic and biological resources for purposes of bioprospecting or any other research purpose; and provides for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting;

28. South Africa also requires disclosure of the use of traditional knowledge or biological resources in patent applications. Section 30 (3A) of the Patents Act No. 37 of 1952 as amended by Act No 20 of 2005 requires that:

> "(3A) Every applicant who lodges an application for a patent is accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge to this effect."

This amendment to the Patents Act came into force on 14 December 2007 by proclamation and with the publication of Regulations for the Patents Amendment Act. As a result, every applicant for a patent (with the exception of provisional patent applications) filed in South Africa on or after 14 December 2007 is required to lodge a declaration or statement in respect of traditional knowledge or use of indigenous biological resource, irrespective of the nature of the invention sought to be protected. Also in this respect, on 23 March 2016, South Africa issued the second internationally recognized certificate of compliance following a permit made available to the Access and Benefit-sharing (ABS) Clearing-House.

29. Given the extensive (legal) regime that applies in South Africa, we still experience significant instances of bio-piracy and misappropriation. National regimes are therefore necessary, but insufficient steps to protect traditional knowledge or the use of indigenous biological resources. A multilateral system within the context of the TRIPS Agreement that regulates disclosure and access remains the best guarantee against misappropriation of genetic resources and traditional knowledge.

30. While related negotiations can complement the negotiations of TRIPS issues in the WTO, they are not an effective substitute for achieving results in the WTO TRIPS context. Other international fora lack an effective dispute settlement mechanism to ensure compliance with the obligations, and there is no certainty that these negotiations will be successful in these fora.

6.3 Brazil

31. 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. At the last session of the TRIPS Council, our delegation referred to two examples of patent applications containing genetic resources from the Amazonia region. A mandatory multilateral disclosure requirement would enable a clear assessment of whether those patents complied with the legal requirements in the country of origin.

32. 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. It would create no obligation for the patent examiner to conduct a thorough review of the document provided by the applicant.

33. 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. 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.

34. 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.

35. As a means forward, we would like to support the suggestion by India regarding a briefing by the CBD Secretariat in order to illustrate recent developments at the CBD level. We also support the updating of the Secretariat's report on the matter.

6.4 Ecuador (delivered by Bolivia, Plurinational State of)

36. The distinguished colleague from Ecuador could not attend the meeting this morning so I would also like to read out the statement on behalf of Ecuador and then read Bolivia's statement. So first on behalf of Ecuador: My country's position has been expressed repeatedly in this Council. So we would request that in the consideration of the three items concerned we refer to statements made by my delegation in previous meetings.

37. I would like to refer to Ecuador's proposal submitted a number of years ago on the possibility of the Secretariat preparing an update of the factual notes on the aforementioned topics. Given that the last compilation of the ideas discussed was produced in 2006 we believe that updated versions of documents IP/C/W/368, IP/C/W/369 and IP/C/W/370 would provide us with a clearer idea of what was already discussed for a number of years with the aim of ensuring that Members have an updated picture so that they can contribute to informing the debate on these issues, thus enabling us to move forward in our discussions. A consensus has been emerging around that idea and we are just waiting for one Member to adopt a more flexible position in order to allow us to have that update. So we would call upon that delegation to join the consensus.

38. In view of the above, we reaffirm our position that there should be an opportunity to conduct discussions on the basis of more detailed information, which could be presented by the Secretariat in a neutral manner, without compromising any of the Members' positions. We wish to emphasize this, as each Member's position would remain intact and could, moreover, be substantiated by further up-to-date information.

6.5 Bolivia, Plurinational State of

39. Bolivia's stance on this matter is well known. Bolivia believes that a development-oriented outcome in Buenos Aires should at least include a negotiating mandate on disclosure of the source of origin. In this regard, modifying the patent system could discourage the biopiracy practices that we have seen since the TRIPS Agreement was adopted at the WTO.

40. In addition to disclosure of the source of origin, it is necessary to include substantive provisions that prevent the patentability of life forms and parts thereof, such as genetic resources, and traditional knowledge associated with genetic resources. The possibility of patenting life forms and parts thereof was encouraged by the adoption of Article 27.3(b), which, unlike any other international rule, has promoted the undue appropriation of such resources through the patent system. This has allowed for an increase in private monopolies on life forms, genetic resources and gene sequences, among other things, by merely isolating and characterizing them, which has negative consequences for the innovation itself and for scientific research, as well as access to its findings. 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.

41. Document TN/C/W/59 would be a good basis on which to move ahead with the process in this Council, with a view to achieving a tangible pro development outcome at the Eleventh Ministerial Conference.

42. Our position on observers is also well known. We believe that the issue of observer status must be addressed in a balanced manner, and in its entirety, in order for the representative institutions of most Members to have this status. Until now, I had never understood why there was opposition towards the Secretariat of the CBD and the South Centre having observer status in the Organization.

43. In conclusion, I would like to reiterate our support for Ecuador's proposal that the Secretariat update its factual notes describing relevant developments in recent years.

6.6 Indonesia

44. In regard to the triplets agenda items, Indonesia would like to reiterate its view that the relationship between the TRIPS Agreement and the CBD should be reflected in this Council by ensuring and maintaining the cohesion, coherence and consistency between the two. These two internationally agreed instruments must be implemented in a manner that is mutually supportive with respect to their objectives. Since the CBD and the Nagoya Protocol have formed a basis of the protection of genetic resources and/or associated traditional knowledge with provisions on prior informed consent for access and fair and equitable benefit-sharing, the TRIPS Agreement needs to reflect these stated provisions to avoid misappropriation and oblige Members to take necessary measures to ensure fair and equitable benefit-sharing. The protection of genetic resources is of paramount importance to Indonesia, and we consider that a legal obligation to establish a mandatory disclosure of origin as a requirement for patent applications will not only prevent misappropriation and enhance transparency on the utilisation of genetic resources and/or associated traditional knowledge but will also provide greater legal certainty as to the rights and obligations of the providers and users of genetic resources.

45. Indonesia would also like to add that we should not delay substantive discussions in this Council for reasons that this issue is being negotiated in other fora, such as WIPO. The discussions that take place in this Council should reinforce what has already been agreed to at the multilateral level such as the CBD and should complement negotiation or discussion in other fora. We believe that parallel discussion will enhance the effort and understanding of achieving a fair and balanced trading system with regard to intellectual property. On that note, we would also like to suggest that the TRIPS Council meetings not be held coincidently with meetings of the Intergovernmental Committee on GRTKF at WIPO. If possible these meetings should be held back-to-back to enable our capital-based experts, which for many of us are one person for both fora, to be able to attend both meetings. Indonesia will also take this matter during the IGC meeting be held in the same week. Last but not least, Indonesia would like to use this opportunity to re-convey its support for the proposal by Group of W/52 and of W/59 to revise Article 27.3(b) and Article 29 of the TRIPS Agreement.

6.7 Egypt

46. 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 as contained in the Doha Work Programme. Therefore we urge other Members to engage in this issue of high importance to developing countries as part of the conclusion of the DDA. Technical discussions on this issue have been ongoing for more than 15 years so far. We believe that TRIPS Agreement should be amended in order to provide that Members shall require an applicant for a patent relating to biological materials or associated traditional knowledge to disclose the source and the country of origin of the biological resources and associated traditional knowledge used in the invention. Furthermore, the applicant shall also provide evidence of prior consent and evidence of fair and equitable benefit-sharing under the relevant national regime.

47. Finally, we would like to support the proposal to invite the CBD Secretariat to attend the next meeting of the TRIPS Council in order to appraise the Members on the Nagoya Protocol.

6.8 China

48. The relationship between the TRIPS Agreement and CBD is an important issue in the TRIPS Council. China always attaches great importance to this issue and participates in the discussions, which are quite useful for clarification. China hopes Members are constructively involved in this discussion.

49. Regarding the substantial issues, China notes that the majority of Members support to amend the TRIPS Agreement so as to ensure the mutual supportiveness between the TRIPS Agreement, the CBD and its Nagoya Protocol. China believes that the introduction of a mandatory disclosure requirement, and benefit sharing, could prevent misappropriation and erroneous patents. And providing the information concerning the prior informed consent and benefit sharing would not be burdensome, while the benefit-sharing arrangement on contractual basis and the database solution would not serve the purpose of sufficient protection for genetic resources.

50. As to disclosure, China has 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 patent in two documents TN/C/W/52 and TN/C/W/59, co-sponsored by different Members.

51. As regards procedure, China believes that the discussion and negotiation in WIPO/IGC would not hinder the Members to find a solution in WTO. Furthermore, the Ministers have given the Council the mandate to examine the relationship between TRIPS and CBD. Therefore, Members should follow the instruction and mandate to work to find a solution. In this regard, to strengthen the understanding so as to carry on with the constructive discussion in this Council, China supports to invite the CBD Secretariat to brief on the Nagoya Protocol. China also hopes that the Secretariat could update the three factual notes.

6.9 United States

52. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues. As observed by Indonesia, many delegates in this room split their time between the WTO and the WIPO this week as WIPO IGC is looking at addressing unresolved issues and working on a common understanding of core issues using an evidence-based approach and examples of national experiences. With respect to the various requests made today the United States is not in a position to support these requests but remains open to discussions including bilaterally with delegations, in between and at the margins of the TRIPS Council meetings. To that end we look forward to meeting with Ecuador tomorrow afternoon and reporting back on any progress that may be made.

53. As for the relationship between the TRIPS Amendment and the CBD, in past sessions of the TRIPS Council a number of delegations noted that they believe that there is a need to avoid erroneous patents that involve the use of genetic resources and related traditional knowledge.

We agree that there is a need to avoid erroneous patents but we disagree that the disclosure of origin would help improve the quality of patents, and as noted by India in past sessions of the TRIPS Council, traditional knowledge and cultural practices can be prior art and would be fully taken into account in the patent examination procedures.

54. Finally, the United States welcomes the interventions of WTO Members describing their recent actions to implement the Convention of Biological Diversity and the Nagoya Protocol. We believe that all WTO Members can benefit from a better understanding of the policy decisions made by the other WTO Members who are party to the CBD or are signatories to the CBD in deciding whether to ratify the protocol or in implementing it. We do not however support the CBD Secretariat providing an intervention at this time as we have previously explained.

6.10 Japan

55. With regard to agenda items 4, 5 and 6, this delegation would like to reiterate our position that it is necessary to seek appropriate ways to deal with the misappropriation of genetic resources. This means we should bear in mind that any measures taken must not adversely affect the existing intellectual property system or hinder the creation of innovations utilizing genetic resources and associated traditional knowledge.

56. This delegation is firmly convinced that the disclosure requirement would discourage industries from conducting research and development activities on biological materials overseas. This is the very consequence of the disclosure requirement that Japan has been concerned about. Therefore, Japan believes that the disclosure requirement is not an adequate means for dealing with such misappropriation; so therefore, we have to avoid including it in the intellectual property system.

57. In addition, this delegation believes the WIPO IGC is the most appropriate forum for holding technical discussions on IP aspects. The 34th Session of IGC is being held this week. Japan remains willing to contribute to discussions on these issues in a constructive manner.

6.11 Canada

58. Canada continues to firmly believe that the TRIPS Agreement and the Convention on Biological Diversity are complementary and that there is therefore no need to amend the TRIPS Agreement in this regard.

59. Canada would like to reiterate our view where by matters related 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.

60. As noted at previous TRIPS Council meetings, 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 also support the update 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.

61. Canada would also like to note its continuous support for the important work of the WIPO IGC, particularly the discussions underway this week at WIPO. Canada remains an active and committed participant in this important work and welcomes both the concrete discussions and exchange of national experiences at WIPO on these issues.

62. Similar to our positions expressed at the IGC and our openness to briefings from the CBD Secretariat and the updating of the factual notes by the Secretariat, Canada would welcome further detailed presentations by any interested Members containing the latest information on the operation and functioning of their national IP regimes concerning genetic resources and traditional knowledge, to inform other Members in this Council. Canada has appreciated similar

presentations on other categories of IP at recent meetings of the TRIPS Council, such as those made by our US and EU colleagues last November concerning their regimes on trade secrets and presentations made by a variety of Members under the "IP and Innovation" item in recent years, to give but a few examples. We would welcome presentations on national regimes concerning genetic resources and traditional knowledge at future meetings of the TRIPS Council.

6.12 Australia

63. Australia considers the World Intellectual Property Organization's IGC is best placed to consider the complex and important intellectual property issues relating to genetic resources and associated traditional knowledge.

6.13 Switzerland

64. As a co-sponsor of document TN/C/W/52, in which a large part of the membership proposed modalities language for all three TRIPS issues under discussion, i.e. the GI register and GI extension as well as the disclosure of source requirement for patent applications, this delegation would like to reiterate its continued interest in moving this matter forward.

65. The TRIPS Council must continue discussing those outstanding implementation issues, exchange national and international experiences and engage constructively in finding solutions within the mandates given.

66. Switzerland also supports the proposal that the CBD Secretariat informs about and presents the Nagoya Protocol to the Council, in whatever mode the Council deems to be appropriate. We also support Ecuador's proposal that the WTO Secretariat updates its factual notes on the TRIPS/CBD and GI issues to include the Council's discussions of the recent years.

6.14 Korea, Republic of

67. On the triplet agenda items, I would like to register our positions expressed in the previous Council meetings.

6.15 Chairperson

68. Let me share with you my observations. First of all, I am very pleased to know that two delegations are having bilateral meetings tomorrow afternoon on one of the outstanding issues. I hope that will be a fruitful meeting. If delegations wish to involve me in the bilateral consultations, I am always available. And I will also, as I said, reach out to some of you to see whether we can find a solution to some of the outstanding issues. My second observation is that unfortunately I think today we cannot agree on the request to update the three factual notes prepared by the Secretariat on previous discussions, or for a CBD briefing to be held at a formal Council meeting. I have heard one delegation suggesting that maybe we should consider a CBD briefing in whatever mode that is acceptable to Members. And in that connection I recall that, in the last formal meeting of this Council, we have also heard one delegation suggesting that maybe the CBD briefing could be organized when the Council meets in an informal mode, for example, as a back-to-back session before our next formal meeting. I just want to know if Members would like to react to these suggestions.

6.16 United States

69. We do not support the briefing of the CBD Secretariat in informal mode at this time.

6.17 South Africa

70. In respect of the small group meeting which you (the Chair) presided over last Friday, it would be useful if you would be able at our future meetings to give feedback on the discussions that we had, I think it would be useful in informing of some of the opinions that have been expressed. Specifically on the issue of the briefing by the CBD, I believe that the proposal was not necessarily that it be done in informal mode but perhaps as a side-event to future meetings of this Council, so this is also another option that is on the table and that Members could consider.

6.18 Chairperson

71. Would anyone like to respond to that suggestion about a side-event not necessarily the Council in an informal mode? There does not seem to be any comments on this one, so I will further explore with interested delegations about that suggestion and see if we can come up with any ideas for the October meeting of the TRIPS Council.

AGENDA ITEM 7: NON-VIOLATION AND SITUATION COMPLAINTS

7.1 Switzerland

72. We would like to confirm that our position has not changed since the last meeting, as summarised in IP/C/M/82/Add.1. There are a few arguments, however, that opponents of non-violation complaints under TRIPS, including India, took up in the last Council meeting, which we would like to briefly respond to.

73. Non-violation claims form an inherent part of the Dispute Settlement Understanding (DSU). They are essential for ensuring the balance of rights and obligations also within the TRIPS Agreement and help secure that legitimate obligations are not circumvented or avoided. Non-violation complaints are an instrument which is open to all members, designed to make sure that all parties are adhering to their responsibilities.

74. The language of Art. 64.1 TRIPS clearly and unequivocally states that:

> "The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this agreement (i.e. the TRIPS Agreement) except as otherwise specifically provided".

Thus, the question was never on whether non-violation and situation complaints were to apply but rather on the modalities and conditions that would apply to such types of complaints.

75. According to Art. 64.2 TRIPS a moratorium of five years was established during which situation and non-violation complaints would not apply. Consequently, the intention was clear that, once the period of five years had expired, non-violation and situation complaints in GATT Article XXIII were to be applied. Further, non-violation complaints are expressly provided for under Article 26 of the DSU. The WTO agreements have never excluded non-violation complaints from intellectual property matters in general. The moratorium and provisions under Article 64 TRIPS only concern non-violation and situation complaints under the TRIPS Agreement itself.

76. The TRIPS Agreement does not exclude GATT 1994 from the field of intellectual property, and in return, GATT 1994 contains no general exception broad enough to cover intellectual property laws and regulations, as indicated by Matthew Kennedy in his book *WTO Dispute Settlement and the TRIPS Agreement: Applying Intellectual Property Standards in a Trade Law Framework (OUP 2016).*

77. Thus, GATT 1994 and TRIPS apply concurrently. This becomes particularly apparent when looking at the TRIPS Agreement's preamble. The first and second clause of the preamble show that the intention of TRIPS was to complement GATT, as new additional rules were needed concerning the applicability of the basic principles of GATT 1994 and of relevant intellectual property agreements. More so, several agreements in Annex 1A to the WTO Agreement have elements in common with TRIPS and can overlap with them. For details I refer to Matthew Kennedy and materials of the negotiation history of the TRIPS Agreement.

78. For example, it is evident for the TBT agreement's scope to overlap with TRIPS due to product marking and labelling requirements, which are closely related to the subject matter of certain TRIPS obligations. Thus, the argument that the TRIPS is a *sui generis* agreement distinct from GATT and GATS has, in our opinion, no solid ground. The TRIPS Agreement forms an integral part of the WTO framework as well as the DSU.

79. The TRIPS Agreement is also a market access agreement. As was repeatedly pointed out, the TRIPS Agreement protects market access for IP-related products and services. The preamble explicitly states that the objective and purpose of the TRIPS Agreement is to ensure that measures and procedures to enforce intellectual property rights do not undermine the legitimate trading system. The Agreement's Preamble also indicates the expectations that TRIPS negotiators had regarding market access for IP-protected goods and services. The objectives outlined in the preamble of the agreement were taken from the initial mandate for negotiation in the 1986 Punta del Este Declaration.

80. In the TRIPS negotiating group, various proponents of the agreement stressed the fact that the value of trade concessions negotiated under the GATT were being impaired by inadequate or excessive protection of intellectual property rights.[1] Therefore TRIPS was intended to help reduce market distortions that existed prior to its negotiation by establishing adequate minimum standards and principles concerning the availability, scope and use of trade-related intellectual property rights. This is also why we consider any claims according to which non-violation and situation complaints are unnecessary and inconsistent with the interests of WTO Members to be unfounded.

81. What is the purpose of the non-violation remedy? We also take the view that the establishment of the procedure for non-violation complaints does not primarily aim to prevent a tariff concession or specific commitments on trade in services from being adversely distorted by additional trade measures taken. There are three GATT panel reports which considered non-violation claims based on general obligations rather than specific tariff concessions, finding that GATT Article XXIII:1(b) is not limited to tariff benefits: The 1985 Panel Report in European Economic Community - Production Aids Granted on Canned fruit, L/5778, not adopted, para. 50; 1988 Panel Report on *Japan - Semi-conductors*, para 82; and 1990 Panel Report on *United States - 1955 Waiver*, cited in IP/C/W/212 on page 6 and IP/C/W/124, Annex 4.

82. Establishment of a non-violation claim. The Indian and other delegations have suggested that introducing non-violation claims could have a debilitating effect on member's regulatory policy space. We appreciate those concerns. Yet, apart from the fact that non-violation complaints are regarded as exceptional remedy[2], the standards and requirements for bringing forward a non-violation complaint are likely to be very high.

83. It has been suggested that bringing forward a non-violation complaint principally requires the establishment of three criteria. First, there must be an application of a measure by a WTO Member against which such a complaint is brought (1). Here, by virtue e.g. of Articles 7 and 8 of the TRIPS Agreement as well as the Paragraph 6 System, certain measures are per se excluded from such complaints. In general terms, the application of TRIPS flexibilities would, as was previously outlined by this delegation, most likely to be excluded.

84. Were the panel to find that a measure was not excluded by these provisions or flexibilities, in a next step, second it would examine whether there was a benefit accruing to the complaining Member (2), and third whether this benefit was being nullified or impaired as a result of the application of the measure (3).

85. Apart from the fact that identifying the potential benefit under the TRIPS Agreement may cause substantial difficulty, the requirement of nullification or impairment of a benefit is not presumed and must be demonstrated by the complainant on the basis of solid evidence.

86. According to Article 64.3 TRIPS, a decision to extend a moratorium can only be agreed upon consensus. Thus, further extension of the moratorium under Article 64.2 TRIPS should no longer be agreed. While we believe that there is no need to define specific modalities for NVCs under TRIPS Agreement, we remain open for comments and proposals pertaining to the scope and modalities for non-violation and situation complaints as well as for the Council to enter into closer and more specific analysis thereupon.

[1] Meeting of Negotiating Group of 23 September 1987, Note by Secretariat, MTN.GNG/NG11/3 (8 October 1987) para. 8.

[2] Decision of the Ministerial Conference on *TRIPS non-violation and situation complaints* (WT/L/842) of 17 December 2011.

7.2 India

87. I would also like to thank the delegation of Switzerland for providing some explanations on the issues raised by other Members, including India. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged.

88. In the run-up to the Ministerial Conference in Nairobi it would be worth noting that there is a great confluence of interest on making such complaints inapplicable to TRIPS. We are not convinced by the reasons provided by several Members of its place in the TRIPS context. While whether the TRIPS Agreement is a market access agreement may or may not be relevant for its applicability, it is clear that the drafters did not unequivocally apply non-violation complaints 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 agreed 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.

89. For some of the comments made by the Swiss delegation, I would like to refer to our submission contained in document IP/C/W/385/Rev.1 where we have stated why non-violation and situation complaints are unnecessary under the TRIPS Agreement.

90. The TRIPS Agreement, unlike other WTO agreements, is a *sui generis* agreement which is not designed to protect market access or the balance of tariff concessions but, rather, to establish minimum standards of intellectual property protection, which, if abused, may even undermine market access.

91. Non-violation and situation complaints are unnecessary to protect any balance of rights and obligations inherent in the TRIPS Agreement, as these are reflected in the Agreement's principal obligations and flexibilities, and the Agreement explicitly states that WTO Members are not obliged to implement more extensive protection (Article 1). They are also unnecessary to protect market-access commitments embodied in the GATT or GATS, or any other notion of a balance of concessions struck in the Uruguay Round, as these are adequately protected by those agreements and other Annex 1 agreements.

92. Rights and obligations in the TRIPS Agreement are best performed through good faith application of its provisions, in accordance with established principles of international law recognized by the Appellate Body, and do not require recourse to the legally imprecise notion of non-violation and situation complaints.

93. 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 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 or 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 IPR might facilitate trade and investment, the obligations under the TRIPS Agreement cannot be characterized as market access concessions.

94. Serious concerns remain regarding the debilitating impact that non-violation complaints in TRIPS can have on the regulatory policy space of Members, on TRIPS flexibilities, as well as on

increasing the complexity of interpreting the TRIPS provisions. It can not only have a chilling effect on Member's exercise of their IP regimes but also severely restrain the ability of Members to achieve other public policy objectives.

95. 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 the 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.

96. We also wish to reiterate that until there is a consensus on the scope and modalities of the applicability of non-violation complaints to TRIPS, such complaints should not apply to the TRIPS Agreement.

7.3 Brazil

97. Brazil would like to reiterate its understanding that non violation and situation complaints should not be applied to the TRIPS Agreement. While we thank Switzerland for their statement, we remain unconvinced by the arguments presented today.

98. For the cases where a Member assesses that the obligations of the TRIPS Agreement are not being properly fulfilled by another party, Article 64 of TRIPS unambiguously establishes a dispute settlement mechanism which could be invoked and duly used in cases before the Dispute Settlement Body. Claims that the availability of NVSC would prevent Members from evading their TRIPS obligations are not supported by evidence and no concrete cases were presented up to date by demanders.

99. As provided in document IP/C/W/385/Rev.1, concessions under the TRIPS Agreement cannot be characterized as "market access" under GATT. The TRIPS Agreement, like other WTO agreements, is a *sui-generis* treaty 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. The *sui generis* nature of intellectual property with regard to the standards set in GATT led the negotiators of the Uruguay Round to the TRIPS Agreement, instead of including intellectual property provisions as amendments to the GATT.

100. Furthermore, the fact that no consensus on the matter was reached during the negotiations of the Uruguay Round underlines the fact that negotiating parties were not convinced that it 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.

101. In short, the application of such complaints to intellectual property disputes would generate systemic imbalances and reduce the legal certainty of multilateral IP law, a result that would conflict with the very goal of the multilateral trade system. Its necessity has not been established by demandeurs until this moment, and its application is opposed by the vast majority of WTO Members.

102. Consequently, we propose that the TRIPS Council recommend to the Ministerial Conference 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.

7.4 Argentina

103. Argentina's position is very well known on this issue. We re-iterate that non-violation and situation complaints do not apply to the TRIPS Agreement as has already been explained in document IP/C/W/385/Rev.1 of which Argentina is a co-sponsor together with a large number of other Members.

104. Argentina believes that this Council should recommend to the Ministerial Conference that complaints provided for in 1(b) and 1(c) of Article XXIII of GATT 1994 should not be applicable to dispute settlement under the TRIPS Agreement, as proposed in the draft decision contained in the document IP/C/W/607.

7.5 Bolivia, Plurinational State of Bolivia

105. Like other delegations have also mentioned the Plurinational State of Bolivia believes that non-violation and situation complaints do not apply in the context of intellectual property. Along with a large majority of Members, Bolivia submitted a document IP/C/W/385 with a large amount of information and analysis as to why non-violation and situation complaints should not apply to intellectual property. Applying such complaints would have a very negative impact on the capacity of each Member to regulate in various areas and that is not acceptable for many Members of this Organization. We are not going to repeat the arguments contained in document IP/C/W/385, but we would like to reiterate our position that the TRIPS Council should recommend to the 11th Ministerial Conference to adopt a decision that non-violation and situation complaints identified in Para 1(b) and 1(c) of Article XXIII of GATT 1994 should not be applicable to the TRIPS Agreement.

7.6 South Africa

106. We thank Switzerland for its intervention in this regard and we place it on record that we do not agree with many of the basis of arguments that Switzerland advances, more specifically, in respect of the negotiating history. We believe that the issue of non-violation complaints is necessarily an outstanding issue, unfinished business which was not agreed during the Uruguay Round and as a result, the GATT-ability of the TRIPS Agreement *vis-à-vis* the GATT has always been on the table, and the current debate around this issue is a confirmation of this. Without belabouring the arguments that have been presented in the past this delegation has many times indicated that non-violation and situation complaints are unnecessary and should not apply in the context of the TRIPS Agreement.

107. Specifically, we are further inclined to interpret Article 64.2 to mean that in case the moratorium on the application of non-violation and situation complaints is not extended in 2017, the complaints would not automatically apply to the TRIPS Agreement. Under a strict reading of Article 64.2, these disputes cannot apply until Members agree to the scope and modalities of their application in respect of the TRIPS Agreement.

7.7 China

108. Members might recall that 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, until now, the divergence between Members is still observed.

109. China appreciates the efforts made by the Chair and Secretariat, and hopes Members could constructively participate in the discussion. China reaffirms the position that the 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 in 2015. China welcomes the discussion on this issue in accordance with the decision and mandate given by the Nairobi Ministerial Conference.

7.8 Ecuador

110. As a co-sponsor of document IP/C/W/385/Rev.1, Ecuador believes that this document should serve as a basis for discussions on this agenda item for the reasons set out therein. Ecuador's position is well known. The TRIPS Agreement does not seek to protect market access, as there is no exchange of tariff concessions, but rather that it is a *sui generis* agreement that establishes minimum standards on the acquisition, exploitation, scope and exercise of intellectual property rights. Non-violation complaints are therefore not applicable under the TRIPS Agreement.

111. For this reason, we agree with the countries that consider that the scope and modalities for complaints of the types provided for under Article XXIII:1(b) and 1(c) of the GATT 1994 are not

applicable to the TRIPS Agreement. This is the recommendation that must be made and adopted at the Buenos Aires Ministerial Conference.

7.9 Egypt

112. The position of Egypt is well-known with regard 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 still believe that the best way to overcome this issue is that document number IP/C/W/607 proposed by Peru should be the basis for our future negotiations in this regard.

7.10 United States

113. For the reasons detailed in our previous interventions under this Agenda item the United States continues to maintain its 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 intention of the drafters of the TRIPS Agreement.

114. 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 adjudications, as we have enumerated in our communications to the TRIPS Council which is being circulated to Members as IP/C/W/599, as well as in our recent interventions. The United States has provided detailed and extensive analysis in each of our statements under this item over the past several years. We have explained the legal basis for such claims in the GATT and the TRIPS Agreement text, the Panel and the Appellate Body jurisprudence involving NVNI disputes, the extensive safeguards that exist to protect Members' rights and obligations under the TRIPS Agreement in concrete descriptions regarding how such disputes would work in practice. As we have detailed in past interventions, and will share today to respond to remaining concerns of some Members, NVNI claims have a long lineage in the WTO and in international trade law generally. The applicability of such claims to the WTO Agreements is the rule, their non-application is the exception. The TRIPS Agreement moratorium is the exception. Some delegates have recently raised concerns that NVNI would have a negative impact on TRIPS exceptions. If NVNI has had no negative impact on exceptions under GATT, GATS, and the Agriculture, Government Procurement and other WTO Agreements, we wonder why NVNI would impact exceptions under the TRIPS Agreement. The answer is that there is no evidence that suggests that such claims would have such impacts. We also have heard recently from some delegations that the TRIPS Agreement is not a market access agreement thereby rendering NVNI inapplicable as a result. While we have demonstrated copiously to the contrary and heard good interventions on this point from our Swiss delegation, we again note that such a dialectical or binary view is beside the point. As has been discussed NVNI claims have been brought outside of the GATT-context and assessed on the merits by WTO-adjudicative bodies.

115. To conclude, non-violation complaints are fully appropriate in the context of the TRIPS Agreement and have long been part of the WTO and GATT. Such complaints are exceptional and infrequent, and subject to existing and clear rules of the road including numerous levels of safeguards to ensure security and predictability with respect to the rights and obligations of all WTO Members under the TRIPS Agreement. Non-violation complaints serve an interest of all Members which is to assist Members in protecting against measures that nullify or impair concessions. Non-violation complaints were part of the balance of rights and obligations in the TRIPS Agreement and the time has come to allow for the moratorium on non-violation complaints to expire.

7.11 Japan

116. Japan's view on this issue has not changed. Both clarity and predictability should be ensured when applying non-violation and situation complaints to the TRIPS Agreement. From this point of view, making factual analyses on applicable specific and concrete circumstances of non-violation and situation complaints would facilitate examination in terms of the scope and modality of non-violation and situation complaints in the area of the TRIPS Agreement.

7.12 Sri Lanka

117. Sri Lanka would also like to join the majority of Members who sponsored the proposal on non-applicability of non-violation and situation complaints under the TRIPS Agreement. My delegation's position is well known and we support a permanent solution by making non-violation and situation complaints inapplicable under the TRIPS Agreement. We understand that there is a need for Members to reach a definitive agreement in this regard and would like to assure the fullest cooperation of my delegation in future consultations.

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

118. 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

119. No statements were made under this agenda item.

AGENDA ITEM 10: TECHNICAL COOPERATION AND CAPACITY BUILDING

120. No statements were made under this agenda item.

AGENDA ITEM 11: INTELLECTUAL PROPERTY AND INNOVATION: INCLUSIVE INNOVATION AND MSME GROWTH

11.1 European Union

121. Allow me to make the first intervention on this point that we co-sponsored. It is part of a very important debate that we have been having for the last five years at least here in this TRIPS Council about concrete benefits that intellectual property brings to innovation and we have decided now to choose some points that we would discuss with bit more at length so in the course of two or three sessions to allow more in-depth debate with Members and also give them time to collect their experiences and to share them with us. In that sense, as well as to help feed the debate together with the other co-sponsors, we prepared a short summary of the issues that could be discussed under the theme that we have today which is Inclusive Innovation and MSME growth. I will not repeat what is in that paper but instead I would like to share with you the intense activity of the EU and of its member States in tailoring intellectual property to the smaller companies and to those who have fewer resources to manage their research and their discoveries and their quality products, so making intellectual property more accessible to all. So, the crucial role of the intellectual property in the success of start-ups and innovative MSMEs has long been recognized, it allows innovative businesses to appropriate the results of their creativity, inventiveness and R&D investment, and creates an incentive for further investment in innovation.

122. Recent data from the EU Intellectual Property Office shows that businesses using IP rights perform better and this is particularly true in the case of MSMEs. Recent studies show that in the EU these kinds of small companies owing IP rights have almost 32% higher revenue per employee than MSMEs that do not. They also expand their work force faster and pay higher salaries. Intellectual property is therefore important for smart and sustainable growth. Yet, the same data show that there are few MSMEs, even in the EU, that actually make use of intellectual property. The study showed that around 9% of these small companies registered intellectual property rights as compared to 36% for larger companies. The study also gives us a view on why many SMEs do not use the intellectual property system, and this is sometimes because they are not aware of the benefits of it, they lack the necessary expertise or they find some of the procedures too costly. This is why it became evident for us that there was a need to support the smaller companies in accessing, using and exploiting the intellectual property system and we have been working on this challenge since then.

123. Given that an information and knowledge based economy with strong innovation performance is made up of businesses whose most valuable assets are intangible, all innovative

and creative start-ups and MSMEs need to be aware of the advantages of using IP and the dangers of neglecting it. Once protected these rights have to be managed to generate value and to enable innovation to play its true role. A variety of different strategies and support measures are applied by EU member States in order to encourage and help MSMEs in the use of the IP. For instance, Portugal financially helps its MSMEs to register IP rights, not only in Portugal but also EU-wide and in third countries. Another example, the UK Intellectual Property Office currently funds 250 audits for high-growth businesses engaged with business support programmes run by the European Enterprise Network, the Welsh Government or Scottish Enterprise. This specialized service provides an in-depth analysis of a business IP, including opportunities for increasing revenue, as well as any potential risks, together with recommendations for increasing the value of their intellectual property catalogue.

124. The Czech Republic provides financing and IP pre-diagnoses services to its MSMEs. This aims at providing advisory service on how to efficiently create added value and protect intangible assets; and is targeted at particular small and medium-sized enterprises and innovative companies. A tailor-made analysis will be carried out assessing the state of the protection of the intangible assets for these companies. In France, the National Institute for IP has been developing throughout the years policies of support and financial aid to MSMEs which include personalized support for these companies, the provision of services in the form of information searches in various IP data basis, training adapted to companies, and work in regional partnership with innovation development agencies. On the EU side, in our single market strategy of 2015 and building on the experience of these and other Member states, the Commission announced that it will come forward with EU-level measures to support the use of IP by MSMEs. Delivering on that commitment, the Commission has now undertaken to put in place a package of IP support measures for these companies which will have the effect of improving coordination and consistency in addressing sub-optimal use of IP by them across the EU. These measures include, among others, streamlining European IP-awareness schemes for MSMEs and providing pre-grant assistance, developing an EU online information tool to promote IP sharing and an IP mediation and arbitration network for MSMEs. And third, encouraging the creation of European-level insurance schemes for litigation and IP theft. The measures will be delivered on the basis of a partnership approach between the relevant Commission services, the EU member State authorities, the EU IP Office and other relevant stakeholders.

125. Let me develop a little bit each of these three points, starting with information and awareness. Different initiatives at EU national and local levels exist to raise awareness on IP, but the challenge has been to ensure that messages are streamlined, easily accessible and that they address the real business needs of innovative MSME enterprises. The Commission in partnership with the EU Intellectual Property Office will streamline IP awareness schemes for this type of company and will support exchange of best practices through an EU-coordination platform. This will involve the development of a common portal of materials for information and training and of common training of trainers. Awareness actions need to be complemented with more concrete actions to support MSMEs in the access and use of intellectual property.

126. As I mentioned, some member States provide individualized advice on the IP potential of a forum's intellectual assets within each specific market context. These services that I mentioned before, known as IP pre-diagnostic services, can be particularly effective as a way of helping these kinds of companies, both to assess the value of their IP assets and to include intellectual property fully into their business strategy. The Commission will finance a project of IP pre-diagnostic services to be implemented in a coordinated manner with member States and the EUIPO and the other stakeholders. It will build on existing experience but will comprise a more thorough coverage of such services across the EU. And will systematically consider EU-wide IP rights within the whole IP spectrum.

127. In particular, patents are relatively expensive and the patent system can be complex for MSMEs. Today, protecting an invention throughout the European Union Single Market can be achieved through the European Patent Office, but only at a non-negotiable cost. Pre-grant costs and patent attorney fees represent an important charge for MSMEs and start-ups in order to market their innovative products and services across the entire EU market. Considering this factor we see that with less than 1% of MSMEs own patents in Europe. The Commission will help innovative companies and start-ups that want to patent in Europe to use European patents. A pilot project will be launched to finance these companies in requesting and being granted patents. The subsidy will cover 50% of the pre-grant costs for European patents as well as a part of attorney's

fees. This will support such innovative small companies in the early years in developing their innovative products by significantly reducing patent costs. This should also create a cycle to facilitate their access to finance and investment. Such an initiative could in the future be extended to other European IP titles and notably EU trademarks and community designs or the future unitary patent, once it is in force. And it could cover both private and professional advice, which is a main source of expense for these titles.

128. The second area of support to SMEs is facilitating the use and enforcement of intellectual property. To get innovative start-ups and MSMEs enterprises to benefit from the IP system, whether by registering rights or by applying other IP protection methods is not enough. Once such enterprises own their IP rights they face subsequent challenges on how to make use of the system. With the appropriate tools these companies could generate more income through licensing or sales of their protected intellectual property, as well as raise more funds for investment. Small businesses, however, will not receive the full value of their intellectual property rights if they cannot enforce them when needed. Evidence suggests that enforcing intellectual property titles is costly and complex, especially for these kinds of small and medium-sized companies and when facing large entities.

129. In this context, the previously mentioned Single Market Strategy announced that the Commission will pay specific attention to this type of companies in the context of an on-going revision of our enforcement directive. MSMEs need to pay attention not only to their own IP rights but also to the IP rights of others. In a knowledge-based environment even IP-savvy companies of small dimension need help to find commercial partners. A tool with patent licensing information could be very useful to facilitate such partnerships and avoid costly disputes. The Commission will therefore work with the network of EU Member states authorities to develop such a platform for knowledge sharing and business matchmaking on technologies covered by current and future patents. This will be done in the course of this and next year.

130. The platform will offer organized and comprehensible information, such as know-how, key-contractual conditions and partnering in order to facilitate licensing between parties. This platform will serve as service to find information on the licensing possibility of patents in force in different EU Member states. While all entities would benefit from such a tool, it would particularly help the smaller companies and start-ups to license in and license out technologies across Europe. Also, alternative lighter and faster methods of solving legal disputes, namely through arbitration and mediation, can be very useful for these smaller companies, as an alternative to litigation in court. This, in particular, if such arbitration and mediation can be provided at an affordable cost. These methods also allow for a more proportionate settlement than simple out-of-court bilateral agreements, while the involvement of an experienced IP specialist as an independent expert ensures a more equitable outcome. The Commission will strive for the availability of mediation and arbitration services covering the whole spectrum of intellectual property accessible across the entire EU and designed in an MSME-friendly way. They will be available online and potentially through local intermediaries, for instance, such as chambers of commerce and will dovetail with broader legal mediation.

131. To conclude, very briefly on the third point that I mentioned, which is work on IP litigation insurance: the ability to enforce rights is essential for IP to keep its value, but as I mentioned before, smaller companies do not necessarily have the financial or legal means or even human resources to do so. IP litigation insurance, if it was more broadly available for small companies, would allow for the sharing or transfer of the financial burden and risks associated with IP litigation. However, these studies that have been conducted show that the market for insurance products for IP litigation has to date been too limited. The Commission will therefore seek to encourage insurance companies to enter this market in respect of EU-wide intellectual property titles and will assist innovative micro and small medium-sized enterprises to access such services. To this end, a two-year pilot-project on multi-territory patents will be launched, after which the initiative will be evaluated and, if appropriate, continues and possibly will be extended to other IP titles.

132. With this I conclude my remarks for today. As you can see, there is quite a broad range of measures that are being explored in the European Union and together with our member States. Best practices are being developed and we would be very happy to debate these with colleagues here today and also to listen to the experience of the co-sponsors and of all the other Members that will intervene on this point.

11.2 United States

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

134. We benefitted greatly and appreciated the contributions on inclusive innovation and MSME co-operation shared during the last session by so many delegations. The United States is pleased that the co-sponsors of this item seem to have identified a theme for the year that enjoys wide-spread and diverse support among the TRIPS Council Membership and I think this demonstrates to the public our commitment to work together on important and timely IP issues. As we described in our previous intervention, MSMEs are critical to the American economy. They create jobs, spur innovation and foster entrepreneurial spirit. One of the ways that US policy makers have contributed is by taking a global perspective to MSME development. This helps ensure growth and competitiveness of US MSMEs, so that they may take advantage of the same opportunities available to larger companies.

135. Today, thanks to advances in technology, it is easier than ever before to access the global market place. The digital economy is booming, creating new opportunities we could not have imagined even a decade ago. With these advances, borders are collapsing often pushing companies to go global even before they may feel ready to do so. In addition to understanding local markets, intellectual property-landscapes and business practices specific to different countries are crucial for MSMEs to successfully enter new markets. Too often, MSMEs find themselves unaware of government and private sector resources and best practices when starting and growing their businesses. As evidenced by many of the previous sessions' interventions the government can play an important role as a catalyst for the private sector by developing ecosystems for MSMEs, start-ups and entrepreneurs to thrive and become the successful businesses of tomorrow.

136. With respect to growth, the IP system provides MSMEs and all companies with a confidence to invest in themselves as a way to continuously enhance, refine and distribute a viable product or service for the market place. The US Federal Government provides key resources to make sure that innovators have what they need to turn a great idea into a successful business and take advantage of global opportunities. The US Government wants to make sure that US MSMEs have knowledge of access to and benefit from existing government resources aimed at realizing international opportunities. For example, the Global Innovation Forum (GIF) is a non-profit organization that partners with the Department of Commerce to connect businesses, start-ups, and development and university leaders with public policy makers to understand the opportunities and challenges associated with engaging in the global marketplace in the digital age. Key points of emphasize include securing intellectual property in the early stages of a company and securing access to finance.

137. GIF identifies and connects the diverse set of stakeholders from executives of multinational corporations, start-up CEOs and venture capitalists to university leaders, researchers and public policymakers and provides thought leadership on issues related to how companies, entrepreneurs, researchers and just about anyone can innovate and access global markets in the digital age. This programme was created due to the strong demand from the MSME community for the government to provide technical assistance on exporting their goods and services. Additionally, their incubators and accelerators across the United States help MSMEs scale up, for example, the Cambridge Innovation Centre (CIC) in Massachusetts is a shared work environment for MSMEs and other companies. This business incubator has a strong track record of success, having hosted nascent companies such as Facebook, Paypal, Google Android's development and Amazon.com, when they were in their growth phase. CIC's mission is to develop ecosystems that allow entrepreneurs to create new products and companies better and faster. They achieve this by providing infrastructure and actively building start-up communities in the premium locations of future focus cities.

138. Another start-up incubator, 1776, which has roots in Washington D.C., but has since expanded internationally, connects MSMEs to the information they need to help them build highly skilled businesses through curriculum, to export mentors who can help start-ups to quickly solve

problems, to market through their partners and to obtain capital through their investor network and seed funds.

139. In addition to incubator and accelerator networks, regional innovation clusters provide MSMEs with three sources to foster innovation and in turn generate growth for individual MSMEs and industries. Regional innovation or industry clusters are geographic concentrations of interconnected companies, suppliers, service-providers as well as academic institutions, government agencies and other organizations that provide specialized training, education and resources. By facilitating knowledge exchange and the pooling of resources these active networks drive innovation and job creation boosting regional and national competitiveness. Building trust among the cluster of players is essential for achieving high levels of collaboration that lead to developing, commercializing and bringing innovative products and services to market.

140. Strong intellectual property regimes are critical for engendering this trust and collaboration and for forming international partnerships. As research over the past few decades has shown, clusters exist in all types of economies and are more prevalent in locations that achieved better performance relative to their overall stage of development. They play a fundamental role in driving regional economic competitiveness by encouraging higher rates of job growth, wage growth, new business formation and innovation in regions they are located in.

141. Other US Government programmes are for grants to advance invention in capacity building activities in communities across the country and help stimulate inclusive innovation growth. In 2016, 35 organizations including non-profits, institutes of higher education and entrepreneurship-focused organizations from 19 US States received nearly $15 million to create and expand cluster focus, proof-of-concept and commercialization programmes, and early stage seed capital funds, through the Department of Commerce, Regional Innovations' Strategies Programme (RIS). This programme is a national initiative designed to support the creation of centres for innovation and entrepreneurship that increase the rate at which innovations, ideas, intellectual property and research are translated into products, services, viable companies and ultimately jobs. The diverse group of awardees has reached urban and rural areas across the United States, including the programme's first investments in historically black colleges and universities in the South, a women-focused early-stage capital fund in Texas, a Native Americans-centered proof-of-concept programme in Oklahoma and urban innovation hubs honing in on fashion technology and social innovation in New York and Louisiana, respectively.

142. The RIS programme advances innovation and capacity building activities in regions across the country by addressing two essential core components that entrepreneurs need to take their ideas to market: Programmatic support and access to capital. The RIS programme is critical to ensuring that entrepreneurs have access to the tools they need to move their ideas and inventions from idea to market. One awardee, Biotech Innovation Incorporated, is a non-profit public-private partnership in Maryland that supports the progression of early state bio-health technologies and companies from research to commercialization. Their project is focused on harvesting assets in the form of technology and ideas from the sources of research, intellectual property and entrepreneurial community at large. The grant will allow the organization to review more technologies, spur the development of new companies from the technology, create connectivity through our regional industry cluster and, around new opportunities, raise capital, and overall provide a unique growth opportunity for early-stage businesses.

143. These public-private partnerships are vital to the process of discovery, the commercialization of new products and to the growth in cities and communities across our country and are necessary to create the inventions that could reshape our economy and our way of life. These initiatives promote IPR protection by providing MSMEs with an innovative ecosystem and the resources to help them protect their IPR at an early stage. Strong IP protection is critical in scaling up, forming partnerships and ultimately going global. These aforementioned programmes through partnerships, education, training and matchmaking provide MSMEs with the resources needed to protect their IP, grow their businesses, create jobs and build a more competitive economy.

11.3 Australia

144. Australia joins other co-sponsors for this discussion today on 'Inclusive Innovation and Micro, Small and Medium-Sized Enterprise Growth'. Australia has established a number of IP and

Innovation initiatives to help MSMEs utilize and protect their intellectual property and to promote MSME growth including through scaling up their initiatives, collaboration and commercialization. Australia will highlight three programmes today: the IP Mediation Referral Service, an accelerator service for SME known as the ON Program and the Entrepreneurs Programme.

145. The first: Mediation-Referral Service: IP Australia plans to establish a domestic intellectual property Mediation Referral Service where IP right holders will be able to access mediation as a low cost and affective alternative to resolving IP related disputes. The Mediation-Referral Service will consist of a register of qualified, accredited and specialist private sector mediation providers listed on the IP Australia Website. The register will provide details on the fees and contact details of each listed provider allowing parties to IP-related disputes to engage with mediators. IP Australia has also collaborated with the Arbitration and Mediation Center of the World Intellectual Property Organization to develop new resources that provide alternative dispute resolution services online. This new service provides Australian businesses, including MSMEs, with improved access to mediation, arbitration and expert determination services, and will enable parties to settle IP disputes in a time and cost-efficient manner.

146. The second: Australia's publicly funded research institute, the Common-Wealth Scientific and Industrial Organization, also known as CSIRO, launched the 'On-Program' in July 2015 to empower researchers to play an active role in the commercialization of service-based technology and help restrain researchers and their collaborators to develop practical commercialization and venture building skills. In July 2016 ON expanded its eligibility criteria to include all publicly funded researchers, an expansion made possible by A$20 million of additional funding from the Australian government's National Innovation and Science Agenda. This programme consists of a pre-accelerator aspect known as the ON Prime for innovative researchers at early stages of investment readiness, and a separate national science at technology accelerator–programme known as ON Accelerate for innovative researchers closer to commercialization. To date over 130 research teams have completed this programme, and 27 universities and a number of government departments have partnered with this programme. Participating teams retain ownership of their intellectual property. One SME, known as Cardihab, graduated from the first round of the ON Accelerator programme in February 2016, and is one of the many success stories of this initiative. This small company uses web and mobile application based technology to enable medical practitioners to provide more timely advice in supporting patients with heart disease.

147. The third programme is called the Entrepreneurs' Programme. This programme is a flagship initiative, operating at an individual firm level, drives growth and competitiveness among SMEs. This programme takes 'facilitation first' approach and provides easy to access advice, assistance and tailored support to SMEs, including IP support, to help them become more competitive and growth focused. It is a flexible programme designed to address the individual needs of SMEs. For example when SMEs are seeking to collaborate with the publicly funded research organization, the programme ensures that participants are provided advice in all aspects of this work including their IP. The programme operates with a national network of over 130 advisors assisting participants drawn from a wide range of industry groups to ensure participants are provided was relevant, tailored and expert support.

148. Australia has provided some examples of intellectual property and innovation initiatives that are designed to promote sustainable growth of MSMEs. We encourage other Members to join us in sharing national practices.

11.4 Japan

Slide 1
149. Please allow me to mention that handouts of this short presentation[3] can be found just outside the entrance of this room. At present, there are approximately 3.82 million companies in Japan and 99% of those companies are MSMEs. That is to say, most of the companies in Japan are MSMEs. Raising the MSMEs' awareness on intellectual property will broaden the base of intellectual property. By utilizing intellectual property, MSMEs can develop and local communities can be revitalized, which will eventually lead to the economic development of the country. We believe that this holds true not only for Japan but also for every country in the world. In addition, it is a fact that MSMEs play an important role in the economic development of their respective countries.

Slide 2
150. First, please look at the pie chart on the left. Although MSMEs account for 99.7% of the total number of companies, as I mentioned, they filed about only 14% of all applications. The number of foreign patent applications filed by Japanese MSMEs is also only about 16%.

151. Next, please look at the bar graph on the right side. This graph shows the correlation between patent possession and operating profit on sales in Japan. MSMEs without patents have only 1.8% in operating profit on sales, while MSMEs with patents have 3.5%. For comparison, the operating profit on sales for large companies is 2.6% in all industries.

152. Accordingly, the operating profit on sales by MSMEs with patents is higher than that for large companies. Therefore, the fact that companies with patents achieve good business performance indicates that intellectual property has a positive effect on corporation results.

153. Since there is still ample room for MSMEs to utilize intellectual property both domestically and internationally, it is necessary for the government to accelerate initiatives for strengthening intellectual property strategies of MSMEs.

Slide 3
154. One of the measures taken by Japanese government was setting up Comprehensive IP Support Service Counters. As shown in the upper left box, there are various issues and problems with IP, starting from the planning stage up to developing solid corporate management.

155. Accordingly, the Japan Patent Office (JPO) started supporting MSMEs by establishing service counters in all 47 prefectures in Japan. These Service Counters provide full services to assist MSMEs with IP issues and problems free of charge. Persons working at the Counters provide a one-stop service to solve problems on the spot.

156. Working in cooperation with IP specialists and external organizations, the Service Counters provide solutions for highly specialized issues and problems. The IP specialists are attorneys-at-law, patent attorneys, former business persons, designers, brand specialists, and specialists on Intellectual Property in foreign countries.

157. Recently, the Comprehensive IP Support Service Counters started a new service, which is offering consultations on issues and problems with aquaculture, agriculture, forestry and fisheries, in cooperation with the Ministry of Agriculture, Forestry and Fisheries. That new service also covers Geographical Indications (GI) and plant breeders' rights (PBR) for seeds and seedlings.

Slide 4
158. Lastly, let me explain two examples of MSMEs making use of the Comprehensive IP Support Service Counters. This first example was a company that successfully grew its business by utilizing IP rights. The company discussed its problems with the staff at the Service Counters, trying to decide whether to file a patent application or to keep its technology as a trade secret. It wanted to protect its proprietary technology the best way possible. The Service Counters provided guidance and support on a license agreement. As a result, the company was able to obtain a patent right and successfully conclude a technical partnership agreement with a manufacturer.

[3] RD/IP/16 available in English only.

This is one of the successful examples in which a company grew its business by utilizing the Service Counters.

159. The second one is a good example in which a company succeeded in expanding its business overseas. The Service Counters helped the company file foreign patent applications and conclude a non-disclosure agreement and a manufacturing licensing-agreement with an OEM in a foreign country. This is one of the examples in which an MSME succeeded in filing overseas applications and grew its business overseas, by receiving assistance from the Service Counters.

160. As these examples show, Japan believes that it is vital to implement initiatives to further strengthen intellectual property strategies based on MSMEs effectively using their intellectual property.

11.5 Singapore

161. MSMEs make up 99% of the businesses in Singapore, so facilitating the sustainability and growth of the experience is important for our overall economic growth, especially in the context of increasingly innovative and creative global economy. The Intellectual Property Office of Singapore (IPOS) has three initiatives to help MSMEs consolidate their gain by protecting their new ideas and products to existing IP frameworks and using these IP rights to access financing and develop IP management systems to enable their effective use.

162. The first initiative is IP Value Lab, collaboration between IPOS and several private equity funds to help grow innovative MSMEs with the technology of an IP based business modules into globally competitive companies. IP Value Lab does this by helping the private equity funds identify companies with the best IP and offer strategies for harnessing this IP to gain a competitive advantage. It recently partnered with a private equity fund to grow 10 to 15 companies from or through Singapore. One of the first companies to benefit from the scheme is NSP-Tech which designed a lancet for a safe and painless blood prick test and blood sampling called Safety Set. The key inventive step behind the compact design of Safety Set was its use of a rotational mechanism to drive the lancet with a speed and precision needed to minimize pain. This is a boon for patients who need to obtain blood samples regularly, such as diabetics. NSP obtained both patent and trademark protection for Safety Set and won numerous awards for it in 2016 including WIPO's IP Enterprise Trophy, IPOS's Award for Technology Patent, the President's Design Award and the Unity Best Product Award. NSP is now working on further improving the design of the lancet and investing in developing new products.

163. The second initiative is the IP Financing Scheme which enables companies to gain access to debt financing using their intangible assets, such as patents, trademarks and copyrights as collateral. The first such project was approved for Masai Group International in June 2016, and enabled the company to monetize its patents and trademark portfolio in order to pursue brand marketing and invest in R&D. Around 25% of Masai's loan would be designated for IP protection efforts such as shutting down websites selling counterfeit versions of its products. MSMEs in Singapore also have access to the Capability Development Grant, which provides assistance to MSMEs to deal with costs associated with conducting audits of IP assets, developing an IP management system or conducting IP intelligence activities. While these initiatives are still in their nascent stages, they are already helping MSMEs harness innovation to keep pace with technological advancements, remain competitive and identify opportunities to scale up. We hope that over time MSMEs will take a greater interest in the potential offered by the use and the protection of their IP for their growth. We hope that our presentation today has been useful and we look forward to further discussion at the TRIPS Council on how Members, particularly the developing countries can build up their MSMEs' capacities through an IP innovation initiative.

11.6 Canada

164. According to a 2014 "Survey on financing and growth of SMEs" conducted by Canada's Ministry of Innovation, Science and Economic Development, it was found that SMEs that hold formal IP are four times more likely to export, 64% more likely to be fast-growing companies and 32% more likely to seek financing. It was also determined that larger SMEs are more likely than smaller SMEs to innovate and hold IP. Indeed, as the size of the businesses surveyed increased by number of employees, so too did the percentage of SMEs that introduced at least one type of

innovation that held at least one type of IP. For instance, among Canadian businesses with between one and four employees just over 34% introduced at least one type of innovation and just 21% held one type of IP, whereas among those businesses between 100 and 499 employees the proportions of businesses that introduced at least one type of innovation and held one type of IP rose to over 50% and 51% respectively. As well, the number of SMEs in Canada that have introduced at least one type of innovation and hold some type of IP protection has increased overall in recent years. The number of SMEs that introduced at least one type of innovation and held some type of IP protection rose 4% for both of these indicators, to 42% and 21% respectively, since the previous survey was conducted for the 2009-2011 period.

165. One of the questions facing policy makers is how to design the IP system to support and facilitate the growth of MSMEs. While one of the fastest ways is to boost productivity and grow is to innovate, the resources available for innovation are also tied to a firm's size. This means that MSMEs are often constrained in their ability to dedicate resources to innovation, and are therefore limited in their ability to grow and compete internationally. In Canada, for instance, MSMEs make up the largest proportion of Canadian firms, but account for proportionally far less R&D spending than large businesses. Ensuring that the IP system supports MSMEs, by providing for the availability of business services and specialized tools, is therefore key to ensuring that small businesses have the capacity to grow and compete alongside larger firms.

166. In Canada, the Canadian Intellectual Property Office (CIPO) is committed to enhancing its IP awareness and education programming to deliver tailored and responsive products, services and training to innovators and SMEs. CIPO's IP Education and Awareness Program will extend its reach and impact by co-developing programming for and with relevant partners, increasing its regional presence, and working with others in the innovation network to market and provide IP education and awareness tools to clients. CIPO's IP Education and Awareness Program offers services in three areas:

167. First, the *IP4Business* provides a suite of products designed to provide businesses with the tools and information that they need to better acquire, manage and leverage their IP assets. These products and services include IP guides, brochures, videos, an online IP strategy tool, training, checklists, fact sheets, and digital content designed to increase awareness of IP in particular high growth-potential markets and sectors.

168. Second, CIPO's *IP Academy* provides a suite of seminars and training services for businesses, partners and intermediaries, including those for specific markets and sectors. The IP Academy will offer a bank of speakers, massive Open Online Course (MOOC) webinars, IP boot camps, (search-a-thons,) case studies, and custom training programs for accelerators, incubators, university technology transfer offices and more.

169. Third, the Program will also support an *IPHub*, which comprises a network of services, including a digital platform, referrals, consultations, and advisory services for participants in the IP marketplace.

170. In addition, the Government of Canada offers a range of services and programs aimed at supporting MSME growth more broadly. For instance, Canada's National Research Council (the NRC) provides assistance to SMEs through the Industrial Research Assistance Program (IRAP), by way of technical and business advisory services to better equip clients to conduct R&D, commercialize new products, processes and services, and to access new domestic and international markets. The IRAP's industrial technology advisors assist clients at various stages of the innovation process to build their innovation capacity, for instance, through technology and business assistance, literature and patent searches, and strategic intelligence. IRAP also connects SMEs with partner organizations that can provide further assistance such as financing, R&D, IP services, and technology transfer.

171. The National Research Council also offers a single access point called Concierge, where SMEs can find high-quality, timely advice to help them innovate and grow. Providing free, one-on-one guidance to SMEs, the Concierge service connects SMEs with Innovation Advisors, namely industry experts with extensive networks that provide clients with high-quality referrals and services, to help SMEs navigate available innovation resources and support programs.

172. Another key constraint faced by MSMEs is financing. Indeed, many small business entrepreneurs may find themselves unable to dedicate time and resources to pursuing growth opportunities such as hiring talent, boosting productivity, or seeking new markets. Moreover, there are a number of costs associated with protecting IP, from administrative fees to hiring IP professionals such as patent agents. The government of Canada offers a number of resources to MSMEs in this regard. For instance, the business Development Bank of Canada (or BDC), which is a federal Crown corporation owned by the Government of Canada, provides financing and advisory services with a focus on SMEs. BDC provides a number of financial services to SMEs, such as start-up financing and small business loans, as well as BDC's *Xpansion Loan* which is designed to help businesses realize products that are key to growth, such as expanding their market, investing in technology, developing new products, applying for IP protections, and purchasing IP licenses.

173. As well, with a view to encouraging small businesses (and universities) to use the patent system, certain CIPO fees for obtaining and maintaining a patent are reduced by 50% for "small entities". Canada's Patent Rules define a small entity as one that employs 50 or fewer employees or that is a university department. In order to take advantage of the reduced fees for small entities, applicants must submit a small entity declaration before or at the time of their fee payment, if there is not already one on file.

174. These are just some of the services and programs offered to SMEs in Canada, aimed at supporting their growth and expansion. Canada would be pleased to provide additional information on any of these services and programs to other Members upon request.

11.7 Switzerland

175. We thank the co-sponsors for tabling this important topic on the agenda and for allowing a further inclusive discussion on the fostering impact that IP can have on MSMEs.

176. The question of how IP can contribute to growth of micro, small and medium size enterprises could be answered with the question of what the right tools for enabling success and growth are. This is a question that has to be asked not only in business as such, but likewise in sports, music or arts in general: Also the most talented athletes and players need the adequate support and the right tools to perform at their best. This applies to runner Haile Gebrselassie and tennis player Roger Federer, to jazz pianist and prodigy Joey Alexander or to artist Lucia Fainzilber, they all rely on the right equipment and suitable framework conditions.

177. It is those conditions and the right tools at hand which allow a player or an MSME to make a difference and grow. Such tools complement talent and hard work, and they can be crucial to succeed in the market. We will present two examples to illustrate how IP acts as such a tool. And how it can be a door-opener for inclusive growth and contribute to future prosperity.

Example 1: COLIPRI - Colombian-Swiss Intellectual Property Project
178. In 2013 Colombia and Switzerland started a fruitful cooperation project. The project overall aims to strengthen the use of intellectual property rights in Colombia, and in particular to contribute to higher competitiveness and added value of Colombian products. Colombia's intellectual property system is at an advanced stage. Accordingly, the project focuses primarily on addressing specific requests.

179. One of the project's achievements is the support for local geographical indication supply chains, both in the food and handicraft sectors. For example, in the past four years the project has supported the registration of the so-called *Bocadillo veleño guava paste* as a geographical indication*. Bocadillo veleño* is Colombia's most traditional fruit sweet and is produced by MSMEs in a very specific region called Vélez. Its distinctive characteristics are based on unique climatic factors and human know-how.

180. In 2013, the original product of Vélez was losing an estimated 51% of market share due to copies produced in different regions. Furthermore, its reputation was declining and its name was on the verge of becoming generic for this type of sweet. This month, *Bocadillo veleño* is being registered as a GI in Colombia, after 4 years of preparation work. Thereafter, it will be up to the producers of Vélez to enforce their GI from now on. With the GI protection in place, they now have a powerful tool to defend their market share and proceed against freeriding and unfairly

copied products, which amount for an estimated annual USD 12 million on the Colombian internal market.

181. IP and in particular, geographical indications or collective trademarks also can be an important tool to enhance local growth potential. All local producers, as long as they produce in accordance with the rules established by the specification requirements, get access to a strong and well protected marketing asset.

182. This is especially relevant for micro and small enterprises, which lack the necessary funds for marketing their unique products on a wider scale. Moreover, the registration of GIs can also help to support more vulnerable population groups such as rural communities and ethnic minorities. By better marketing their products, GIs are expected to increase local producers' income and are an important tool for growth. Furthermore, the mentioned project also supports community development and capacity building. Thereby, it further contributes to establishing favourable conditions for a business-enabling environment.

183. As such, the project supports the Colombian government's aim to increase competitiveness, to diversify its economy and to narrow the income gap between its rural and urban population. As a GI publicised by modern ways of promotion, it eventually enhances protection abroad, in countries protecting GIs, including against unfair competition, and acting as a piece of evidence of the protection in a legal action.

Example 2: Bioburn

184. GIs and trademarks primarily protect producers' efforts and investment over time and enable them to market their products. Furthermore and as is well known, intellectual property plays a key role in the development and diffusion of new technologies. To invest in research and development, firms and researchers need to trust that legal certainty is guaranteed and that the Intellectual Property System is reliable and the enforcement of their rights works efficiently. The right framework conditions facilitate innovation and allow for new technologies to be developed and made accessible.

185. With our second example we would like to highlight how new technologies can improve a region's business environment and growth perspectives. The given example refers to a company called Bioburn and how its technology is used in Uganda.

186. Bioburn, a Swiss enterprise, invented and patented a technical method which allows to transform biological waste into biomass very efficiently. Subsequently, consumers can use the biomass as fuel. In 2016, Bioburn started a promising cooperation-project in Uganda. The project was also supported by the Swiss Government.

187. In rural regions of Uganda, there is a huge potential for biomass fuel. Together with their local partners, Bioburn intends to use agricultural waste and turn it into fuel. They experimented with different sorts of agricultural waste. Intensive testing over a long period of time which showed that cacao bean and pod waste of farmers seems to be the most suitable resource for efficiently producing the fuel. With its local approach, the project can create new value chains. Local production in rural regions offers new jobs and income opportunities. And this is not only true for well-established companies but especially also for small farmers. Moreover, because biomass is often cheaper than conventional fuels, the used technology can also contribute to reducing ecologically harmful incentives of deforestation. In addition, the fuel's lower price benefits consumers. Bioburn's patented technology offers significant economic benefits for producers, consumers and the economy as a whole. It is of great importance for future prosperity that such technologies are being continuously developed and diffused.

188. And this is where national and multilateral IP-regulation comes into play: it offers necessary incentives for research and development since it protects against freeriding, for a limited period of time, and at the same time provides the tools for diffusing as well as facilitating the licensing of the technology in question. In the case of the *Bocadillo veleño guava paste* it is the GI protection system which is an important tool for facilitating the growth of MSMEs, in the case of Bioburn it is the patent system doing the same.

189. In conclusion, the two examples show how IP has economic effects in various ways: First, it can build new and strengthen existing value chains. Second, it can contribute to a stable and business enabling environment. And thirdly, it can provide the necessary incentives for research and development as well as for diffusion of new technologies.

190. Taken together, all these factors contribute significantly to a country's growth and future prosperity. Micro, small and medium sized enterprises often manage their businesses with limited financial resources. Accordingly, they especially depend on favourable business regulation. In addition, IP is considered as one key element at the core of innovation. Through these different channels IP can generate a supportive environment for MSMEs to grow and prosper; intellectual property as a proven tool to enable continued success. We are looking forward to hearing from further delegations about their experience, about MSMEs experience and about policy approaches how to support them.

11.8 Chinese Taipei

191. Our own MSMEs account for almost 98% of all our businesses. They are the backbone of our economy and they have played a critical role in fostering our economic development. What we have learnt, however, is that while they display a remarkable capacity for innovation in IP matters, when it comes to drawing up IPR strategies or comprehensive patent portfolios, MSMEs in particular usually struggle due to a lack of resources and support from IPR professionals. So, in order to help MSMEs deal with IPR-related challenges, and to create a more favourable environment for IPR development and innovation in general, our governments have offered MSMEs support in three key areas - expert advice, financial assistance, and information services.

192. To provide expert advice, we have set up the "IP Consulting Centre for SMEs" which makes available a range of customized services offered by experts in the form of IP diagnosis and strategy planning, in areas such as intellectual property rights, technology, law, and market analysis, according to the size and particular needs of the MSME. In this way, MSMEs can get help in the R&D stage for patent searches and portfolio strategies, so as to build their innovation capacity.

193. As far as financial assistance is concerned, we have introduced the "A+ Industrial Innovation R&D Programme"(or the "A+ Programme"), which provides incentives to businesses applying for patents, to encourage them to start building a patent portfolio as early as possible.

194. I can give you some hard numbers to illustrate the success of the A+ Programme since its launch in 2014. By the end of March this year, 2017, a total of 1,079 projects have been approved under the Programme, boosting investments by US$5,67 billion and creating a production value of over 8,68 billion. In addition, by the end of last year, over 9,000 patent applications had been made at home and abroad under this Programme. Of these, over 4,000 patents had been granted - an approval rate of about 45%.

195. Furthermore, in order to support MSMEs conducting overseas IPR litigation or other similar actions, we have launched the "Enterprises Overseas Intellectual Property Litigation Loan", providing guaranteed credit to domestic enterprises in the form of a loan for the expenses in overseas IPR litigation. Loans of up to US$1,68 million are available depending on the project, for a term of seven years at the most.

196. And, finally, a range of information services are made available to MSMEs on request, including trends and analysis of patent applications in specific areas. In addition, there's the "IP SME Corner", a one-stop search platform providing basic IPR knowledge and information on government resources in this area. With this platform, MSMEs can improve both their understanding of IPR matters and their success in acquiring patents.

197. Most MSMEs today face an urgent need to make better use of patent portfolios in order to protect and take advantage of their innovations and R&D results. Our experience is telling us that IP is a key component of smart and sustainable economic growth and development. We would encourage all Members, therefore, to share their policies and experiences in this respect, in the interests of inclusive economic development, and MSME growth in particular.

11.9 Brazil

198. Micro, small and medium-sized enterprises (MSMEs) play a major role in social and economic policies, representing the majority of companies in almost every country in the world and concentrating more than half of all jobs in both developing and developed countries. Therefore, they play a major role in social and economic policies and their participation in international trade is an important issue in the WTO agenda.

199. In this sense, I would like to draw the attention of Members to the Joint Communication circulated during the last session of the General Council WTO regarding the informal dialogue on MSMEs in this organization. A group of members, including Brazil, referred to the importance of promoting the participation of those entities in international trade, pointing out, among other things, that one of the obstacles preventing MSMEs from engaging more in export and import activities is technological development. Technological development is an issue explicitly mentioned in Article 8 of the TRIPS Agreement, underlining the potential contribution that intellectual property might bring to MSMEs. There is, thus, much that can be done in WTO regarding this matter.

200. Our delegation also wishes to highlight that Brazil, Argentina, Paraguay and Uruguay just circulated the paper JOB/GC/127, in which we indicate areas where the WTO could develop measures in favour of MSMEs. In the area of information and transparency, proponents suggest that Members afford better access to information for MSMEs in several aspects, including procedures related to the acquisition of intellectual property rights.

201. Now turning to the invitation of the proponents to share domestic experiences, our National Institute of Industrial Property actively engages with MSMEs in order to disseminate information about the steps necessary for obtaining intellectual property protection in Brazil and abroad. The INPI also provides an on-line course, elaborated in partnership with WIPO, which brings an overview of the legal requirements for the protection of IP. While the on-line course is not specifically directed to MSMEs, data available indicates that MSMEs and individual persons are the main users of the course.

202. Furthermore, in order to overcome the challenges those companies commonly face, the Ministry of Industry, Development and Foreign Trade provides support to MSMEs in a myriad of actions, such as the elaboration of a their business plan.

203. Lastly, Brazil participates in the CIBEPYME, the Iberoamerican Platform of Industrial Propriety which is directed to small and medium companies. The initiative provides easily accessible information about the many types of intellectual property, as well as a consulting service focused on the concrete needs of small and medium companies.

204. This is not, of course, an exhaustive list of all the actions and we hope it can contribute to the discussion.

11.10 Hong Kong, China

205. Hong Kong, China is pleased to share our support measures to SMEs in relation to IP trading. SMEs are the backbone of our economy; they constitute of 98% of our local business establishments and account for about 46% of the total employment in the private sector in Hong Kong. The Hong Kong, China (SAR) Government attaches great importance to SMEs and tries to provide a business-friendly environment for them. Our Government has been providing multi-layered support for them through operating various funding schemes, building the necessary infrastructure and providing the latest market information and other business advisory services in relation to IP trading through relevant government departments and quasi-government organizations. The surge in global demand for IP in recent years and increasing international trade in IPRs opened up a world of new opportunities. IP commercialization is very important to the further development of a knowledge-based economy. We saw the potentials here and decided to implement a number of support measures in relation to IP trade.

206. First of all, our Government has set aside US$3 million as from 2015 to 2016, for three years to support a series of new measures. These include the provision of free initial consultation

services to raise the IP awareness of SMEs, organizing a sponsoring IP-related training to help SMEs build up their IP manpower capacity, launching an IP manager's scheme to support SMEs in building up their manpower capacity on IP management and commercialization, and rolling out promotion and public education campaigns. Our Intellectual Property Department launched a dedicated website, in March 2015, to provide a one-stop shop for disseminating IP trading information such as types of IP, trading IP, managing IP, protecting IP and many other resourceful features. The Intellectual Property Department launched the IP managers' scheme in 2015. The scheme aims to assist Hong Kong enterprises, especially SMEs, to build up their IP manpower capacity, and to increase competitiveness through IP management, so as to grasp the opportunities brought by IP trading. The scheme encourages enterprises to appoint a staff member in a managerial position as their in-house IP manager, who will be responsible for overseeing the compliance management, exploitation and commercialization of IP assets. Over 500 SMEs have joined the scheme, as of mid-May 2017. The training and resources on IP management are provided for the IP managers to carry out their duties within the enterprises. The Intellectual Property Department in collaboration with our Law Society in Hong Kong launched the IP consultation service scheme in September 2016, to provide one-on-one free IP consultation services to SMEs with a will to raising the awareness of IP and developing effective IP management and commercialization strategies. Advisory areas cover IP registration, IP due diligence, IP management and IP licensing. This scheme is well received by SMEs.

207. Last but not least, we have also been reaching out to different industries and SMEs such as movie and toy to promote cross-sector IP trading, since the latter half of 2015. And the responses so far have been very encouraging. Key players in the respective views have a better understanding of the potentials of the IP and the prospects of cross-sector commercialization.

11.11 India

208. In para 5 of the document (IP/C/W/622), the co-sponsors have selectively quoted from the study about the informal economy, by de Beer, Fu & Wunsch-Vincent (2013: 39) to support their position that IP must be considered as a relevant aspect for innovative micro-sized enterprises. However, one of the important observations by de Beer, Fu & Wunsch-Vincent in their study about the informal economy, is 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.

209. The co-sponsors of the agenda item "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. There have been many studies to show that intellectual property is only one element in a larger innovation ecosystem and IP laws alone do not promote technology development. For instance, according to the Trilateral study by WTO, WHO and WIPO:

> "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."

210. The MSME sector in India, consisting of 36 million units, 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.

211. 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 MSME 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. Another scheme entitled "Support for Entrepreneurial and Managerial Development of SMEs through Incubators" is operational since April 2008, to assist incubation of innovative business ideas that could be commercialised in a short period of time, resulting in the formation of MSMEs that have distinctive presence in the market. More details about these schemes could be found on the website www.msme.nic.in

212. A national innovation survey has been conducted during 2011-12 in India, by the Department of Science and Technology (DST). 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, from 26 states and 5 Union Territories across various industrial sectors in the country.

213. 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 players in the market, regulatory requirements etc. IPR related issues are not found to be of any concern for the innovation activities of the firms.

214. 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 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."

11.12 China

215. The growth of micro, small and medium size enterprises can contribute to the innovation and economic development. A suitable intellectual property system can effectively assist enterprises, especially MSMEs. However, China also believes there are many factors contributing to improvement of the innovation and development capacity of MSMEs, attention should not be paid to the importance of intellectual property rights only.

11.13 El Salvador

216. In El Salvador the Law on the promotion, protection and development of micro and small enterprises provides that the National Commission for Micro and Small Enterprises (CONAMYPE) has certain responsibilities in the area of entrepreneurship, and is in charge of defining, formulating, promoting, implementing and coordinating programmes and instruments to promote entrepreneurship and the building of an entrepreneurial and business culture, as well as a culture of corporate social responsibility and sustainable environmental management.

217. The National Registration Centre's Intellectual Property Registry is the administrative authority responsible for administering intellectual property rights in El Salvador. It regulates the acquisition, maintenance, protection, modification and licensing of trademarks, commercial advertising slogans or signs, trade names, emblems, geographical indications and appellations of origin; the registration of patents, utility models and industrial designs; and the deposit of works protected by copyright and related rights. Under the Intellectual Property Law, the Registry is also responsible for fostering the dissemination of information on, and promoting awareness of, intellectual property right protection.

218. For a number of years now, both institutions have assisted MSMEs with intellectual property procedures and have helped to implement various support programmes that cover advisory services and training in the area of innovation and intellectual property.

219. These programmes include the following:

- The *"Opulencia Pipil"*platform: In 2014, CONAMYPE created the *Opulencia Pipil* platform, with a view to providing support to the artisanal sector by organizing a fashion show

linked to artisanal production and national identity. The funding for this initiative was provided by the Special National Telecommunications Administration Privatization Resource Fund (FANTEL). The platform seeks to showcase the innovative nature and quality of artisanal products made in the country, and to open up new marketing channels for artisanal enterprises.

- The *"Un Pueblo Un Producto"*("One People One Product") strategy: This programme seeks to promote innovation and creativity through the use of local resources and endogenous development, with a view to enhancing community capacity and improving the quality of life of community inhabitants through the development and marketing of products originating in their communities.

- Artisanal development groups: This is a CONAMYPE initiative to form associations within the artisanal sector with a view to enhancing entrepreneurship, promoting the marketing of artisanal products, and encouraging the consumption thereof at both national and international level.

11.14 Korea, Republic of

220. Korea has already shared our effort to promote SMEs' innovation at the APEC level at the November TRIPS Council meeting last year. I would like to refer to that intervention which was about the project of "Guidebook for SMEs' IP-Business Cycle"which is to provide APEC Economies with standardized SME-friendly IP policies.

11.15 ARIPO Secretariat

221. From January this year ARIPO has undertaken a number of initiatives to assist its member States, which includes workshops organized either solely or in collaboration with other partners, especially WIPO, the Japan Patent Office, Intellectual Property Offices of Member states and others. ARIPO's flagship this year is to work with the main intellectual property generators, i.e., with the universities and the research and development institutions. In that regard we have organized workshops in Sierra Leone, which is taking place on 14-15 June; and in Zambia, Lesotho and Rwanda. We have also organized a number of seminars with universities in our host country, Zimbabwe. The main theme of these workshops and seminars is to create awareness among teachers and students on the importance of intellectual property in universities and research and development institutions which will, in turn, assist in the creation and development of MSMEs.

222. Furthermore, we have realized that many universities and research and development institutions in ARIPO member states lack intellectual property policy, which defines the effective use of intellectual property systems.

223. It is against this backdrop that alongside the workshop on awareness creation, ARIPO and WIPO are developing a model of institutional intellectual property policy for an effective use of the IP system by universities and research and development institutions in Africa, which among others provide guidelines on establishment of start-ups. As mentioned earlier these are some of the highlights of the initiatives that ARIPO has undertaken to assist member states in improving the IP systems, but as was the case in 2016, a detailed report will be provided for 2017

AGENDA ITEM 12: INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: COMPULSORY LICENSING

12.1 South Africa

224. The communication (IP/C/W/630) dated 31 May was circulated at the request of the delegations of Brazil, China, Fiji, India and South Africa. The Agreement on Trade-Related Aspects of Intellectual Property Rights of the WTO established minimum standards of protection that each government has to give to the intellectual property of fellow WTO Members. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to these rights, and the minimum duration of protection. WTO Members have the flexibility to design their national intellectual property systems within the minimum standards set by the TRIPS Agreement in cognizance of a country's economic,

developmental and other objectives including public health. The TRIPS Agreement attempts to strike an appropriate balance between the interests of rights of holders and users.

225. Article 7 of the TRIPS Agreement entitled 'Objectives' recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge in a manner conducive to social and economic welfare and to balance the rights and obligations. The search for a balance between the need to protect IPRs and to provide incentives for R&D on one hand and on the other hand to address concerns about the potential impact of such protection on the health sector, in particular its effects on prices, has been an important consideration in the WTO's work. The TRIPS Council also recognizes that the principles of IP protection are based on the underlying public policy objectives.

226. Article 8 of the TRIPS Agreement entitled 'Principles' states that WTO Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to the socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Article 8.2 further states that appropriate measures may be needed to prevent the abuse of IPRs by right-holders or to resort to practices which unreasonably restrain trade or adversely affect international transfer of technology.

227. In furtherance of the objectives and principles of the TRIPS and enshrined in Articles 7 and 8, a number of safeguards or flexibilities have become an integral part of the TRIPS framework. These flexibilities can be used to pursue public health objectives. However, to implement these flexibilities action is needed at the domestic level by incorporating them into national IP regimes, keeping in mind each country's individual needs and policy objectives. Key TRIPS flexibilities include transition periods for LDCs extended by the WTO until 1 January 2033, differing IP exhaustion regimes, refining the criteria for grant of patentability criteria, pre-grant and post-grant opposition procedures, as well as exceptions and limitations to the patent rights once granted, including the regulatory review exception or Bolar exception to facilitate market entry of generics, compulsory licenses and government use. For pharmaceutical patents, these flexibilities have been clarified in and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. WTO Members have the flexibility to interpret and implement TRIPS provisions in a manner supportive of their right to protect public health.

228. Another new flexibility was added by the Doha Declaration which was put into practice in 2003 by the WTO with a decision enabling countries that cannot manufacture medicines for themselves to import pharmaceuticals made elsewhere under compulsory licenses. In 2005, Members agreed to make this decision permanent through the Protocol Amending the TRIPS Agreement which entered into force on 23 January 2017 after two thirds of Members had accepted it. The amendment provides legal certainty that generic versions of patent-protected medicines can be produced under compulsory licenses specifically for export to countries with limited or no pharmaceutical production capacity.

229. Many governments have not used the flexibilities available under the TRIPS Agreement for various reasons, such as capacity constraints or political pressure from states and corporations, as mentioned in the UN Secretary General's High Level Panel Report on Access to Medicines. Moreover, even where some developing countries used the flexibility available to them under the TRIPS Agreement to address public interest objectives through measures which are fully consistent with the TRIPS Agreement, these attempts have been challenged legally, as well as politically. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violate the integrity and legitimacy of the system of legal duties and rights created by the TRIPS Agreement as reaffirmed by the Doha Declaration.

230. A slew of regional trade agreements containing 'TRIPS+' standards of IP protection and enforcement have the potential to significantly affect the policy space available for effective and full use of TRIPS flexibilities. The most common 'TRIPS+' provisions in free trade agreements that affect the pharmaceutical sector are (i) the definition of patentability criteria, (ii) patent term extensions, (iii) test data protection, (iv) the linkage of regulatory approval with patents and (v) enforcement of IPRs, including border measures. Such provisions can delay the marketing of generics and increase prices of medicines. Investor-to-state disputes under regional or bilateral

investment protection agreements are also emerging as significant threats to the use of TRIPS flexibilities in the public interest.

231. Ironically, the above-mentioned challenges to the use of TRIPS flexibilities to further the public interest objectives underlying IP protection have been occurring in spite of the emergence of laws and jurisprudence in developed countries that seek to limit the scope of IP protection and enforcement. For example, in the 'Myriad-Genetics' case of 2013, the US Supreme Court had ruled unanimously that naturally occurring genes cannot be patented even if they are isolated. In 2003, the US Federal Trade Commission had proposed tightening the 'non-obviousness' standard in order to limit the grant of unwarranted patents. There is a growing concern about an imbalance between intellectual property and public interest with regard to health technology, for example, patents and related monopoly rights. Without sufficient use of balancing exceptions and limitations to protect the public interest, companies are permitted to maintain high prices and exacerbate the crisis of access around the world where many patients cannot afford medicines and force governments with finite health budgets to rationalize care.

232. Increased copyright protections create similar problems of access to knowledge goods limiting the ability of many people around the world to access print, audio, or visual works of education or entertainment that we take for granted. These are only a few examples of the problem. There is a need to pursue a developmental-oriented approach towards formulating IP laws and policies rather than to pursue an iconic classic approach to IP for development.

233. More than twenty years after the adoption of the TRIPS Agreement there is a need for discussion in the TRIPS Council on the relationship between IP and the public interest and to broaden the understanding of how the IP system can be more responsive to public interest considerations. While this issue is very pertinent for developing countries, it has also been a topic of significant policy debate even in developed countries. During the course of meetings of the TRIPS Council in this year and later, WTO Members could exchange views and experiences on measures within the IP system that they have adopted to promote the public interest, including but not limited, to compulsory licensing, patentability criteria, IP and competition, and the Bolar exception.

234. The sponsors of this communication invite delegations to share their experiences on the use of compulsory licenses for accessing health and other technologies. Compulsory licensing occurs when a government allows someone else to produce the patented product or process without the consent of the patent owner. Article 31 TRIPS lays down a set of conditions for issuing compulsory licenses of patents. The Doha Declaration on the TRIPS Agreement and Public Health states that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". Despite the clarity of this language, WTO Members around the world seeking to make use of compulsory licenses as tools to create access to affordable medicines have faced various challenges or barriers.

235. Some possible grounds for compulsory licences are suggested in Article 5a of the Paris Convention, for example, abuse of patent rights, including failure of the patent holder to work the invention, and in Article 31 of the TRIPS Agreement, for example, national emergency and public non-commercial use. However, this list is not exhaustive. The Doha Declaration on the TRIPS Agreement and Public Health confirmed what was already implicit in the TRIPS Agreement that WTO Members have the freedom to determine the grounds upon which compulsory licences are granted. They are thus not limited to emergencies or other urgent situations, as is sometimes mistakenly believed. A range of grounds have been set out in national laws, such as non-working or insufficient working, anti-competitive practices, public interest, dependent and blocking patents and government use.

236. The sponsors of this communication invite Members to share their national experiences and examples of using compulsory licences. The information exchange could serve to enhance the understanding of Members on various grounds available for the issue of compulsory licences and the problems faced by Members while using them. We have also circulated guiding questions which I summarize as such: what grounds are available in the national laws to issue compulsory licences; what are the difficulties faced by WTO Members in using compulsory licences including constraints such as insufficient or no-manufacturing capacities; how the measure of compulsory licence was used by governments to obtain price reduction form patent holders; and what was

the result of using compulsory licences in terms of price and access to affordable products and technologies.

12.2 India

237. At the outset, I would like to thank the delegations of Brazil, China, Fiji and South Africa who are also co-sponsors of this agenda item. We would also support the statement made by South Africa while introducing our submission contained in document IP/C/W/630.

238. The TRIPS Agreement attempts to strike an appropriate balance between the interests of rights holders and users. The TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives. In furtherance of the objectives and principles of TRIPS enshrined in Articles 7 and 8, a number of safeguards or flexibilities have become an integral part of the TRIPS framework. These flexibilities can be used to pursue public health objectives.

239. During the 1980s and 1990s, antiretroviral medicines used to treat HIV/AIDS were priced beyond the reach of most people who needed them in developing countries. Countries like Brazil, Thailand, South Africa and others have used flexibilities under the TRIPS Agreement, including compulsory licenses to bring down the price by increasing the supply of generic ARV medicines for a fraction of the price of the patented equivalents. Indian generic companies, especially CIPLA, played an important role by announcing in early 2001 that triple therapy could be manufactured for less than a dollar per day, as compared to the price of standard triple therapy at US$ 10,000 per patient and year. Indian generic companies made ARV medicines accessible to all those who needed the drugs but had previously not been able to afford them.

240. As regards compulsory licensing, Article 31 provides Members complete freedom to decide the grounds for issue of compulsory licences. The Doha Declaration on the TRIPS Agreement and Public Health has also duly confirmed what was already implicit in the TRIPS Agreement – that WTO Members have the freedom to determine the grounds upon which compulsory licenses are granted.

241. There have been many studies that examine the possible grounds for issue of compulsory license. For instance, the diversity in the grounds for issue of compulsory license is documented in the United States Congressional Research Service Article titled "Compulsory Licensing of Patented Inventions" by John R. Thomas, dated 14 January 2014, which mentions that "depending upon particular national laws, the grounds for government award of a compulsory license may include: (i) circumstances of national emergency or extreme urgency; (ii) where the invention serves vital public health needs; (iii) a strong societal interest has arisen in access to the patented invention; (iv) the patent owner has failed to practice the patented invention in the jurisdiction that granted the patent within a reasonable period of time; (v) the patent owner has abused its economic power in such a manner as to violate the antitrust laws; and (vi) in circumstances where multiple patents held by different owners cover a particular technology. For example, combination therapies, such as triple antiretroviral drugs, may be subject to more than one patent. In such cases, if one patent owner refuses to license, then the technology may not be marketed absent a compulsory licensing".

242. I would like to share with you briefly the details of India's law with regard to compulsory licensing. Sections 83 to 94 of India's Patent Act contain detailed provisions regarding compulsory licences, including those that generic companies can apply for, government use licenses, those issued in cases of national emergency, extreme urgency and public non-commercial use and compulsory licenses for exports.

243. India has issued only one compulsory licence so far. In March 2012, Indian generic manufacturer NATCO Pharma was granted a compulsory licence to manufacture Bayer's drug Sorafenib Tosylate (Nexavar) used for the treatment of kidney and liver cancer. Bayer was granted a patent and received marketing approval for Nexavar for the treatment of liver and kidney cancers in 2008. Bayer would have supplied 200 patients in 2011, which was a little more than two percent of the affected population. The primary reason for this abysmally low coverage vis-a-vis the need was the exorbitant treatment cost of nearly Indian Rs.284.000 (US$4,370) for

a month's treatment which priced the medicine out of reach of almost all people in India. Patent rights cannot be allowed to impede protection of public health.

244. NATCO pharma proposed to sell the generic form of Nexavar for Rs.8,800 (US$135) a month. The Controller of Patents in India granted a compulsory license under section 84 because the TRIPS Agreement allows Members to adopt measures to protect public health and Bayer did not meet its duty under the Indian Patents Act, as the patented invention was not available to the public at a reasonable price, and it was not worked in the territory of India. The Indian Courts have upheld the decision of the Controller General of Patents to grant a compulsory licence to NATCO Pharma to manufacture the generic version of Nexavar in India.

245. Now, I would like to provide brief details of use of compulsory licences in a few other Members. According to an article entitled "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options" by Jerome H. Reichman[4], the United States threatened Bayer with a compulsory license on ciprofloxacin (Cipro) in 2001, which the U.S. intended to stockpile as a defence against anthrax. In response, Bayer drastically lowered its price. The Italian Competition Law authorities issued compulsory licenses against Merck, on certain antibiotics, for abuse of a dominant position in 2005; against Glaxo, for refusal to license a patented migraine headache drug in 2006; and against Merck again for refusal to license a treatment for baldness in 2008.

246. In *Apple Vs Motorola*, filed in the United States District Court for the Northern District of Illinois (Eastern Division), Judge Richard Posner, in June 2012, while dismissing with prejudice the patent infringement suits, cited the decision in eBay Inc. v. MercExchange, L.L.C. He specifically noted that a "compulsory license with ongoing royalty is likely to be a superior remedy in a case like this because of the frequent disproportion between harm to the patentee from infringement and harm to the infringer and to the public from an injunction".

247. The September 2016 Report of the UN Secretary General's High-Level Panel (HLP) states that many governments have not used the flexibilities available under the TRIPS Agreement, including compulsory licences, for various reasons, ranging from capacity constraints to undue political and economic pressure from states and corporations, both express and implied.

248. The HLP Report also refers to Resolution No 2475 by the Ministry of Health of Colombia that was a pathway for issuance of compulsory licence to access Imatinib, in public interest, for treatment of Leukaemia. The Report also states that many domestic and foreign parties have tried to dissuade the Colombian Government from issuing a compulsory license as provided by the TRIPS Agreement and the Doha Declaration. We request the delegation of Colombia to share their experiences in this regard.

249. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violate the integrity and legitimacy of the system of legal duties and rights created by the TRIPS Agreement and as reaffirmed by the Doha Declaration.

250. I conclude by quoting the recommendations in the HLP Report on compulsory licences: "Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments".

251. We look forward to hearing other delegations' experiences regarding the use of the TRIPS flexibility, i.e. compulsory licensing.

12.3 Brazil

252. I would first like to thank the delegations of China, India, Fiji and South Africa who are also co-sponsoring this agenda item.

[4] Published in the Journal of Law, Medicine and Ethics in 2009, 37 (2): 247-263.

253. The proposal for inclusion of the item on 'Intellectual Property and the Public Interest' aims at spurring the discussion regarding the many facets of IP within the broader socio-economic framework of Members. The complex and complementary relationship between these aspects is a topic that merits careful reflection and broad discussion by Members.

254. IP addresses the public interest by providing incentives for innovation. At the same time, governments have the responsibility of safeguarding the public against its potential negative impact, notably on competition. A balanced IP system, therefore, provides powerful incentives for innovation with the least effects on the competitive landscape; in economic terms, it will stimulate the pro-competitive dynamic effects of intellectual property while limiting and controlling its potential anticompetitive static effects.

255. An efficient IP system, by definition, results from a delicate balancing act. There is no one-size-fits-all approach. Rather, a flexible policy space is necessary to allow each Member to develop and adapt the set of IP regulations more adequate for its individual reality. This is to be done, of course, within the boundaries of the internationally agreed objectives, principles and standards, to ensure predictability and mutual confidence. One of the tools to reach that result is the use of exceptions and limitation to IP rights, an intrinsic element of the law of every Member. They serve a number of purposes by conferring the necessary flexibility to guarantee national security and to shape public policies to meet, *inter alia*, development, competition, and health surveillance goals. Therefore, they will generate an increased societal welfare without unreasonably prejudicing the legitimate interests of the patent owner.

256. In recognition of the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives, Articles 7 and 8 TRIPS contain clear language regarding the relationship between public interest and the protection and enforcement of intellectual property rights.

257. The discussion under this agenda item has, among its goals, the increase of knowledge regarding those aspects and the exploration of possible solutions for developing, as well as for developed countries. As an initial effort to broaden the understanding of how the IP system can be more responsive to public interest considerations, the proponents would like to mention the topic of compulsory licenses.

258. The judicious use of compulsory licences assists countries to uphold the delicate balance of the TRIPS Agreement. While the topic is commonly referenced to with health issues, compulsory licensing can be used in other cases as well. As we all know, neither Article 31 TRIPS nor Article 5A of the Paris Convention contains any restriction with regard to the ground on which a compulsory license may be issued, a view confirmed by the Doha Declaration on TRIPS and Public Health.

259. Under Brazilian law, right holders may be subject to compulsory licences if they exercise patent rights in an abusive manner, or if they engage in abuse of economic power. In the case of dependent patents, for instance, anticompetitive behaviour can be established if the holder of the main patent fails to reach agreement with the patent holder of the dependent patent on the exploitation of the earlier patent.

260. We would like to refer to a concrete case in order to further contribute to the debate. In 2007, Brazil issued its first and only compulsory licence to date, regarding the antiretroviral efavirenz, for public non-commercial use. The underlying intention was to guarantee that HIV patients received appropriate treatment from the Brazilian Public Health System, as efavirenz was used by 40% of all HIV patients in Brazil at the time. Previous to the compulsory license, the Brazilian Government engaged with the patent owner in several meetings with the view of reaching a negotiated solution. Those negotiations, however, did not lead to an agreement in terms and conditions adequate for addressing the public interest.

261. In conjunction with the procedures necessary for the compulsory license, the Brazilian Government initiated the preparation for the production of efavirenz. As we all know, issuing a compulsory license is the initial element of a complex process that involves many actors.

262. The first step was to comprehensively analyse the invention as disclosed in the patent application, clarifying aspects of the phases of production. The disclosure of an invention as

mandated by Article 29 of the TRIPS Agreement is an important element of the patent system and could be explored in future discussions under this agenda item.

263. The second step for the public laboratories responsible for manufacturing the medicine was to take advantage of a limitation contained in Article 43, subsection II of the Brazilian Industrial Property Law. The Article states that patent rights do not extend to acts carried out by [unauthorized] third parties for experimental purposes, in connection with scientific or technological studies or researches. It aims at maintaining the incentives for research and studies by third parties, thus allowing the progress of science and technology. Further to those actions, the last step required to initiate the production of the medicine under the compulsory license was to obtain regulatory authorization from the Brazilian health authority, known as ANVISA. To fulfil this requirement, Brazil used another aspect of IP rights, this time related to clinical test data.

264. In spite of strictly following the requirements contained in the national and international legal framework, the Brazilian Government faced legal disputes in national courts, which were initiated by the owner of the patent. These disputes, however, were not successful.

265. As a result of such efforts by the Brazilian Government, and taking full advantage of legally permissible limitations and exceptions, it was possible to substantially reduce the price of efavirenz from US$ 1.59 to US$ 0.45 per tablet at nominal prices. This helped to ensure the adequate provision of medicine to HIV patients who needed to take it on a daily basis to keep the disease under control.

266. Thanks to successful public policies combined with the steady availability of innovative drugs, Brazil is able to provide treatment to the vast majority of patients diagnosed with HIV/AIDS. Nowadays, among those receiving treatment in Brazil, 90% of them have no detectable viral load, a sign of success of the treatment. This result is only possible with the active participation of Government, pharmaceutical companies and patients associations, in line with the higher level goals of the IP system.

267. The recent entry into force of the Protocol Amending the TRIPS Agreement demonstrates the need to have mechanisms that preserve at the same time the adequate remuneration of IP Rights and the rights of governments to adopt measures necessary to protect the public interest. Another recent development of interest is the publication of the United Nations Secretary-General's High Level Panel on Access to Medicines, which contains many recommendations regarding the interplay between intellectual property and access to medicines.

268. Brazil believes that respect for intellectual property and efforts to promote the public interest in sectors of vital importance to a country's socio-economic and technological development are not mutually exclusive. A balanced intellectual property system, with built-in flexibilities as well as complementary policies and incentives, is the best way to incentivize innovation in all fields of technology.

269. We would like to invite other Members to express their views and share their experiences regarding the topic, providing a rich discussion which would be beneficial to all countries and generate additional inputs to the TRIPS Council.

12.4 China

270. China would like to thank the other co-sponsors for including this important item on the agenda. China attaches great attention to TRIPS and public interest issues. China's Patent Law and implementing 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 the purpose of easy operation.

271. China believes the discussion on intellectual property and public interest should be open and inclusive. WTO Members could exchange views and experiences on how to take full advantages of TRIPS flexibilities, and effectively solve the public interest problem.

12.5 Fiji

272. Fiji would like to thank the delegations of China, India, South Africa and Brazil as co-sponsors of this agenda item and the submission of document IP/C/W/630. For a small economy, the issue of intellectual property and public interest is important and for Fiji, in particular, in relation to ensuring that there is access to medicines for our citizens. The constitution of Fiji takes reasonable measures within its available resources to achieve the progressive realisation of the right of every person to health, *inter alia*, to ensure that the person is not denied access to medical treatment.

273. Achieving an effective and efficient functioning health system is a priority for the Fijian Government and access to affordable medicines complements this priority. The Government of Fiji has put in place a free medical programme for all Fijians. Fiji attaches great importance to the TRIPS Agreement. On this note we also believe that striking the appropriate balance between the interest of right holders and users is essential. The more markets are available for an importing country such as Fiji to access quality and affordable medicines, the better it will be from a socio-economic perspective for its citizens.

274. As mentioned by other proponents, Fiji is also of the view that there is a need for discussion in the TRIPS Council on the relationship between IP and public interest. Fiji looks forward to learning from the experiences of the membership on the use of compulsory licences in accessing health and other technologies in this relation.

12.6 Ecuador

275. Ecuador thanks the delegations of Brazil, China, Fiji, India and South Africa for requesting inclusion of this item on the Council's agenda in order to address the critically important issue of intellectual property and the public interest and the implications of compulsory licensing.

276. Article 8 of the TRIPS Agreement mentioned in the proponents' communication refers to the fact that Members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

277. Taking this principle as a basis and using the flexibilities available under the TRIPS Agreement in its Article 31 to further public interest objectives, Ecuador has had to adopt and implement laws providing for compulsory licensing in order to meet legitimate public health needs of Ecuador. This prompts me to touch upon my country's experience in granting compulsory licences so as to give the population broader access to medicines.

278. One of the justifiable grounds for issuing this type of licence under Ecuadorian law was to regard compulsory licensing as a tool for the Government to break the monopoly on patented medicines and be able to import or manufacture equivalent, lower cost pharmaceuticals that have no brand name but are just as effective. This ensures that the entire population has access to the medicines and treatments they need, strengthens the public health system and enhances people's quality of life.

279. By means of Executive Decree No. 118, in 2009 the National Government declared access to medicines to be a matter of public interest, a decision that enabled Ecuadorian and foreign laboratories established in the country to apply for compulsory licensing of patented medicines in order to produce and market them domestically.

280. With a view to conducting scientific research and developing active ingredients for the production of cheaper, generic medicines, the State owned pharmaceutical company ENFARMA was created that same year and tasked with providing the comprehensive public health network with a timely and efficient supply of essential medicines, as well as contributing to raise the percentage of the population with access to medicines for the treatment and cure of diseases.

281. The Ecuadorian Intellectual Property Institute (IEPI) has approved nine applications to produce mass consumption medicines. The first three licences were issued for the antiretroviral

drugs ritonavir, lamivudine and abacavir, which the Ministry of Public Health supplies free of charge for the treatment of HIV/AIDS patients.

282. The reason for issuing these licences was that, according to IEPI data, Ecuador has around 37,000 HIV infected patients and some 700 deaths from the disease are reported each year. The data indicate that as a result of compulsory licensing the Ministry of Public Health has saved 30-70% on the cost of purchasing these medicines, which have to be supplied by the State.

283. In addition to the licences issued for antiretrovirals, licences were subsequently granted for etoricoxib (Arcoxia), a drug of proven efficacy in the treatment of acute pain diseases; mycophenolate sodium (MYFORTIC), used for kidney transplant recipients; sunitinib, an anticarcinogen for the treatment of renal cell carcinoma (RCC) and gastrointestinal stromal tumours (GIST); and certolizumab, used to relieve the symptoms of rheumatoid arthritis the first licence to be issued in the area of biotechnology.

284. With compulsory licensing the National Government aims not only to achieve a significant reduction in the prices of medicines but also to strengthen the country's pharmaceutical industry so that the largest possible number of imported drugs can be replaced by domestically produced medicines in the future.

12.7 Bolivia, Plurinational State of

285. Let me begin by congratulating the sponsors of this agenda item. The promotion of flexibilities under the TRIPS Agreement is something which has not been sufficiently encouraged in the developing world, and we would like to share some thoughts in this respect.

286. For different reasons, Bolivia has not had recourse to compulsory licensing. However, we are convinced that the use of this instrument deserves greater promotion, particularly, for instance, in the case of access to medicines.

287. We believe that WTO Members should make full use of the policy space available under the TRIPS Agreement to meet the needs of their countries and peoples, and this requires the support of the international organizations in the form of capacity building to enable them to use these instruments.

288. We also believe that governments should adopt and implement legislation to facilitate the granting of compulsory licences to meet legitimate developmental or public health needs.

289. We have witnessed on more than one occasion, in the Latin American region, the pressure that has been brought to bear on certain countries when they have wanted to use compulsory licensing. This reality did not escape the notice of the UN Secretary General's High Level Panel on Access to Medicines which, in a report published at the end of 2016, not only encouraged the use of compulsory licensing, but also called upon certain countries and the private sector to refrain from applying explicit or implicit pressure as well as tactics or strategies that undermine the right of WTO Members to use the flexibilities provided for under the TRIPS Agreement. According to the High Level Panel, cases of undue political and commercial pressure should be reported to the WTO and debated among Members in order to discourage such unwarranted practices.

12.8 United States

290. The United States welcomes the opportunity to offer a few initial observations on the general theme of IP and the Public Interest and the concept paper before us discussing the issue of compulsory licensing. The United States has long held that intellectual property rights protection is very much consistent with furthering the public interest and that international cooperation, to strengthen and provide confidence in domestic IP systems can help maximise these benefits. The co-sponsors' concept paper (IP/C/W/630) suggests that this agenda item will perhaps discuss public interest in a way that fails to fully account for the benefits of protecting IP. One potential negative effect for the co-sponsors' view of the public interest could be that it discourages Members from striving towards, and upholding robust domestic IP regimes, and therefore denies the public the benefits of critical future innovations and creative endeavours.

291. Before addressing the topic of compulsory licences, I would like to respond to one of the co-sponsors assertions that 'TRIPS +' provisions and free trade agreements can do a disservice to public interest. We would encourage them to consider some of the many benefits that have been ascribed to IP protection. For example, a 2016 study analysing the launch of 642 new drugs in 76 countries concluded that patent and price regulation regimes strongly effect how quickly new drugs become commercially available in different countries. Price regulation delays launch, while longer and more extensive patent rights accelerate it. Furthermore, US Intellectual Property and Innovation Policies have not only helped encourage investment in pharmaceutical innovation, but have also facilitated the approval and utilisation of generic drugs. According to recent data, generic medicines account for 89% of all prescriptions dispensed in the United States. I share this research to help provide the perspective that IP and patents should not be viewed as intrinsic barriers to access. To properly address barriers to access we must look at factors outside the IP system.

292. In fact, the most recent estimates are that approximately 85% of medicines under WHO model-list of essential medicines are off-patent. Factors that are relevant to the access question include pricing and procurement policies, taxes, mark-ups and tariffs and other national policies or lack thereof that have ultimately resolved in higher costs for consumers and for health systems. Unfortunately, the theme of today's agenda item does not explore these critical factors as it deals exclusively with the subset of medicines that is patent-protected in the territory.

293. Moving on to the issue of compulsory licensing, as affirmed in the Doha Declaration on TRIPS and Public Health, the United States respects its trading partners' right to protect public health and, in particular, to promote access to medicines for all and supports the vital role of the patent system in promoting the development and creation of new and innovative life-saving medicines. Consistent with these views, the United States respects its trading partners' rights to grant compulsory licences in a manner consistent with the provisions of the TRIPS Agreement and encourages its trading partners to consider ways to address their public health challenges while maintaining intellectual property systems that incentivise the investment and research necessary to develop innovative new medicines.

294. The United States continues to encourage all WTO Members to promote a stable and predictable patent system that can nurture innovation. WTO Members can and should ensure supportive environments for innovators to achieve success and make significant contributions to innovative growth in their country. Many pharmaceuticals, whether essential drugs or not, have their origins in countries with strong patent systems. Robust and predictable patent systems provide interested parties with incentives necessary to encourage them to invest many years in significant financial resources into worthy endeavours without a guarantee of success. Compulsory licensing diminishes the exclusivity of the patent grant and undermines the incentive for innovation and investment that is a critical component of technological progress.

295. A common view of innovative companies is that compulsory licences could prevent them from regrouping their investments in research and development. When these companies make investment decisions, they consider the ability to secure and maintain patent rights in a given market. The United States' system permits the use of a patent without the right-holders' authorisation only in very rare and narrow circumstances and the US Patent and Trademark Office has never issued a compulsory licence. In fact, it does not have the authority to do so. We urge other Members to exercise caution and careful deliberation on issues related to compulsory licensing as they have significant implications that could negatively affect investment in R&D for the treatments of tomorrow and restrict investment into new markets. The United States welcomes the opportunity to convey our views and we encourage the co-sponsors to seek topics that appeal to the diverse array of Member interests and that provide encouragement for upholding robust IP systems.

12.9 Indonesia

296. Indonesia supports the proposal made by the delegations of India, Brazil, China, Fiji and South Africa on Intellectual Property and the Public Interest. As highlighted by the delegation of South Africa, TRIPS sets minimum standards and allows Members to deliberate further under national IP systems by taking into consideration the balance between the interests of right-holders and the public. This is particularly vital with regard to public health interests. The tendency to introduce new obligations and extended protection through regional trade agreements containing

'TRIPS+' standards will affect Member's policy for making use of TRIPS flexibilities and disregards the objective that IP should contribute to the promotion of innovation and transfer of technology.

297. Some are of the view that innovation and technology begins with providing an increased protection for inventors. But for many developing countries, the capacity of inventors is limited by the inaccessibility to data, technology and information needed to further the research and development. Therefore, for developing countries it is about such access that results in improved capacity as well as affordable prices. The use of TRIPS flexibilities should not be hindered, based on the notion that it negates the rights of IP holders. Instead, it should be born in mind that every private right comes with the responsibility, particularly where the public is concerned. We should refrain from asserting pressure on any government wishing to apply TRIPS flexibilities and exceptions, and resist any attempt to derail from the objectives of the Doha Development Agenda.

298. Indonesia, as a country that has adopted a mechanism for implementing flexibilities i.e. compulsory licensing, in its national law, would support the initiative for discussions in this Council on the relationship between IP and the public interest. Indonesia would be open to share its views and experiences in implementing compulsory licences and discuss with Members how to address challenges and potential risks posed by 'TRIPS+' standards. Like many other countries, Indonesia is still facing difficulties in delivering adequate health services and medicines to all of our citizens. One of the reasons is due to insufficient raw materials and manufacturing capacity. But this should not be interpreted as an export potential to a relatively big market which almost always results in expensive prices. Instead, governments should be encouraged and permitted to implement policies to enable the development of their industries. In accordance with the Doha Declaration, we believe that every Member has the freedom to determine the grounds on which compulsory licences are granted and that it is not limited to emergency situations, as some would have liked to convince us. It is therefore important that governments are induced to take measures that help public policy objectives and that this Council contributes to discussions on this matter.

12.10 Colombia

299. In Colombia, compulsory licenses are recognized legal instruments in the framework of multilateral and bilateral trade agreements, as well as in Decision No. 486 of 2000 of the Andean Community. The grounds for granting compulsory licenses are: lack of exploitation; reasons of public interest, emergency or national security; abuse of dominant position; and patent dependency.

300. The procedure for the declaration of public interest is established in the Colombian legislation. This procedure begins when the Ministry in charge of formulating and adopting the policies of the pertinent sector considers that it is necessary to issue a declaration. The Ministry will then compose a Technical Committee of at least one delegate from the Ministry, one from the Ministry of Commerce, Industry and Tourism and one from the National Planning Department. This Committee has to examine and evaluate the documents submitted, request concepts or technical support from other entities, and make a recommendation to the Minister on the decision to declare the existence of reasons of public interest or not. The recommendation will be made available to all interested parties for at least 10 days in order to receive comments. Thereafter, it will be forwarded to the Minister along with all submitted comments.

301. The resolution issued by the corresponding Ministry or Administrative Department stating that there are reasons of public interest that merit the issuance of a compulsory license must identify the situation that affects the general interest, establish the circumstances that led to the declaration and the reasons why the licence is to be granted. The aspects related to the specific scope of the compulsory licence that will be granted will be determined by the Superintendence of Industry and Commerce. Two applications for declarations of public interest have been submitted in order for the State to grant a compulsory license for medicines.

302. The first case concerned Kaletra (HIV/AIDS), in 2008. Several NGOs filed applications for a compulsory license. The grounds for the request were: the increase in the number of people infected; that the consumption of the drug had doubled in the previous year; and that the patent of the drug had allowed maintaining higher prices than under competition. From the analysis carried out by the Ministry of Health, it was determined that there were no grounds for declaring

the existence of reasons of public interest in order to grant a compulsory license. However, the price control mechanism was utilized and a reference price for the drug was established.

303. Glivec (Imatinib) was the most recent experience. As provided by Resolution 2475 of 14 June 2016, the Minister of Health declared the existence of public interest regarding Imatinib, but not for granting a compulsory licence. The Ministry of Health requested the National Commission of Prices of Medicines and Medical Devices to consider applying the regime of direct price controls to Glivec, using a general methodology that simulates conditions of competition. Imatinib (active substance) is a very effective drug used to treat chronic myeloid leukaemia and other types of cancer.

12.11 Japan

304. This delegation believes that sharing experiences on this matter may be beneficial, as long as this is an ad hoc agenda item and an information-sharing session without connection to any future negotiation.

305. For the purpose of having meaningful discussions, we would like to make two comments. First, when discussing matters such as intellectual property and public interest, we should make a distinction between matters directly related to the Amendment of the TRIPS Agreement; and other matters that may need a clear explanation of why such other matters need to be discussed here.

306. Second, the Doha Declaration, its statements and the resulting amendment of the TRIPS Agreement all rest on an intricate balance. On the one hand there is the need to make sure that common drugs become common for everyone. On the other hand we have the need to protect intellectual property to encourage development of new and effective drugs so that our stock of common drugs will continuously be updated. This balance is necessary to meet our common objective, which is to protect public health, as described in Paragraph 3 of the Doha Declaration.

307. We would also like to recall the Chairman's Statement JOB (05)/319, which was read out prior to the adoption of the Amendment. I quote: "Members recognize that the system that will be established by the amendment should be used in good faith to protect public health and, without prejudice to paragraph 3 of the Article 31bis of the amendment, not be an instrument to pursue industrial or commercial policy objectives".

308. Thus, we should be cautious in determining the scope of discussions when we mention compulsory licenses, such as the statement that "they are thus not limited to emergencies or other urgent situations"in paragraph 12 of the document submitted by the co-sponsors (IP/C/W/630). This might disturb the balance and objective defined by the Doha Declaration and the related articles of the TRIPS Agreement. Such arguments would need to be justified based on evidence and facts, before we are able to have any meaningful discussions.

12.12 Switzerland

309. Due to the recent circulation of the submission, we will keep our intervention brief and may come back to this point at the next Council meeting.

310. Public interest is a very important topic. The current system of intellectual property protection fully integrates a balance between private and public interests. In their submission, the co-sponsors focused on access to medical products. Switzerland would like to highlight that access to medical products constitutes one of the main objectives of its health policy, notably with regard to its foreign relations.

311. We wish to recall that a patent only grants so-called 'negative rights', in other words the right to prevent others to use the patent owner's invention without authorization. A patent does not confer a discretionary power over pricing upon its owner. It is inherent to the system that investment in R&D and marketing of innovative medical products are financed via the patent system through exclusive rights' revenues, which in the short-to-medium term may be reflected in the prices of medical products. In the long term, however, the patent system constantly nurtures

a pipeline of new generic products. These usually become available after the patent protection period has expired and at a lower price.

312. As to IP provisions in free trade agreements: reliable and solid rules on intellectual property rights provide for the necessary legal certainty to encourage not only the investment in new and better drugs for unmet medical needs, but also to allow for the use of licencing (in and out) of technological innovation – of any products, including medical products. In the mid- to long term, the IP system plays an essential role with regard to availability and accessibility of medical products and is therefore affirmative of the right to health. The Swiss delegation is aware that a good intellectual property framework is not the only requisite for foreign direct investment, but one among many others.

313. We thank all co-sponsors for tabling this topic. Submission IP/C/W/630 makes reference to compulsory licensing. Whilst such licences may be a legitimate tool for very specific circumstances, Switzerland considers them as a tool of last resort. We are, however, aware that the intellectual property system is not a panacea for solving all aspects to address the challenge of better access to medical products. There may be policy and market failures that need to be addressed.

314. The Swiss Government provides, for example, technical and financial support to the WHO to set up a public observatory where research and development activities are monitored worldwide. Our Government further supports a committee for the prioritisation of research needs. Switzerland has also given technical and financial support for a voluntary fund to finance priority research and development initiatives.

315. Funding of the selected innovative demonstration projects remains insufficient. The Swiss matching fund provided to complement contributions from low- and middle-income countries has not been fully used by these countries. To date, we have only been able to disburse US$700'000 out of US$2 Mio. This is surprising.

316. We also invest in public-private partnerships for the research and development of medical products (so-called product development partnerships), especially in the area of poverty- and neglected tropical diseases, including Medicines for Malaria Venture (MMV), Drugs for Neglected Diseases Initiative (DNDi) and the Global Antibiotic Research and Development Partnership (GARDP).

317. Furthermore, this delegation would like to highlight that Switzerland is currently financing a feasibility study conducted by the Medicines Patent Pool which looks into the challenges and opportunities of potentially expanding MPP's business model.

318. In summary, instead of advocating the use of compulsory licences, this delegation strongly believes in the promotion of initiatives and approaches which incentivise research and development and, by the same token, improve access to medical products for people in low-and middle-income countries. And this is one important example of how the IP system serves the public interest. We believe that building on voluntary and inclusive efforts (such as the Medicines Patent Pool, the Global Fund's e-procurement platform or WIPO Re:SEARCH), rather than disincentivising research into the development of new and better medical products, is the way forward and corresponds to the collaborative spirit of the 2030 Agenda for Sustainable Development.

12.13 European Union

319. It is the formally established position of the European Union that a balanced system of intellectual property rights which takes into account legitimate interests of users and right-holders fully serves the public interest. It is for this reason that national and international systems of intellectual property rights have been created for well more than 100 years. In the European Union, according to Article 17 of the Charter of Fundamental Rights, intellectual property is a fundamental right of every European citizen. Additionally we believe that TRIPS provides a reasonable balance and its rules and flexibilities allow countries to have a pragmatic and flexible approach that can help them to maximize the potential of their own intellectual assets and further their integration into international trade while achieving broader societal welfare.

320. In that sense, today's debate seems to confirm our assumption. In previous interventions, we heard a number of stories of how the system has functioned and how it has been used by countries within the extent that is legally permitted to negotiate and to enhance access to medicines. This debate will actually confirm that the system is well-suited and it has reached a carefully crafted balance. We have also heard countries that even if they are asking for more flexibility they have decided themselves not to use them.

321. But let me recall some of the functions of IP. It is known that the primary function of an intellectual property right is to permit the right holder to exploit his idea or creation in commercial activities, thus contributing to innovation. Other less frequently mentioned benefits include, for example, providing guarantees regarding the quality and safety of products. Many counterfeit products place our children's and citizens' safety or health at risk; for instance where vehicles' spare parts or medicines are concerned. Enforcing intellectual property rights in respect of such products guarantees at least that the product's origin is known and that the products are genuine and safe; whereas counterfeit products often do not comply with the applicable safety standards. This is especially true for trademarks but often patent licensing contracts for instance also include quality insurance clauses. Would it be in the public interest to weaken such safety mechanisms?

322. Another benefit of IP is the dissemination of information on innovation. Even where a company or a university or an individual does not intend to protect its own invention, its staff and researchers can still make use, for instance, of patent information from others. The disclosure of the invention to the public is part of the contract to get time-limited protection. Patents are the most prolific and up-to-date source of technological information and contain detailed technical data which often cannot be found anywhere else. It is estimated that up to 80% of current technical knowledge can only be found in patent documents. Moreover, this information is rapidly available, as most patent applications are published 18 months after their first filing. Searches in patent literature can be conducted by anyone by using for instance the free-of-charge Espacenet patent database. It provides access to more than 90 million patent documents from all over the world, classified by technological areas on the basis of international patent classification. Would it be in the public interest to keep all of this information secret instead?

323. Additionally, IP rights often play an instrumental role for small and medium-sized companies including start-ups and spin-offs, in trying to convince third parties to provide financing to them, to attract investment, or to grant loans, etc. In the absence of tangible assets, their ideas, creativity and innovation are the only assets that these companies will have, depriving them of the possibility to exploit them. This would clearly not be in the public interest.

324. To conclude, let me turn briefly to the issue of access to medicines and the discussion on pharmaceutical patents that was mentioned in the last part of the communication. The current innovation model based on patents has delivered consistent progress in global public health, continuously leading to important new and improved treatments, as well as much extended life-expectancy, both in developed and developing countries. Medicines are not created by public authorities, but by pharmaceutical industries. As all industries, they need an adequate return on investment to finance innovation. The challenge obviously is how to use all levers available to public authorities to promote access to affordable medicines without negatively affecting the R&D by the pharmaceutical industries and therefore the availability of new and innovative medicines. Like others have mentioned before, let us also recall that evidence shows that, indeed, there are many different significant causes for lack of access to medicines which renders it simplistic and misleading to attribute this problem merely to or even principally to intellectual property-related aspects. In fact, intellectual property issues seem to play a minor role in the problem, but a disproportionately large role in the debate.

12.14 Korea, Republic of

325. I thank the proponents and other delegations for sharing their experiences which provide useful information for the implementation of compulsory licenses.

326. Korea is of the opinion that the current TRIPS Agreement with the amendment effective since January this year could address the concerns raised in the High Level Panel Report. Korea

believes that the issue of access to medicines needs a comprehensive approach, as various factors other than patents affect access.

12.15 Australia

327. Australia notes the communication from Brazil, China, Fiji, India and South Africa regarding Intellectual Property and the Public Interest: Compulsory Licensing. Australia notes existing TRIPS flexibilities and welcomes, in particular, the recent entry into force of the TRIPS Protocol. Australia supports full utilisation of TRIPS flexibilities. We are open to hearing the views of other Member States in this regard.

AGENDA ITEM 13: INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

13.1 WTO Secretariat

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

329. Since the last TRIPS Council Meeting in March, the Trade Policy Reviews of Japan, Mexico, Belize, Mozambique, Switzerland and Liechtenstein have taken place. I am pleased to report that Members continue to substantively contribute to the discussions on TRIPS-related issues during these reviews.

330. Members continued to engage in a constructive dialogue on a wide range of trade related IP issues, including: implementation of the TRIPS Agreement; exhaustion regimes; copyrights and related rights; copyright infringement exceptions; protection of software; protection of well-known and non-traditional trademarks; revocation procedures for trademarks; the protection of geographical indications; patent protection for agricultural chemical products; extension of patent protection periods; protection of undisclosed information and test data; compulsory licences; plant variety protection; enforcement of IP rights, online and at the border; functioning of the "piracy mailbox"; protection of trade secrets and their enforcement at the border; support for SMEs using the IP system; establishment of technology licence offices at universities; IP dispute resolution system; national IP strategies; IP chapters in regional trade agreements; and accession to the WIPO Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired or Otherwise Print Disabled.

331. The Secretariat continues to collaborate on IP-related issues for Trade Policy Reviews and the preparation of the DG's Monitoring Reports. As in the past, this update is intended just to give Members an overview of the issues that have come up in these reviews for their background information.

AGENDA ITEM 14: OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANISATIONS

14.1 India

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

333. 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 side events on the report of the HLP on Access to Medicines. South Centre already has observer status in WIPO, WHO, CBD and many other UN bodies.

334. The Convention on Biological Diversity (CBD) fulfils 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.

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

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

14.2 South Africa

337. As of the last TRIPS Council meeting, there remain 13 pending requests for observer status in the TRIPS Council. This delegation believes that pending requests should be assessed on their own merit, particularly in respect of the competence and interest that respective organizations have in the world of the TRIPS Council. South Africa supports, based on the aforementioned considerations, the granting of permanent observer status to the South Centre and the CBD Secretariat.

338. In respect of the African Regional Intellectual Property Organization, and the African Intellectual Property Organization, several Members have expressed support for these organizations to be granted permanent observer status beyond ad hoc status currently enjoyed on a meeting to meeting basis and we also support the granting of permanent observer status to these organizations.

14.3 United States

339. The United States' position remains the same and we continue to object to the CBD and other organizations that India proposed being included as observers to the TRIPS Council. However, we would be willing to continue our informal consultations with the Chair on this issue.

14.4 Ecuador

340. Ecuador maintains the position it expressed at previous meetings in order to support the participation of two organizations, the South Centre and the Secretariat of the Convention on Biological Diversity, as permanent observers to this Organization.

14.5 Indonesia

341. Indonesia would like to reiterate its position in supporting the approval of the request from the South Centre and the CBD Secretariat as permanent observers of the TRIPS Council.

342. As we all know, the South Centre is an intergovernmental organization that helps developing countries combine their efforts and experts to promote their common interest in the international agenda. It is an independent intergovernmental think tank created to analyse the specific problems of developing countries and encourage them to value and share their common experiences as well as provide intellectual and policy support for them to act collectively and individually including on IPR related matters.

343. The CBD, an internationally legally binding treaty with objective to encourage actions which will lead to a sustainable future, is often seen as the key international instrument for sustainable development. As one of the WTO objectives is to expand the production of entre-aide in goods and services we are allowing for the optimal use of the world's resources in accordance with

the objective of sustainable development. We think that the involvement of the CBD in the WTO especially in the TRIPS Council will actually benefit WTO to attain that objective.

344. To sum up granting the observer status to both organizations will benefit the progress for the discussions that have taken place in TRIPS Council. Its role would contribute to a more meaningful participation of developing countries in TRIPS Council discussions.

14.6 Brazil

345. Brazil supports the approval of the request from the South Centre and the CBD as a matter of priority. The South Centre is an organization that provides imports to the developing countries in the course of their activities in Geneva. They combine their efforts and expertise to promote common interest with the developing countries in the international arena. The South Centre encourages developing countries to value and to provide intellectual policy support for them to act collectively and individually, particularly in the international level. The organization has an observer status in several international organizations; in the WTO it is an observer to the Committee on Trade and Development. Its first request dates back to 1999. It would contribute to a more meaningful participation of the developing countries in TRIPS discussions without in any way harming the interest of other Members.

346. Regarding the CBD, it is an agreement ratified by as many as 196 parties that represents a dramatic step forward in the conservation of biological diversity. Like other permanent observers to the TRIPS Council the CBD is directly implicated in a number of items of the TRIPS Council's permanent agenda. A specific adding regarding relationship between the TRIPS Agreement and the CBD is part of the Agenda for every TRIPS Council meeting. Those questions could greatly benefit from the participation of the CBD Secretariat as an observer. To reiterate our view that decisions should be made as a matter of priority. We find a delegation currently opposing it to present reasoning behind its opposition what has not occurred so far.

14.7 Egypt

347. We would like to support the statement of India on the request to grant a permanent observer status to both CBD Secretariat and the South Centre.

14.8 Venezuela, Bolivarian Republic of

348. I support all the others that have provided their support to the CBD and to the South Centre for them to participate as observers in this Council. We are convinced that they will provide value added, we feel that this is a good opportunity and will be favourable for the outcome of our work.

14.9 China

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

AGENDA ITEM 15: OTHER BUSINESS

15.1 Singapore

350. As mentioned ASEAN organized a lunch panel as part of the UNCTAD E-commerce week on 27 April. The event was organized because we saw value in trying to find synergies between the discussions being held in UNCTAD and in the WTO on the development aspect of the E-commerce. The Panel on "Can E-Commerce Trade Rules Help MSMES In Developing Countries?" featured panelists from the WTO, Singapore, Cambodia, the Global Express Association, and the International Trade Center. The Thai Vice Minister for Commerce Winichai Chamchaeng provided opening remarks. The Panel had a broad discussion on the issue including on existing WTO rules that apply to E-commerce and the comment types of E-commerce rules found in FTAs. The Panel also shared how E-commerce has enabled MSMEs to better integrate into the global economy. The Panel also heard that interest in E-commerce cuts across the development levels in ASEAN having already committed to some E-commerce disciplines for example in the ASEAN Australia-New Zealand FTA. It was also shared that ASEAN Members

were looking to negotiate an ASEAN E commerce agreement. The documents that we have tabled summarize a reflection and key take-aways from the lunch panel. We look forward to engaging constructively with other interested Members on how to take the work on E-commerce forward.