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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 5-6 JUNE 2018

Chairperson: H.E. Ambassador Dr Walter Werner (Germany)

Addendum

The present document contains the statements made during the Council for TRIPS meeting held on 5-6 June 2018.

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

1 ELECTION OF THE CHAIR

1.1 WTO Secretariat

1. As you will recall, when the TRIPS Council last met on 27 February, the General Council was yet to agree on a slate of names of chairpersons for WTO bodies. At that time, the Council for TRIPS could not, therefore, elect its Chairperson for this year. For that reason, the TRIPS Council agreed to elect its new Chairperson at the beginning of the present meeting, with the understanding that, as soon as the General Council had agreed on the slate of names for Chairpersons, the TRIPS Council Chair-designate would take up his role and hold consultations in preparation of this meeting, pending her or his formal election.

2. At its meeting on 7-8 March 2018, the General Council noted the consensus on the slate of names for chairpersons for WTO bodies. On the basis of the understanding reached by the General Council, I propose that the TRIPS Council elect H.E. Ambassador Dr. Walter Werner from Germany as its Chairperson for the present year.

2 NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

2.1 WTO Secretariat

3. The Council has received the following notifications from Members since its meeting of 27 February 2018:

Under Article 63.2

4. Mexico has notified two Decrees, which amend and supplement various provisions of the Industrial Property Law concerning a specific regime for geographical indications, the period of protection of industrial drawings, designs or models, and the opposition periods for patent and trademark applications (IP/N/1/MEX/I/13 and IP/N/1/MEX/I/14 respectively).

5. Mexico has also notified its General Declaration on Protection of the Appellation of Origin "Yahualica", which protects the fresh and dried tree chili fruit belonging to species with specific taxonomic classifications (IP/N/1/MEX/G/7).

6. The United States has notified updated trade secrets laws for all its states as well as for the District of Columbia, Puerto Rico and the United States Virgin Islands. Since the circulation of the revised draft agenda, these notifications have been made available in documents IP/N/1/USA/U/4 to 56.

7. Canada has notified its revised Trademarks Act and Patent Act (to be circulated in documents IP/N/1/CAN/T/5 and IP/N/1/CAN/P/13). These Acts were amended by Bill C-30 to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its member States and to provide for certain other measures.

8. After circulation of the revised draft agenda, the Kyrgyz Republic has submitted 16 notifications, including the notifications of its main dedicated IP laws and regulations, other laws and regulations or their amendments (to be circulated in document series IP/N/1/KGZ/…).

Under Article 69

9. Ukraine has updated its contact points for the exchange of information and cooperation on trade in infringing goods. Cambodia has notified new information regarding its contact points. The Members' transparency toolkit page has been updated accordingly.

2.2 Canada

10. Canada is pleased to present notifications IP/N/1/CAN/18 and IP/N/1/CAN/19, which provide background on recent legislative changes to Canada's *Patent Act* and *Trade-marks Act*, respectively. We would like to thank the Secretariat for accommodating Canada's submission of

both notifications prior to this meeting, and note that both will be circulated in due course. In the meantime, Canada would like to take this opportunity to provide an overview of both notifications.

11. The first notification (IP/N/1/CAN/18) provides an overview of recent amendments to Canada's *Patent Act* under Bill C-30 (*An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures*), which entered into force on 21 September 2017. Bill C-30 amends the *Patent Act* under new sections 104 to 134, to make available a Certificate of Supplementary Protection (CSP) for eligible new medicinal ingredients or new combinations of medicinal ingredients that are contained in human and veterinary drugs, following expiry of an eligible patent. The rights of a CSP match those of the patent as they apply to a medicinal ingredient or combination in a drug, with a few exceptions.

12. Bill C-30 also amends section 55.2(4) of the *Patent Act* to allow the Governor in Council to make regulations that will ensure that disputes brought under Canada's *Patented Medicines (Notice of Compliance) Regulations*, which constitute Canada's pharmaceutical patent linkage regime, provides litigants with an equivalent and effective right of appeal.

13. Canada's second notification (IP/N/1/CAN/19) provides an overview of recent amendments to the *Trade-marks Act* under Bill C-30. Specifically, Bill C-30 amends the *Trade-marks Act* to protect agricultural products and food products as geographical indications, including associated rights, exceptions, product categories denoting the scope of rights, and other associated provisions.

2.3 United States of America

14. The United States welcomes the opportunity to notify US state-level trade secrets statutes, which do not represent changes in state law.

15. The United States previously notified the Defend Trade Secrets Act, which was enacted in law in May 2016. This Act has provided the United States with a federal civil cause of action to help defend against trade secrets misappropriation.

2.4 Mexico

16. Mexico wishes to inform the TRIPS Council that it has notified the WTO of two reforms to its Industrial Property Law and of the General Declaration on Protection of the Yahualica chili, which designates "Yahualica" as a new protected appellation of origin.

17. Firstly, concerning the reform of the Industrial Property Law with regard to patents, trademarks and geographical indications, which was published in the Official Journal on 13 March 2018 and notified in documents IP/N/1/MEX/16 and IP/N/1/MEX/I/13, my delegation wishes to briefly describe the changes introduced as follows:

18. The opposition period for patents has been reduced from six to two months.

19. The period of validity for industrial designs has been changed to a five-year term, renewable for successive five-year periods for a maximum of 25 years, and the expiry of such periods will be regulated in the event of non-renewal.

20. Patents, utility models and industrial designs will be published in the Industrial Property Gazette, upon approval of the formal examination. The same procedure will be followed for divisional applications.

21. The reform also includes changes to the regime for the protection of geographical indications and appellations of origin, which I will explain in further detail under agenda item 9 on the review of the application of the provisions on geographical indications under Article 24.2 of the TRIPS Agreement.

22. Secondly, with regard to the second reform concerning trademarks, which was published in the Official Journal on 18 May 2018 and notified in document IP/N/1/MEX/18 and IP/N/1/MEX/I/14, Mexico carried out the legislative procedure to incorporate certification marks

into the Mexican industrial property system and introduced regulations inherent to non-traditional marks, to which we will refer in the relevant session. The purpose of this reform is to ensure a balanced system that is in keeping with Mexico's geographical, historical and trade conditions.

23. Thirdly, Mexico notified the WTO of the General Declaration on Protection of the Appellation of Origin "Yahualica", which was published in the Official Journal on 16 March 2018 and by the WTO in document IP/N/1/MEX/17 and IP/N/1/MEX/G/7. The Yahualica chili is the 16th Mexican appellation of origin. It is produced in 11 municipalities in the states of Jalisco and Zacatecas, which have developed a cultivation method derived from an artisanal process to obtain the fruit, and which distinguishes it from other chilies produced in other regions. The Yahualica chili is the main ingredient in a number of Jaliscan dishes, and therefore has now become a symbol of identity for the population of the region.

2.5 Chile

24. Chile wishes to congratulate Mexico on the recent reform of its industrial property law, which – as was noted by the speaker who presented it – seeks to ensure that Mexico has a robust and user oriented system that is up to date and aligned with the international system.

25. We are confident that the reform was prepared fully in keeping with Mexico's international obligations, and we note that the new version of the law provides for separate registration for geographical indications, complementing the domestic system for appellations of origin. By using intellectual property tools to provide appropriate protection and recognition for the products in question and management models that allow for their proper positioning, local economies can be stimulated in a way that preserves the relationship between products and places and provides value to each participant in the value chain, from the producer to the end consumer.

26. The incorporation of geographical indications into the law means that many products today with specific characteristics that are fundamentally but not exclusively attributable to their geographical origin can benefit from protection and recognition, which differentiates them in the market and has a direct impact on local communities and economies.

27. This reform is fully in line with the laws of other countries in the region, which also promote the positioning of their local products. This is the case of Chile. For almost 13 years, we have had in place a register of geographical indications and appellations of origin that is open to all types of products, whether domestic or foreign, and a Seal of Origin programme that promotes the use of those rights as an effective means of protecting, preserving and showcasing the unique, traditional products of our country for the benefit of the communities where those products are made.

28. We appreciate and welcome Mexico's legal reform in the area of geographical indications, as we see that it complements and completes the system for appellations of origin. It is an example and an inspiration to those who wish to promote the use of these essentially collective rights for the benefit of the local communities that keep the traditions of our countries alive and maintain their cultural richness.

2.6 WTO Secretariat

29. At past successive Council meetings, we have reported on the development and implementation of the e-TRIPS project, which includes a Notification Submission System (NSS) and an Information Gateway.

30. We have reported to the Council over many recent meetings on the development and implementation of the e-TRIPS project. The WTO is custodian of a vast amount of notification and review material concerning TRIPS, and much related documentation. The central purpose of the e-TRIPS project is to make it easier for you, as delegates, to check and to update your notifications, and to make it easier to access and make use of this material. It fits entirely within the framework for notification and documentation procedures already laid out in the TRIPS Agreement itself and in the past decisions of this Council, and thus respects fully the guidelines set for us as the Secretariat. It is simply meant to offer a more user-friendly and efficient way of handling just the same material.

31. The e-TRIPS comprises (i) a way in for new information – the Notification Submission System (NSS), (ii) a way out for the information, once processed – the TRIPS Information Gateway, and (iii) an information management system (IMS) that enables the Secretariat to work more efficiently with TRIPS information, to ensure it flows more efficiently, to ensure the accuracy and consistency of documentation, and to support Members in making effective use of the information.

32. As Members, your encounter with the system naturally arises when providing updated notifications, and when you seek to consult information on the record. The NSS will be our recommended tool for the first function, and the TRIPS Information Gateway for the second.

33. We are happy to announce that the first of these, the e-TRIPS NSS, is very close to completion. We aim to launch it for your optional use this summer, in advance of the busiest period for submission of new material, in the lead-up to the final Council meeting of the year. We will be reaching out to delegations at that time through a workshop and demonstration, and we will remain on hand to respond to requests for briefings and demonstrations more informally for individual delegations. At the same time, we will be turning to refining and developing the TRIPS Information Gateway – the improved means of gaining access to and using this information – although this will take some more time, as we are anxious to ensure that it is designed and implemented in a way that meets your diverse practical needs.

34. What will the launch of the e-TRIP NSS mean for you? The e-TRIPS NSS is an entirely optional online tool for submitting TRIPS notifications, reviews and reports. The existing pathways for submitting notifications in other ways remain entirely open, but the intention is to provide a user-friendly tool for Members to be able more easily to identify the gaps in their current notifications. We hope that it will be a practical, user-friendly and efficient way to submit your information to the WTO Secretariat and to generally stay current with your TRIPS notification obligations.

35. We have endeavoured to build the principles of transparency into the system. As examples, you will be able to see how many notifications you have submitted, how many are being processed by the WTO Secretariat, and how many have been issued. To allow you to streamline as much as possible, a feature to create templates is also in place.

36. We appreciate that learning how to operate any new database system requires training. In that regard, we will make training sessions and materials on the use of the new system available, and this will form a regular part of our technical assistance activities. Further, we will reach out to you within the coming few months regarding an informal training session, to be held at the WTO, on how to use the e-TRIPS NSS.

37. The e-TRIPS Gateway will give access to a database of WTO information related to the TRIPS Agreement – including your notified IP laws, your interventions at the TRIPS Council, your submissions to the TRIPS Council, among other types of TRIPS notifications, review materials and reports. Due in no small part to your interest and feedback, we have made a considerable amount of progress in developing the search and reporting features.

38. We would like to brief you on just a sample of the types of features you can expect to see on the e-TRIPS Gateway.

39. For example, you will be able to see, in just a couple of clicks, all TRIPS-related materials submitted by a Member, within a given time-frame.

40. The e-TRIPS Gateway will also enable you to search the text of notified laws.

41. The last feature we would like to highlight this morning is one which will allow you to produce a custom report of selected interventions in the TRIPS Council. What will this look like?

42. After specifying your search criteria, you can select interventions you would like to view and then produce a simple Word document that contains those interventions you selected, along with some key information such as the dates of the meeting and the name of the agenda item.

43. Similar to last summer, for those who may recall, we will be in touch regarding a very informal demonstration session to be scheduled this summer for interested delegations where the features will be explained in more detail, and we would invite your feedback and comments.

44. In addition to this, we will soon have a -test site- of the e-TRIPS Gateway available for you to test and offer your suggestions and feedback. As we are still working on uploading all of the past TRIPS data, we will not be able to roll out the complete test site to you. However, as the TRIPS data is uploaded onto the gateway, more search forms and features will become available for you to test.

45. In that light, we will send an email to our TRIPS delegate mailing list, letting you know when the test site is available. Also, you are welcome to register your interest in receiving a version of the "test site" of the e-TRIPS Gateway. Please send an email to IPD@wto.org.

46. To close, we thank you for your interest and engagement in this project – especially all of the heightened interest over the past year. We appreciate very much that many of you have taken the time to strenuously test the system and provide feedback on your experience. This feedback loop has permitted us to create something we truly believe will facilitate easier and more practical access to TRIPS documentation and information, and to optimize our own internal procedures.

47. I emphasize that the e-TRIPS systems are entirely within the requirements of the Agreement itself and the existing decisions of this Council concerning notification requirements.

48. We are sincerely grateful for both your bearing with us during these past few years of its development, and for those delegates who took the time to test the NSS earlier this year. Your invaluable comments have helped us improve and fine-tune this system.

3 REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

49. No statements were made under this agenda item.

4 REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

5 RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY

6 PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

6.1 India

50. India is an ancient civilization with a rich body of 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. India is also one of the seventeen identified mega bio-diverse countries of the world, home to a vast and a rich diversity of biological resources.

51. TRIPS CBD linkage is important for India and other developing countries because it seeks to address bio-piracy. It has been a long-standing demand that patents should not be granted for existing traditional knowledge and associated genetic resources. This is all the more important for India, which has been a major victim of bio-piracy.

52. Pursuant to the Convention on Biological Diversity (CBD), India has been active, in taking steps to implement its provisions leading to conservation of biodiversity, its sustainable use and equitable sharing of benefits. We enacted the Biological Diversity Act in 2002, notified the Biological Diversity Rules in 2004 and also established a three-tier institutional structure.

53. India also developed a Traditional Knowledge Digital Library (TKDL) database to prevent misappropriation of traditional knowledge at international patent offices to tackle bio-piracy. India has signed TKDL Access Agreement with ten International Patent Offices.

54. TKDL attempts to overcome language and format barriers by scientifically converting and structuring the available contents (Around 0.3 million medicinal formulations) of the ancient texts on Indian Systems of Medicines into five international languages, namely, English, Japanese, French, German and Spanish. The results obtained by India's Traditional Knowledge Digital Library (TKDL) in 206 cases where the patent applications were either withdrawn/cancelled/declared dead/terminated, or where the applicant had to amend the claims or when the examiners rejected the application on the basis of TKDL submissions brings out the interaction that traditional knowledge can have with the patent system.

55. But, improving prior art searches through the TKDL was only one part of the solution. Further, TKDL represented only a subset of the universe of available traditional knowledge and the realm of traditional knowledge in areas other than herbal cures and genetic resources was not covered by it.

56. 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 this requires an international solution, to be effective.

57. Article 16.5 of the Convention on Biological Diversity clearly recognizes "that patents and other intellectual property rights may have an influence on the implementation of this Convention". It mandates that the Parties "shall cooperate in this regard, subject to national legislation and international law, in order to ensure that such rights are supportive of and do not run counter to its objectives."

58. The Nagoya Protocol of the Convention on Biodiversity (CBD) entered into force on 12 October 2014 and 105 Countries, including India have ratified the Protocol, till now. The Doha Ministerial Declaration in paragraph 19 mandated that the TRIPS Council examine the relationship between TRIPS and CBD, and the protection of traditional knowledge and folklore.

59. However, TRIPS Agreement continues to ignore numerous IPR-related obligations in the CBD which are of interest to the developing countries. The disclosure proposal (IP/C/W/474) which was submitted in 2006 was followed up by the submission TN/C/W/52 in June 2008 with the support of 109 Members. The latest submission on this issue TN/C/W/59 in April 2011, which is a draft decision to enhance mutual supportiveness between TRIPS Agreement and CBD" has been proposed by a vast majority of WTO Membership, including India. This proposal seeks amendment of TRIPS Agreement by inclusion of a new Article 29 bis for disclosure of origin of genetic resources and/or associated traditional knowledge.

60. We also need to take note of the recent developments of the 2030 Agenda for Sustainable Development to which we are all committed, specifically calls for promoting access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, as internationally agreed, in targets 2.5 and 15.6;

61. Given the mandate given by our Ministers in Doha and the mandate under the Sustainable Development Goals 2.5 & 15.6, to avert misappropriation of existing knowledge, promote conservation of the genetic resource with the view to maintain diversity and protect livelihoods of those who are directly dependent on them, it is imperative we expedite our work towards a positive outcome.

62. In light of these and to look at possible ways to energize negotiations on the subject in the WTO, I am happy to inform that Centre of WTO Studies, Indian Institute for Foreign Trade, New Delhi and South Centre, Geneva are organizing an International Conference on the TRIPS-CBD Linkage: Issues and Way Forward on 07-08 June at Room no. IX of the UN Palais. The event is co-sponsored by the Permanent Missions of Brazil, India, Indonesia and South Africa to the WTO. We invite you all for the two-day deliberations.

63. It would be quite useful to the delegates of the TRIPS Council, if the CBD Secretariat is requested to brief the TRIPS Council on the latest developments in the implementation of the Nagoya Protocol. The briefing by the CBD Secretariat would be very important to understand the implications of the entry into force of the Nagoya Protocol, which has been acceded by 105 Members, on the TRIPS Agreement. We reiterate our demand for a formal briefing by the CBD

Secretariat in the interest of the large majority of Members. We also support Ecuador's proposal for updating the three factual briefs by the Secretariat.

64. I conclude by stating that the TRIPS-CBD issue is one of the outstanding implementation issues and positive outcomes on this is an important deliverable of the Doha Round for the developing countries.

6.2 Ecuador

65. Ecuador's position on these three agenda items is well-known. For five years now, I have been bringing our views, which remain substantially unchanged, to the attention of other Members. This is the last time I will address you, so, while I run the risk of boring you, I will reiterate once again that, in our view, we must encourage discussion on revising Article 27.3(b) of the TRIPS Agreement so as to enable the Council to reflect and adopt new rules on the patentability of all life forms or parts thereof. We take the view that we cannot possibly endanger or adversely affect life forms of peoples and cultures. This type of patent should therefore be prohibited, since life or parts thereof should not be considered a tradeable good subject to inventions and, therefore, patents.

66. On numerous occasions we have expressed our firm belief in the relationship between the Agreement on TRIPS and the Convention on Biological Diversity (CBD), and we therefore reiterate the need for multilateral legal instruments that can improve the use of genetic resources, traditional knowledge and traditional cultural expressions, and give them effective and adequate protection. We congratulate the institutions that have organized the International Conference on TRIPS-CBD Linkage at the UN Palais des Nations on 7 and 8 June 2018, an event that will encourage discussion on the important relationship between the two instruments.

67. Lastly, I would like to take a few minutes to talk about the updating of the factual notes on the three aforementioned issues, which has become a taboo subject for one delegation that we feel has not understood Ecuador's objective. We recognize the progress made on this matter, in that it has practically been agreed that this update should take place; all that remains is for the United States to join the agreement that has slowly been forming.

68. Some progress has even been made by sitting down with that delegation and explaining what Ecuador was seeking to achieve by putting forward this possibility, and we must thank the previous Chair for her good offices in this respect. My delegation remains open to continuing consultations with the delegation of the United States in order to achieve consensus. We thank the US delegation for its openness and willingness to engage in these consultations.

69. My delegation has done its utmost to reach an agreement and ensure some follow-up on the request made in November 2012 for the Secretariat to update the factual notes on the relationship between the TRIPS Agreement and the Convention on Biological Diversity (IP/C/W/368/Rev.1), the review of the provisions of Article 27.3(b) (IP/C/W/369/Rev.1), and the protection of traditional knowledge and folklore (IP/C/W/370/Rev.1). The last compilation of ideas was produced in 2006, which is why we need updated documents that will enrich the debate and help us move forward in the discussions. The sole objective of the idea proposed is for Members to have 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, moreover, more of the information conveyed during our discussions would be available to us, compiled in the Secretariat's updated versions.

6.3 South Africa

70. We recall Paragraph 19 of the Doha Ministerial Declaration pursuing a work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of the declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore.

71. A large group of developing country Members proposed an amendment of 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 TN/C/W/59 which requires access and benefit sharing, prior informed consent and disclosure of the source of material when a patent is applied for. South Africa is a Contracting Party to the Convention on Biological Diversity and ratified the Nagoya Protocol on Access to Generic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in 2013 which came into force October 2014.

72. Despite 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 resource and traditional knowledge. While related negotiations, such as the WIPO IGC process, can complement the negotiation 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 negotiations will be successful in the other fora.

73. In respect of procedural issues, this delegation once again calls on the Secretariat to update the three factual notes contained in documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1. We believe that an update of these documents will stimulate a debate that is characterize by persistent restatement of long held positions. We further support a briefing by the CBD Secretariat on the Nagoya Protocol and subsequent developments.

6.4 Brazil

74. Brazil has a well-known position on the importance of promoting the neutral support between the TRIPS Agreement and the Convention on Biological Diversity (CBD), which is contained in document TN/C/W/59.

75. As mentioned by our colleague from India, national initiatives to regulate the relationship between IP and biodiversity are important, but they show their limit when other countries can use genetic resources without respecting the principles enshrined in the CBD. This is why we support an amendment to the TRIPS Agreement to introduce a mandatory requirement of disclosure of the origin of genetic resources in patent applications. Misappropriation of genetic resources and associated traditional knowledge could only be properly addressed with the full disclosure requirement in patent applications. This would allow monitoring and tracing the use of genetic resources, bringing strength and transparency to the international patent system. It is important to emphasize that, in the proposed mechanism to preclude misappropriation of genetic resources and associated traditional knowledge, patent offices would be nothing more than a checkpoint to collect and to disseminate information. It would not in any way represent an unnecessary burden to the national systems of IP or to applicants.

76. As you mentioned, there were great, recent developments at the CBD level, with the entering into force of the Nagoya Protocol. I would also that the UN convention on the law of the sea is discussing a treaty on the on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. More recently, the UN sustainable development goals have given us a clear mandate to safeguard biodiversity and to promote compliance with Nagoya.

77. Therefore, Members would greatly benefit from an update of the factual notes, as proposed by Ecuador and South Africa. This update does not prejudge positions of delegations, as those documents are restricted to facts, and would be the very least to address Member States' concern with the protection of their genetic resources, in which regard intellectual property has a concrete effect. The relationship between the TRIPS Agreement and the CBD is also one of the outstanding implementation issues of the WTO. We urge delegations to show a constructive spirit in order to have a sustainable discussion on a topic that is ever more important. Lastly, we also join our voices to invite you all to the International Conference on TRIPS and CBD, which will be held this week at the Palais des Nations.

6.5 Benin, on behalf of the LDC Group

78. At this stage of our work, the LDC Group would like to comment not only on agenda item 4, "Review of the Provisions of Article 27.3(b)", but also, in light of the mandate set forth in paragraph 19 of the Doha Declaration, on items 5, 6 and 8.

79. The LDC Group would like to reaffirm its Members' keen interest in examining, within the context of the work of the TRIPS Council and in accordance with Article 27.3(b) of the TRIPS Agreement, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore.

80. The use of LDC genetic resources, whether illegal or legal, is not covered by any multilateral regulatory framework. The disclosure of the origin of these resources remains crucial not only for their protection, but also for the sharing of the benefits arising from their use.

81. The review of the implementation of the TRIPS Agreement under Article 71.1 also remains a priority for LDCs. Paragraph 19 of the Doha Declaration in fact provides an additional mandate from our Ministers, establishing a work programme on this subject. There is no deadline for concluding this work programme.

82. LDCs are keen to protect traditional knowledge and traditional cultural expressions against misappropriation, misuse and unlawful exploitation, all of which is important in the context of the WTO mandate.

83. The LDC Group will examine this issue in terms of the real needs and constraints faced by its Members, with a view to submitting its contributions to the TRIPS Council very shortly.

6.6 United States of America

84. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues.

85. The 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.

86. We take note that the WIPO General Assembly has agreed upon the renewal of the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) for the 2018-2019 biennium, as well as the work plan for the IGC for the biennium, and will be meeting soon to discuss these issues.

87. The United States will continue to engage in technical discussions at WIPO's IGC and looks forward to hearing more from the demandeurs regarding data supporting their position on this issue.

88. 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 TRIPS Council meetings.

6.7 Bangladesh

89. On the agenda items 4,5 and 6, we align ourselves with the statement delivered by Benin on behalf the LDC group. Our firm position is already known to all. Although there is no change, I would like to reiterate our position for the sake of record.

90. On agenda item No. 4, that is the Review of the Provisions of Article 27.3 (B), we do not support the patenting of life forms comprising plants and animals. We call for the review of this Article in order to protect developing countries and LDCs from the negative effects of this provision on the key sectors that affect their livelihood such as agriculture, health, food and climate change. This would help ensure *inter alia*: food security and preserve the integrity of rural and local communities. Patenting of life forms at a multilateral level should be prohibited.

91. On the relationship between the TRIPS Agreement and the CBD, we hold that states have the right and duty to protect their traditional knowledge and genetic resources. There is therefore a need to amend the TRIPS Agreement with the view to require patent applicants relating to biological materials to provide information on the source and country of origin of biological resources and traditional knowledge used in the invention.

92. In addition, the applicants must show evidence of prior informed consent from, and benefit sharing arrangements with, the authorities and or persons under the relevant national regime. This disclosure requirement, which is consistent with the transparency principle established in the multilateral trading system, will help to reduce the number of erroneous patents and biopiracy. We believe that whilst the Traditional Knowledge should receive legal recognition, it's protection could as well contribute significantly to the achievement of development goals.

6.8 Japan

93. Regarding this agenda, we have already discussed for a long time at a series of meetings of the TRIPS Council. The delegation of Japan, therefore, believes that our position is well-known among Members, so this time we would like to focus on some major points in our intervention.

94. This delegation would like to reiterate our position that the convention on biological diversity is by nature not relevant with the intellectual property system and 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.

95. This delegation is firmly convinced that the disclosure requirement would discourage industries from conducting research and development activities on biological materials outside their own countries. 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 appropriate means for dealing with such misappropriation, so therefore, we have to make sure not to include it in the intellectual property system.

96. In addition, this delegation believes the WIPO IGC is the most appropriate forum for holding technical discussions on Genetic Resources, Traditional Knowledge and Folklore from IP aspects. Based on the mandate which is renewed in the last WIPO General Assembly, the 36th Session of IGC will be held this month and deal with the issues regarding to genetic resources, using evidence-based approach.

6.9 Switzerland

97. Switzerland would like to thank the delegation of India for its update and information on the conference on the TRIPS CBD linkage.

98. We will participate in the conference with a speaker. In his presentation, the representative of the IP office will also explain how Switzerland implemented in its law a requirement for disclosing the source of genetic resources and traditional knowledge in patent applications.

99. The topic of the conference this week focuses on one of the three elements of the W/52 proposal. Besides the TRIPS-CBD linkage, the proposal further covers the aspect of a better protection for geographical indications, i.e. the GI-register and the GI-extension.

100. All three requests are important topics treated in both the WIPO and here in the WTO. They have been on the agenda for a long time and we call upon the WTO to continue working towards a solution.

101. We believe that an update of the Secretariat's factual notes should contribute to the Council's work, should allow it to take stock of the state of play, and help us identify the way forward.

6.10 Australia

102. Australia considers the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore is best placed, with appropriate technical expertise, to consider the complex issues relating to intellectual property and genetic resources and associated traditional knowledge and cultural expressions. The WIPO IGC is currently undertaking text-based negotiations with the objective of reaching agreement on an international legal instrument, or instruments, relating to intellectual property, which will ensure the balanced and effective protection of genetic resources, traditional knowledge and traditional cultural expressions.

103. We look forward to the WIPO ICG meeting in late June and the opportunity to make progress on genetic resources negotiations for the benefit of all Members and Indigenous Peoples.

104. In relation to TRIPS and the Convention on Biological Diversity, Australia considers the TRIPS Agreement and the CBD are consistent.

105. Australia fully implements our obligations under both agreements, which we view as mutually supportive.

106. In relation to the procedural matters, Australia is open to a briefing by the CBD Secretariat on the Nagoya Protocol, and can be flexible in relation to the Secretariat updating the three factual notes.

6.11 Korea, Republic of

107. Our delegation's view on this issue remains unchanged. Korea still believes that the relationship between the TRIPS and the CBD are complementary, thus there is no need to revise the TRIPS Agreement in this regard.

108. In addition, as many other Members, we also think that the WIPO IGC is the best forum to discuss this issue further. However, we are open to the proposal to have the WTO Secretariat update the background paper on this issue and to invite the CBD Secretariat to brief the Council on the issues related to the CBD, including the Nagoya protocol.

6.12 Canada

109. 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.

110. Canada welcomes the ongoing work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Canada continues to believe that the IGC is the best and most appropriate forum for discussion on these complex issues, providing an important venue to bring together expert views, to discuss their IP-related dimensions in order to identify evidence-based, balanced, appropriate and mutually-beneficial approaches. Canada has been, and continued to be, an active and committed participant to this important work, and welcomes the concrete discussions and exchanges of national experiences at the IGC, which are so important to accurately pinpointing the issues at hand. In this regard, Canada looks forward to the two upcoming sessions of the IGC this summer, to be held June 24-29 and August 27-31, respectively.

111. Similar to our positions at the IGC, Canada also continues to welcome 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 notes the valuable and factual exchanges that have taken place on other issues at recent meetings of the TRIPS Council, such as on “IP and Innovation” and “IP and the Public Interest”, and would welcome presentations on national regimes regarding genetic resources and traditional knowledge at future meetings of the Council, with a view to informing the TRIPS Council Membership in this regard. This suggestion remains without prejudice to our position that the IGC remains the most appropriate forum for negotiations in this area.

112. With respect to procedural matters at TRIPS Council, as Canada has previously noted, and without prejudice to our 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 the matter. Canada could also support the compilation of the update to the three factual notes on the TRIPS Agreement and the CBD (documents IP/C/W/368, IP/C/W/369, and IP/C/W/370) by the WTO Secretariat. Canada remains of the understanding that this would remain a purely factual collating exercise, and in both cases, this is without prejudice to national positions on these issues.

6.13 China

113. The relationship between TRIPS Agreement and CBD is an important issue in this Council. Over years, Members have conducted a lot of useful discussions on this issue. China attaches great importance to TRIPS and CBD and hopes that Members could constructively involve in this discussion presently.

114. Regarding the substantial issues, China notes that the majority of Members support to amend the TRIPS Agreement so as to ensure the mutually support of TRIPS Agreement, the CBD and its Nagoya Protocol. China believes that the introduction of a mandatory disclosure requirement, prior informed consent and the benefit sharing, could prevent the misappropriation and erroneous patents.

115. As to the issue of 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.

116. China also believes the prior informed consent and benefit sharing could make better protection for the genetic resources. While the benefits arrangement on contractual basis and the database solution could not serve the purpose of sufficient protection for genetic resources.

117. As regard to procedure, China supports to invite the CBD Secretariat to brief on the Nagoya Protocol and hopes that the Secretariat could renew the three factual notes（IP/C/W/368/Rev.1, IP/C/W/369/Rev.1、IP/C/W/370/Rev.1）. China believes that the discussion and negotiation in WIPO's IGC could not hinder the Members to find a solution in WTO as Ministers have given the Council the mandate to examine the relationship between TRIPS and CBD.

6.14 Indonesia

118. As Members are well aware, we have extensively discussed these issues for many years. The relationship between TRIPS Agreement and CBD as well as the protection of traditional knowledge and folklore under the agenda items is utmost our priority to us. Our delegation believes that the TRIPS Agreement should be in line with the purpose and objective of the CBD and the Nagoya Protocol. In particular, the provision of prior informed consent and access and benefit sharing. In accordance with this issue, Indonesia is of the view that Article 27.3(b) needs to be provided with legal obligation to take all necessary measures for fair and equitable sharing benefits as required by the CBD and the Nagoya Protocol. The lack of such legal norm in TRIPS will defeat the purpose and objectives of the CBD and the Nagoya Protocol.

119. Finally, would like to take this opportunity to express our support to the International Conference on the TRIPS-CBD linkages as put forward in the initiative by India on 7 to 8 June 2018. We have been undertaking measures at national level in order to prevent misappropriation of genetic resources in our associated traditional knowledge. In order to make the measures to be effective there is a legal obligation to establish a mandatory disclosure requirement in patent applications.

7 NON-VIOLATION AND SITUATION COMPLAINTS

7.1 South Africa

120. During the Uruguay Round, when WTO Members agreed to incorporate the GATT 1947 into the WTO Agreement, they made non-violation and situation complaints, as contained in GATT Article XXIII:1(b) and (c), available with respect to the agreements covered by the DSU. The only current exception is the TRIPS Agreement. In Article 64.2 of the TRIPS Agreement, Members agreed that the DSU would not apply to the TRIPS Agreement for a period of five years after the entry into force of the DSU. In Article 64.3 of the TRIPS Agreement, Members further agreed that during this period the TRIPS Council would examine the scope and modalities for these complaints. This moratorium has been extended eight times, most recently in a Ministerial Decision at the 11th Ministerial Conference in Buenos Aires, Argentina in 2017. In this Decision, Members agreed to maintain the moratorium and directed the TRIPS Council to continue its examination of the complaints. The TRIPS Council was also directed to make recommendations to the next Ministerial Conference, which will be held in December 2019.

121. The non-violation remedy is an "exceptional" remedy (Panel Report, Japan – Film, para. 10.37). Non-violation complaints have been extremely rare under both the GATT and the WTO. Under the GATT 1947, working parties and panels considered only eight cases involving non-violation complaints. Since the establishment of the WTO, only three panels, and the Appellate Body in one dispute, have examined non-violation complaints in any detail (Panel Reports, Japan – Film; Korea –Procurement; EC –Asbestos; Appellate Body Report, EC –Asbestos). These figures are even more remarkable when placed in a historical context: out of 132 adopted and unadopted GATT Panel and Working Party reports, only eight involved non-violation complaints, while out of more than 200 adopted WTO panel reports, just three made findings on non-violation complaints. It is also noteworthy that not all of these non-violation complaints were successful. This experience with non-violation complaints in GATT/WTO jurisprudence suggests that the evolution of the multilateral trading system, and the expansion in the provisions of WTO Agreements regulating non-tariff measures, may have had the effect of making non-violation complaints largely redundant as a remedy.

122. This delegation does not suggest that there is no further scope for discussion of this issue. The proponents of the application of non-violation complaints under the TRIPS Agreement have not provided concrete examples of the kind of scenarios under which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations set out in the Agreement. Thus, it may be useful to clarify what situations proponent Members wish to avoid by having a non-violation remedy available under the TRIPS Agreement and, on the other hand, to ensure that a non-violation remedy in the TRIPS context would not be so broad as to have the effect of expanding the existing TRIPS obligations.

123. Perhaps there is already broad agreement amongst Members that non-violation complaints are of an exceptional nature to which a cautious approach should be taken. This could already constitute a modality that all Members seem to agree on. There seems further scope to address Article 26 of the DSU that sets out special procedures that apply in the case of successful non-violation complaints. In WTO disputes, the usual remedy, under Article 19.1 of the DSU, is the withdrawal of the WTO-inconsistent measure. As non-violation complaints relate to measures that are otherwise legal, Article 26.1(b) of the DSU states clearly that there is no obligation on the respondent to withdraw the measure. Rather, the respondent is required to address the nullification and impairment caused by its measure by, for instance, offering compensation. Members may agree that compensation would be explicitly excluded as an option should non-violation claims apply to the TRIPS Agreement.

124. This delegation stands ready to discuss this issue further with any Member that may have an interest to do so.

7.2 India

125. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged. Serious concerns remain on the debilitating impact, non-violation complaints in TRIPS can have on the regulatory policy space of Members, on TRIPS flexibilities as well as increasing the

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

126. The absence of non-violation complaints in the TRIPS context does not in any manner threaten or dilute the enforceability of TRIPS-related rights and obligations. On the contrary, the application of non-violation complaints in the TRIPS context could potentially present issues relating to rights of IP 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.

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

7.3 Benin, on behalf of LDC Group

128. The LDC Group would like to reaffirm its belief that Members should work towards a fair and balanced permanent solution to the issue of non-violation complaints and agree on appropriate modalities, in accordance with the provisions of Article 64.2 and 64.3 of the TRIPS Agreement.

129. The Group firmly believes that new approaches could help to achieve this result and move Members beyond the stage where they are merely reaffirming established positions. It encourages the Members therefore, to work towards seeking relevant recommendations to make to Ministers or the next Ministerial Conference.

7.4 United States of America

130. The United States' position on this issue remains unchanged and while we recognize that the decision by Ministers in December places a moratorium on Members bringing non-violation nullification and impairment (NVNI) complaints under TRIPS for a period of two years, we reiterate our support for allowing the current moratorium to expire so that Members may bring NVNI complaints in the future, as appropriate.

131. The language of Articles 64.1 and 64.2 explicitly states that, after five years, complaints under Article XXIII: 1(b) and (c) of GATT would be available under the Agreement. Therefore, the United States is of the view that these drafters intended for non-violation complaints to constitute an additional obligation to Members that is not expressed elsewhere in the provisions of the Agreement. Disallowing Members from having recourse to this remedy is the action that upsets this balance.

132. We also disagree with some Members' assertion that NVNI claims could undermine regulatory authority and limit the ability of a Member to undertake policies to promote certain public policy objectives.

133. The United States is of the view that the availability of non-violation complaints will protect Members from evasions of obligations under the TRIPS Agreement while preserving the ability of any Member to implement legitimate social, economic development, health, environmental, and cultural policies.

134. Further, non-violation complaints will only be successful if a measure could not have been foreseen when the Uruguay Round negotiations were underway. Because there are a number of ways to implement social and cultural policy goals, a Member may take this element of non-violation complaints into consideration when crafting measures to protect these goals.

135. Finally, WTO adjudicatory bodies will continue to be bound by Article 3.2 of the DSU, which clearly states that "recommendations and rulings of the Dispute Settlement Body cannot add or diminish the rights and obligations provided in the covered agreements." Furthermore, past GATT

and WTO rulings provide sufficient guidance on the scope of such complaints, which ensure that the scope of any non-violation complaint would have to be precisely drawn and clearly supported with detailed justification.

136. We continue to believe that WTO Members are being deprived of an important tool to enforce their rights under the TRIPS Agreement, which is why we support the expiration of the current moratorium so that complaints of this type may be applicable to the TRIPS Agreement.

137. While we remain of the view that the text of the WTO Agreements and dispute settlement rulings provide Members with sufficient guidance on the application of NVNI disputes to the TRIPS Agreement, the United States remains open to considering specific proposal from Members wishing to further examine the scope and modalities for complaints of these types.

7.5 Ecuador

138. As delegations have stated before, the position of Ecuador has not changed, so we would like our statement at the previous meeting of this Council to appear in the minutes. (See minutes of the eighty-eighth session of the Council held on 27 February 2018: IP/C/M/88/Add.1 para 140).

139. We would like to acknowledge the Buenos Aires Ministerial decision approving an extension of the moratorium. Our delegation maintains its well-known position that non-violation complaints are not applicable to the TRIPS context, as indicated in document IP/C/W/385/Rev.1 co-sponsored by Ecuador. However, our delegation will continue to participate proactively with a view to reaching a mutually satisfactory agreement in the run-up to MC12.

7.6 Bangladesh

140. We thank you for leading the small group discussion prior to this meeting. It was very useful for us in engaging with the stakeholders in a more informal way.

141. As we mentioned on earlier occasions, my delegation's position on the proposed lifting of moratorium on the non-violation and situation complaints is well-known. We would like to see a permanent moratorium in this regard.

142. However, we would like to hear from the proponents of the application their views and ideas about the scope and modalities of proceedings related to non-violation and situation complaints as required by Article 64.3 of the TRIPS Agreement. Only then, the Council will be in a better position to examine and consider the proposal. The concept is still an unknown territory, and unless the scope and modalities are perceived first, we cannot go any further in this discussion.

143. As we perceive it now, if non-violation and situation complaints are made applicable to TRIPS, any issue under the sun can be brought as cases under this umbrella. Clear delimitations, therefore, need to be conceived and thoroughly examined first. We, however, reiterate our readiness to engage with any interested delegations.

7.7 Switzerland

144. Switzerland holds the opinion that non-violation and situation complaints should be applicable also under the TRIPS Agreement. Despite the recurring decisions in the past to further extend the moratorium, we firmly believe that the TRIPS language is very clear in this respect – the moratorium should end and non-violation complaints become applicable.

145. The mandate of Art. 64.2 and 64.3 does not instruct the Council to examine whether or not non-violation complaints should apply under the TRIPS Agreement. Such discussion is outside the mandate's scope. The mandate is clearly limited to the Council examining the scope and modalities for non-violation complaints and then submitting its recommendations to the Ministerial Conference for approval. Although the Ministerial Conference has repeatedly granted an extension to the period, which was initially limited to five years after the entry into force of the WTO Agreement, this has still not brought about any result. And thus, the Council has still not fulfilled its mandate.

146. As we have repeatedly stated and has also been pointed out by South Africa, non-violation complaints are an exceptional remedy. They are solely to provide predictability and security to all Members under the TRIPS Agreement, just as they do under the GATT and GATS. And they preserve Members' ability to implement legitimate social, economic, development, health, environmental and cultural policies.

147. Opponents of the applicability of non-violation complaints under TRIPS have voiced a number of concerns. We would like to further allay those concerns. Firstly, it is important to stress that non-violation disputes cannot be used as a tool to increase the level of intellectual property protection established under the TRIPS Agreement. The DSU applies, and its Article 3(2) prescribes that "recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements." A second important point we recall is that one key condition for a non-violation complaint to succeed is that the challenged measure could not have been foreseeable. The recourse to a TRIPS flexibility is a foreseeable measure, and thus cannot be challenged by means of a non-violation complaint.

148. GATT together with the DSU provide guidance on the applicability and use of non-violation complaints in the context of the TRIPS Agreement. The relevant rules are complemented by a number of panel and Appellate Body decisions. They have conducted a significant analysis of non-violation provisions. Their decisions provide WTO Members with the necessary scope and set of modalities applicable to non-violation complaints, also under the TRIPS Agreement.

149. With the objective of ending the repeated renewal of the moratorium, the TRIPS Council should eventually move forward and resolve the stalemate situation. The sole purpose of Article 64.3 TRIPS was a moratorium for Members to have five more years to discuss the scope and, if found necessary, special modalities for the TRIPS context.

150. Although we believe that rules already in place for dispute settlements in the WTO are sufficient, we are open to considering specific proposals which allow for a more concrete examination of the scope and modalities for non-violation and situation complaints under the TRIPS Agreement. The conditions mentioned earlier in my delegation's statement today may provide a start for such a discussion in the Council.

7.8 Brazil

151. The debate on the applicability of non-violation complaints to the TRIPS Agreement has been part of the Council's agenda for many years and our delegation would also like to recall the importance of addressing the concerns raised by Members more than fifteen years ago in document IP/C/W/385. Since the last Ministerial Conference, in light of the mandate given to this Council, our delegation has intensified work on the study of non-violation and situation complaints, despite the fact that demandeur countries have not provided us with information about scope and modalities. It is up to demandeurs to propose scope and modalities of NVSCs, as all other countries have reiterated their view that NVSC should not apply to the TRIPS, thus there is no need to discuss scope and modalities. To automatically apply GATT cases without addressing TRIPS specificities – and they are many – does not seem the best way ahead. Brazil remains attentive to any proposal that may be brought by them. We have just heard some information provided by Switzerland, which we thank and we will carefully analyse and discuss bilaterally.

152. Based on information available, however, we remain unconvinced of the necessity to provide NVSC in the TRIPS Agreement.

153. Protection against evasion of obligations is fully ensured by the ordinary dispute process available under Article 64.1, which proved itself adequate to guarantee compliance with the provisions of the TRIPS Agreement. It has been invoked and used with great success in the past and no concrete case of the necessity for extending the mechanism to NVSC was presented so far.

7.9 Korea, Republic of

154. Our delegation's view on this issue remains unchanged. We are not convinced by some Members' argument that non-violation situation complaint should be applied to the TRIPS

Agreement. However, we are willing to engage in further discussions on this issue as constructively as possible.

7.10 China

155. Regarding non-violation and situation complaints, China appreciates the efforts made by delegations in Buenos Aires and welcomes the outcome on this issue.

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

7.11 Argentina

157. Argentina's position on this matter is well-known and remains unchanged. We believe that complaints of this type are not applicable to the TRIPS Agreement. This position is based on the arguments set forth in document IP/C/W/385/Rev.1, which Argentina co-sponsored together with a large number of other Members. Argentina is ready to continue constructive discussions on this issue with a view to finding an acceptable and permanent solution.

7.12 Canada

158. Our position on this issue is well-known, and remains unchanged. Canada continues to have concerns regarding the applicability of the NVNI remedy to the TRIPS Agreement.

159. Recognizing that the current moratorium exists based on consensus, we nevertheless trust that Members can continue to discuss these issues in a collegial manner in the TRIPS Council, especially in light of the high concentration of Members with concerns in this area.

8 REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.

160. No statements were made under this agenda item.

9 REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2

9.1 Mexico

161. As mentioned under item 2, the reform of the Industrial Property Law, published in the Official Journal on 13 March 2018, reflects our country's commitment to establishing legal provisions which are equivalent to those of our trading partners and consistent with the TRIPS Agreement and which aim to create schemes to improve the protection of industrial property, so as to promote economic growth and ensure greater certainty in international trade.

162. Mexico's updated replies to the GI checklist were published on the WTO's official website in document IP/C/W/117/Add.14/Rev.1. In accordance with the provisions of the TRIPS Agreement, our country made amendments to the Industrial Property Law, which can be summarized as follows:

163. Geographical indications have been incorporated into domestic legislation, and a common procedure has been established for the processing and use of national appellations of origin and geographical indications. A procedure has been created for the registration of foreign appellations of origin and geographical indications in the national registry, and administrative offences have been established in this area. These reforms have been in force since April 2018 and we consider that they will have a positive impact for users of the industrial property system.

164. The delegation of Mexico wishes to thank you for listening to this brief presentation and reiterates its readiness to reply to any questions by the Members of this Organization.

9.2 Switzerland

165. Switzerland submitted its revised answers to the checklist IP/C/13 in September 2017. We trust that this will enhance the transparency of its domestic system for the protection of geographical indications and will facilitate substantive discussions on the topic in this Council.

166. Considering the fact that most Members' contributions under this agenda item date back a long time, such as to the late 1990s, Switzerland would like to invite other Members to update their answers to the checklist IP/C/13. This will allow Members to rely on accurate information when dealing with the protection of GIs. On this occasion, Switzerland would like to commend Mexico for having submitted an up-date of its responses to the checklist recently.

10 TECHNICAL COOPERATION AND CAPACITY BUILDING

167. No statements were made under this agenda item.

11 INTELLECTUAL PROPERTY AND INNOVATION: THE SOCIETAL VALUE OF IP IN THE NEW ECONOMY – IP IMPROVING LIVES

11.1 Australia

168. Australia is pleased to introduce the discussion on intellectual property and innovation at this meeting, guided by the discussion paper IP/C/W/642 Intellectual Property and Innovation: The Societal Value of IP in the New Economy - IP Improving Lives. Australia is pleased to co-sponsor this agenda item with the European Union, Hong Kong China, Japan, the Republic of Korea, Switzerland, Chinese Taipei and the United States. Our discussion today is designed to highlight the role of intellectual property frameworks and how they support innovation through promoting and protecting the expression of new ideas and inventions, fostering creativity, supporting cross-border collaboration, trade and participation in global value chains. In supporting and incentivising innovation, intellectual property frameworks make a significant contribution to improving lives through social and economic growth and advancement across a wide range of sectors, relevant to developed and developing Members such as education and training, creative works, health, the environment and transport. As part of the 2018 theme under the Intellectual Property and Innovation agenda, the Societal Value of Intellectual Property in the New Economy, Members are invited today to share national and regional experiences on the positive human impact of intellectual property and innovation frameworks and how they improve lives.

169. Turning now to the case of Australia, Australia's intellectual property rules-based framework has played a role in changing the everyday lives of people worldwide through innovations that transcend national borders. We will showcase a number of innovative examples of how intellectual property frameworks have protected new ideas and contributed to improving the lives of people in Australia and around the globe.

170. Turning to the example of Reach and Match, the award-winning innovation – The Reach and Match Learning Kit is an innovative educational kit designed by an Australian woman that empowers children with disabilities and people in main-stream education to learn to together in an inclusive environment. The Reach and Match Learning Kit includes braille and print forms for both visually impaired and sighted children to develop literacy as well as cognitive motor, social and communication skills. It uses a tactile texture with braille markings, bright colours and distinct sounds to enhance the learning experience of all children. Reach and Match has trademark protection, it has won several awards, including one for social inclusion and innovation design. It was also one of the winners at the MIKTA Education and Emergencies Challenge and the inventor will receive a share of AU$2million from the Australian Government's Department of Foreign Affairs and Trade, to help develop and implement the product.

171. The second example is called the Yield. It was designed by an Australian entrepreneur, Ms Ros Harvey, which uses innovative technology and the internet of things to develop agri-business, improve productivity and reduce waste. Ros Harvey's invention, known as The Yield is designed to help deliver food from farm to table. The Yield helps growers take the guess work out of growing, with sensors, apps and data to monitor and predict conditions on the ground so farmers can make faster and better decisions about their crops. The Yield actively uses the IP system, including

trademark protection to support the business. Innovation and the ability of IP protection encourages the creation of inventions like these, which can improve everyday lives. We invite all Members to share their views on how intellectual property and innovation has improved lives.

11.2 European Union

172. Intellectual property rights play a crucial role in catalysing innovation and creativity, promoting economic growth and development, creating jobs, improving the quality and enjoyment of our lives, and combatting the manifold challenges we face as individuals, as nations and as a global community.

173. The societal value of IP in the New Economy becomes obvious in a large number of sectors, and we will see this documented, once all the Members' interventions of today are uploaded in the e-TRIPS database. The EU would like to highlight two of them in its intervention today: Health Care and Transport.

174. The recent report on the State of Health in the EU (State of Health in the EU "Companion Report 2017) concluded that only by fundamentally rethinking our health and care systems can we ensure that they remain fit-for-purpose. This means systems which aim to continue to promote health, prevent disease and provide patient-centred care that meets citizens' needs will have to adapt in a digitalised world. As in many parts of the world, health and care systems in Europe require reforms and innovative solutions to become more resilient, accessible and effective in providing quality care to European citizens.

175. Europe's health and care systems, like in many other regions of the world, face challenges. These are ageing, multi-morbidity, health workforce shortages, and the rising burden of preventable non-communicable diseases caused by risk factors such as tobacco, alcohol, and obesity, and other diseases including neuro-degenerative and rare diseases. We are also seeing a growing threat from infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens. Without innovative solutions, which are often incentivised by properly functioning IP systems, we will not be able to face the challenges of tomorrow.

176. Digital solutions for health and care can increase the wellbeing of millions of citizens and radically change the way health and care services are delivered to patients, if designed purposefully and implemented in an effective way. Digitisation can support the continuity of care across borders, an important aspect for those who spend time abroad or to bring health services to places of the world where due to local factors such services are unavailable now. Digitisation can also help to promote health and prevent disease, including in the work place. It can support the reform of health systems and their transition to new care models, centred on people's needs and enable a shift from hospital-centred systems to more community-based and integrated care structures. The digitisation and a shift from hospital-centred systems will also increase the access of developing countries to high quality health services that were out of reach before.

177. The EU is supporting the development of various approaches in high performance computing, data analytics and artificial intelligence, which can help design and test new healthcare products, provide faster diagnosis and better treatments. But succeeding in these endeavours depends on the availability of new and innovative technologies that ultimately will have to be developed by private health care industries which depend on their ability to retrieve a return on their investment. Without functioning IP systems, this paradigm shift will not happen or the benefits will only be fully exploitable in those places that properly protect IP.

178. Health and care authorities across Europe face common challenges, which can be best addressed jointly. To this end, the Commission has been working with the EU Member States, regional authorities and stakeholders to tap into the potential of innovative solutions, such as digital technologies and data analytics, and in doing so assist EU Member States in pursuing the reforms of their health and care systems. The EU provides its support through funding and actions that promote policy cooperation and exchange of good practice and by ensuring appropriate legal certainty with regards to protecting the relevant IP rights related to the inventions and creations in those sectors. EU funding supports research and innovation in digital health and care solutions, notably through the Horizon 2020 programme. It also supports the building of infrastructure for

cross-border exchange of patient summaries and electronic prescriptions, with funding from the Connecting Europe Facility programme.

179. Cooperation structures have also been developed; for example, the European Innovation Partnership on Active and Healthy Ageing, the Active and Assisted Living Joint Programme, and public-private partnerships such as the Innovative Medicines Initiative and the Electronic Components and Systems for European Leadership. Regional and national smart specialisation and innovation strategies also play a central role in the development of stronger regional ecosystems around the healthcare and innovation domain. Since 2004, two eHealth Action Plans have provided a framework for policy action for the Member States and the Commission, and the eHealth Stakeholders Group has played an important role.

180. The second sector we would like to highlight where the new digital economy will dramatically alter our current lives is transport. Electricity as an energy vector for vehicle propulsion offers the possibility to substitute oil with a wide diversity of primary energy sources. This could ensure security of energy supply and a broad use of renewable and carbon-free energy sources in the transport sector which in turn can help the implementation of the European Union targets on CO2 emissions reduction. Without the incentives of IP protection, the dramatically high amounts of investment needed to change our current transport technology based on combustion engines will not take place.

181. Electric vehicle 'tank-to-wheels' efficiency is a factor of about 3 higher than internal combustion engine vehicles. Electric vehicles emit no tailpipe CO2 and other pollutants such as NOx, NMHC and PM at the point of use. Electric vehicles provide quiet and smooth operation and consequently create less noise and vibration.

182. Electrification of transport (electromobility) is a priority in the Community Research Programme. It also figures prominently in the European Economic Recovery Plan presented in November 2008, within the framework of the Green Car Initiative.

183. The European Commission will support a Europe-wide electromobility initiative, Green eMotion, worth €41.8 million, in partnership with forty-two partners from industry, utilities, electric car manufacturers, municipalities, universities and technology and research institutions. The aim of the initiative is to exchange and develop know-how and experience in selected regions within Europe as well as facilitate the market roll-out of electric vehicles in Europe. The Commission will make €24.2 million available to finance part of the initiative's activities.

184. The development and large-scale deployment of Connected and Automated Mobility (CAM) provides a unique opportunity to make our mobility system safer, cleaner, more efficient and more user-friendly.

185. The needed innovative technology for the upcoming paradigm shift in the transport sector will never available without properly functioning IP systems, IP systems that allow innovators to reap the benefits of their massive R&D investments, which dwarf any public money that even the EU or other developed regions will be able to make available.

11.3 Japan

186. First of all, the delegation of Japan would like to express its sincere appreciation to the Secretariat for providing us an opportunity to share our ideas and experiences. Just for your information, handouts of the slides of this presentation are available at the entrances of this room.[1]

187. Firstly, this delegation would like to mention that innovation can contribute to a higher quality of living, which is also emphasized in the concept paper. Last year, the WIPO introduced "10 Innovations That Are Improving Lives", at WIPO-World-IP-Day. They are examples that improve lives, such as Medical Delivery Drones, which deliver vital medical supplies to patients living in difficult-to-reach parts; and mobile water-safety checking systems that help users to find, monitor and map the quality of water and sanitation sites.

[1] This PowerPoint presentation is available in Room Document RD/IP/21.

188. At the same time, this delegation would also like to emphasize that "Innovation and IP have a positive correlation". For instance, please have a look at the bar graph on the lower left of this slide, which shows the number of patent applications for inventions on data structures field. Looking at this bar graph, you will note the surges of patent applications filed during 2001-2006, the era when DVD technology was developed; and 2009-2013, the era when video-distribution-technology was developed. Picking up this graph as an example, this delegation is of the view that "Innovation and IP potentially have synergy effects to improve people's lives."

189. We now will show you an example of the startup company that made good use of IP to improve people's lives through its product.

190. Slide 2 shows the world's first, fully automatic laundry-folding robot developed by a Japanese start-up company. The product called "Laundroid" was developed by the company "seven dreamers laboratories, inc." Laundroid is based on a combination of advanced technologies, namely image analysis, AI, and robotics. The product was exhibited at the Consumer Electronics Show in 2018. And the company was awarded as the regional final at the Start-up World Cup 2018.

191. The company says, the product can save 375 days of your lifetime because it is estimated that the average person spends about 375 days folding clothes. In this regard, this delegation would like to reemphasize that the product definitely improves people's lives. Taking this opportunity, this delegation would like to show you a short video which illustrates this interesting product[2]

192. This delegation would like to mention how the company succeeded in developing Laundroid. Firstly, the company was smart enough to adopt a comprehensive IP strategy. Specifically, or simply, it carefully chose whether its technology should be opened or closed, that is, filing it as a patent application or protecting it as undisclosed information. Secondly the president of the company took the initiative to raise the employees' awareness of IP by following the IP strategy.

193. In conclusion, such IP-oriented activities led to the company's forming alliances with big companies that also have the latest technologies. Furthermore, having the IP rights, the company improved its credibility, which led to ample fundraising from banks as well as government agencies.

194. This delegation would like to stress here that "the stable and efficient IP system has supported and promoted innovations that improve lives."

195. In this connection, from the viewpoint of governmental policies, this delegation would also like to mention that the Japan Patent Office released a brochure in April this year called "IP Strategies for Start-ups", which targets small-scale companies. This brochure highlights best practices for start-ups, including "Actually faced IP issues with IP" and "How companies in and outside Japan overcame and succeeded" based on real cases. This delegation believes that this brochure can assist start-up companies in developing business strategies utilizing IP, and further contribute to developing innovations that can improve lives.

196. As we have seen in the slides, a stable and efficient IP system can support and promote ground-breaking innovations such as Laundroid that make our lives easier. Since this delegation is of the view that innovation and IP potentially have synergy effects that can improve and make our lives easier, Japan will remain committed to developing the even more user-friendly IP system to encourage further innovations.

11.4 Chinese Taipei

197. As we all know, it is inventions and new creations that provide us with the possibilities and the means to improve lives. And, this holds true in all walks of life.

198. In 1958, Jack St. Clair Kilby and Robert Norton Noyce invented the integrated circuit (IC), and this year marks its 60th anniversary. Since then, the development of the semiconductor

[2] Video not available in this document.

industry has been the driving force behind the digital revolution. Not only has this been the foundation on which modern technologies, such as home appliances, computers, the internet, cloud computing, smart phones, etc., have been built, but it remains the basis of today's emerging technologies as well, such as the Internet of Things (IoT), artificial intelligence (AI), and self-driving automobiles. I believe that the example Laundroid demonstrated by Japan also use ICs. So, we can definitely say that the burgeoning development of the semiconductor industry, and the inventions and creations it has inspired, have improved our lives in so many ways, not least in terms of convenience.

199. I would like now to give you just a very short history of our own development in this field over the last 30 or so years. We made the decision, in the 1970s, to make an all-out effort to develop our own IC industry. From then onwards, the Industrial Technology Research Institute (ITRI) started to introduce US IC designs and manufacturing technologies. These were later combined with ITRI's self-developed technologies, then transferred to the United Microelectronics Corporation (UMC) and the Taiwan Semiconductor Manufacturing Company (TSMC). Little by little, a strong IC industry with an established upstream and downstream supply chain was developed.

200. From 1987, TSMC and UMC focused on the so-called "foundry model" (that is, separating the semiconductor fabrication plant operation from the integrated circuit design operation into separate companies or business units) in order to generate innovation in the manufacturing process. As a result, they have become global leaders in semiconductor manufacturing technologies. In 2017, we were ranked the world's third largest in term of gross industrial output values of the semiconductor industry chain. Of these, foundry had the largest market share globally, accounting for over 70%.

201. In addition to the transfer of technology from the US and the ITRI in the early stages, the comprehensive protection of intellectual properties, such as patents and trade secrets, was also a key element in promoting the expansion of our semiconductor industry. For instance, according to TSMC's Annual Report, "IPRs protect the company's advanced and leading-edge technologies, safeguard its freedom to operate, and enhance its competitive position". And, according to the Annual Reports of TSMC and UMC for 2017, "the combined total of patents granted worldwide exceeded 40,000 as of the year's end". Regarding the protection of trade secrets, the Trade Secrets Act was instituted in 1996. In 2013, a criminal liability clause was introduced into the Act to provide more comprehensive protection for intellectual properties within our territory.

202. Future applications like the IoT and AI will undoubtedly depend on the semiconductor industry as their foundation. We are currently actively pushing for development of industries in areas such as, smart cities, smart manufacturing, automatic vehicles, augmented reality (AR), virtual reality (VR), and information security. Our belief is that the semiconductor industry's existing advantage coupled with our continuing investment will generate more relevant inventions and creations that will further improve the quality of people's lives.

203. Intellectual property and innovation are indispensable forces driving economic growth. I hope you found these examples and experiences useful. We look forward to hearing those of other Members, and we would very much welcome more sharing and discussion of IP policies and experiences between Members in the future.

11.5 Hong Kong, China

204. Innovation and technological progress contribute significantly to improving our lives. The cornerstone of our advancements in research and development is a robust IP regime. It is a principal means for establishing and protecting creations of the mind, and provides a legal foundation for incentivising and commercialising innovations. IP is undoubtedly a crucial part of a successful innovation system.

205. Our Government has been working hard to enhance our IP ecosystem by continuing to implement a series of measures to facilitate and encourage exploitation of the economic potentials of IP, as well as to promote Hong Kong as the IP trading hub in the region.

206. For example, our Government is pressing ahead with the establishment of an original grant patent (OGP) system, which bears strategic significance for Hong Kong to develop into a regional

innovation and technology hub and IP trading nexus. Subject to the progress of essential preparatory tasks, our target is to launch the OGP system in 2019 the earliest.

207. We have also introduced a bill into its legislation in April 2018 to expand the scope of profits tax deductions for capital expenditure incurred for the purchase of IP rights from the existing five types to eight. The three additions are rights in layout-design of integrated circuits, plant varieties and performances. The legislative proposal would encourage businesses to further consider using and purchasing the three types of newly added IP rights. It would also bring about positive effects to the development of the local IP industry and help contribute to a more favourable environment for innovation in Hong Kong.

208. On the other hand, our Government is also assisting our businesses to leverage on their IP assets and engage in cross-sector IP commercialisation in the wake of the knowledge-based economy. I am pleased to share with you today two remarkable inventions which make our lives healthier, safer and more comfortable.

209. The first one is a practical, award-winning face mask invented by a local pharmaceutical and healthcare product company. This face mask can effectively filter airborne particulates and viruses and kill 99% of bacteria within five minutes while maintaining high breathability and comfortability. It received Silver Award at the 2016 International Exhibition of Inventions in Geneva and has been registered as patent and trademark. Another mask developed by the same company received Gold Award at the same event in 2017. The inventions of these face masks are supported and sponsored the Innovation and Technology Fund under our Innovation and Technology Bureau. As at March 2018, the Innovation and Technology Fund has funded around 7400 projects.

210. Another notable example is a Wildfire Detection Robot invented by a young local start-up. This robot helps to mitigate fire disasters and safeguard natural resources. It is the world's first automated detection system which is equipped with thermal imaging sensors and artificial intelligence vision technology to spot fires in areas as small as two metres by one metre and within a five-kilometre radius.

211. This start-up has been recognized through several awards, including the prestigious "Entrepreneur of the Year" at the 2015 IBM SmartCamp Global Finals in the US, and the Asia Pacific ICT Alliance Awards the year after.

212. After obtaining patents relating to the technology of the robot, this award-winning start-up introduced the robot globally across Hong Kong, Mainland China and various countries.

213. To-date, over 100 wildfire detection robots have been deployed in 41 cities in China and Indonesia, while 1.3 million hectares of land are being protected. The company has also successfully carried out projects and conducted demonstration/proof-of-concept worldwide, including in China, Indonesia, Malaysia, Cambodia, Canada, Mexico, Brazil and South Africa.

214. These are just a few successful stories and we believe that there would be more to come. We would continue to support our industries and all stakeholders to harness the power of IP rights and commercial insights and innovations in future.

11.6 United States of America

215. The United States is pleased to co-sponsor this agenda item and contribute to the discussion of the Societal Value of IP in the New Economy – IP Improving Lives. Around the world, new technologies and vibrant creative endeavours are contributing to better outcomes for individuals and societies while increasing the quality of life.

216. IP systems play a critical role. For instance, patent, regulatory data, and trade secret protections provide innovative risk-takers with the confidence needed to devote what may be years and millions of dollars into an endeavour that may or may not produce a return on investment. Copyright can serve as an engine for creativity, cultural preservation, and cross-border cultural exchange. Through advances in technologies, it has never been easier for societies

around the world to interact, share music, movies, or writings, and lend their expertise to solve pressing problems far from home.

217. During the last session of IP and Innovation, we shared information on how IP-intensive industries contribute to the economy of the United States. Today, we will explore the important contributions that innovations and creative content from these industries provides to societies and individuals around the world.

Creative industries

218. Creative industries are helping to unite populations and contribute to cross-cultural exchange around the world through the combination of robust IP protection, trade networks, and technological advances. This includes music, television programmes, books, games, films, fashion, and more.

219. For these and other products and services, technologies have increased the market for these cultural goods, which helps create jobs in a broad number of direct and indirect industries. For example, each successful film or television programme creates opportunities for not only directors and actors, but also costume designers, makeup artists, advertising professionals, lawyers, and more.

220. As legitimate platforms to distribute content continue to flourish, the opportunity to access these products grows. As we examine this topic, the music industry provides a multi-faceted example. Music brings people together, connects diaspora populations to their homeland, promotes cross-cultural awareness and understanding, and helps people to better understand themselves and others.

221. In a recent study conducted in Portugal, researchers found that young students exposed to a six-month musical programme that included both national songs and songs from another culture found that those students who participated in the programme demonstrated a reduced prejudice towards the non-nationals whose music they had learned.

222. Copyright is a critical tool to enable the continued creation of music and robust copyright protection and trade rules help facilitate cross-border exchanges. Content delivery platforms, such as Apple Music and Spotify, have revolutionized how music is listened to, and continues to unite cultures throughout the world. There are over 400 content delivery platforms globally.

223. A healthy music ecosystem, for example, contributes and provides benefits to all aspects of society. There are many different contributors, creators, and investors. However, there are harmful players as well who do not contribute (pirates, stream-rippers, etc), and diminish the ability of creators to generate a positive livelihood.

Agriculture

224. Outside of the arts, society benefits from both large-scale innovation and targeted technological improvements that save and improve the lives of millions.

225. In a multi-stakeholder initiative that includes the African Agricultural Technology Foundation, Gates Foundation, USAID, Monsanto, the International Maize and Wheat Improvement Center, and participating African governments, innovations have been designed to match African farmers' needs.

226. Through the Expanding Water Efficient Maize for Africa programme, these partners have come together to develop, license, and utilize a hybrid maize seed that can more efficiently utilize water and provide pest resistance—two particularly pernicious problems for farmers in this region. To date, farmers in sub-Saharan Africa have planted over 180,000 hectares of hybrid seeds which farmers have reported doubling over previous yields. By voluntary arrangement, over 23 seed companies are licensed to access the hybrids without paying any royalty to the company that developed the technology.

Technology

227. Breakthrough advances in technology are also providing innovators with new platforms to help others. Recently, researchers at the California Institute of Technology developed an app that makes use of an existing device that is worn like sunglass, but composed of high-powered lenses and computer processors, that could improve the lives of millions of visually-impaired individuals. The app, using a high-tech headset, can quickly analyse a room and provide the wearer with audio directions and hints to navigate complicated spaces. The app calls out directions, announces obstacles, staircases, and railings to guide the user to safely reach his or her destination.

228. These types of innovations bring enormous hope and potential to the over 253 million people that the WHO estimates live with blindness or visual impairment. Other applications of this type of technology include providing doctors or trainees with real-time, visual guides to complicated operations, or pilots with new training tools.

USG programmes

229. The United States Government and numerous private sector and other organizations implement programmes that make significant economic and social contributions to society through IP-intensive products.

230. For example, recently, music exchange has been used as a cultural diplomacy tool between the U.S. and Pakistan[3]. The State Department brought selected Pakistani musicians to South by South West, a three-day music festival in the US, for showcases and IP education. The result was perhaps the most unique set of performances at this year's SXSW festival. Musically, the six acts represented a variety of regions and styles

231. Moreover, the Department of Commerce participates in related trade shows and missions in the music and entertainment sector which highlight opportunities for U.S. exporters in the sectors of digital licensing. Some examples are Book World in Prague this past May, and the Hong Kong Filmart this past March. These opportunities drive future export competitiveness, and the highlight the importance of intellectual property protection.

Private sector/non-profit initiatives

232. Many US non-profits, charities, and companies engage in initiatives which make social and economic contributions to society through distribution of copyrighted works.

233. The MIT Enterprise Forum Pan Arab Innovate for Refugees Competition provides rewards for "innovative and tech-driven solutions for life threatening challenges faced by refugees worldwide."

234. Examples of innovations that have emerged from this competition include Flowy, a standalone solar-powered hand-washing basis that helps provide clean hand-washing facilities that conserve both energy and water and NCfilter that can convert dirty to clean water using nanotechnology applied to locally-available waste materials. The diverse teams that participated in the competition included Members from Lebanon, Egypt, Jordan, and many other countries.

235. There are many others, including the Bill & Melinda Gates Foundation, FilmAid, Women in Film's PSA Production Programme, and Dramatic Need.

236. IP continues to drive innovation and creativity worldwide. Governments, the private sector, and other organizations and individuals are undertaking important and exciting work to ensure that the societal benefits of IP are widely shared and applied to the people and populations that need them.

11.7 Canada

237. Canada is pleased to co-sponsor today's discussion on "IP Improving Lives", as part of the three-part theme "The Societal Value of IP in the New Economy." We would like to thank Australia

[3] https://centerstageus.org/news/billboard-behind-us-state-departments-sxsw-focused-cultural-exchange-pakistan

for drafting the discussion paper (IP/C/W/642) as a basis for today's agenda item. We would also like to thank the co-sponsors for developing the discussion under this theme, and those Members that have shared their experiences and insights on this issue so far.

238. As touched upon on in the discussion paper, emerging technologies are increasingly reshaping how we interact and engage with our environments, with implications for education and learning, labour productivity, as well as how our businesses, cities, and markets are organized. The scale and scope of emerging technologies – such as advances in information and communications technology (ICT), 3D printing, artificial intelligence (AI) learning, and automation – will have significant impacts on how we work, interact, live, and govern, as well as overall quality of life. Given the pace of technological change, increasing attention is being paid to the accessibility and adoption of new technologies, to ensure that they meet their potential for improving livelihoods for a diverse community of users. In this regard, it is important to ensure that the IP system is understood and accessible in order to serve its purpose, and support the commercialization of innovation and creation from a wide range of groups.

239. With this in mind, Canada would like to note the recent announcement of our national IP Strategy. Canada's IP Strategy was launched on April 26, 2018, and contains a mix of initiatives aimed at increasing businesses' ability to use the IP system to be more competitive and successful. These initiatives include legislative changes, IP literacy and advice, and tools to support growth. Canada would be pleased to present on these initiatives in greater detail at TRIPS Council meetings in the coming months, including legislative changes under the IP Strategy, but for now, would like to highlight a few initiatives aimed at increasing IP education and aware-ness, as well as the involvement of a broad range of groups in the IP system. In particular, under Canada's Budget 2018, CAD$2 million will be provided to Statistics Canada over three years to conduct an IP awareness and use survey to help identify how Canadians understand and use IP, including groups that have traditionally been less likely to use IP, such as women and indigenous entrepreneurs. As well, Canada's Budget 2018 also proposes to invest CAD$1 million over five years to enable representatives of Canada's Indigenous Peoples to participate in discussions at the WIPO IGC.

240. In addition, the Canadian Intellectual Property Office (CIPO) is developing initiatives through its IP Education and Awareness Programme to ensure that businesses have a sound understanding of IP and can better utilize and leverage their IP assets as part of their business and growth strategies. This includes CIPO's IP for Business and IP Academy programmes, which will deliver seminars and webinars, IP training, and produce a suite of online information products and tools, as well as guides for those seeking IP in export markets. This also includes CIPO's IP Hub, which will deliver and support a suite of networked services, including referral, consultation and support to advisory services.

241. Another way that Canada has sought to make the IP system more accessible for a wider range of groups is by way of recent reforms to the *Copyright Act* in respect of persons with perceptual disabilities, under the 2016 Bill C-11 (*An Act to amend the Copyright Act (access to copyrighted works or other subject matter for persons with perceptual disabilities*). These reforms included amendments to permit the making of large-print books, reduced restrictions on exporting accessible materials, safeguards to protect the commercial market for materials in accessible formats, and exceptions relating to the circumvention of technological protection measures (or TPMs). As was noted when Canada notified these amendments to TRIPS Council (under document IP/N/1/CAN/17), these reforms enabled Canada to accede to the WIPO *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled* on June 30, 2016, with the treaty subsequently coming into force on 30 September 2016.

242. As these examples and initiatives articulate, a key avenue to providing that innovation and IP systems improve livelihoods is in ensuring that those that stand to benefit from these systems are involved at all stages of the process, "from the ground up" so to speak. IP education and awareness is one such avenue for ensuring that a wider range of previously under-represented groups are involved in the IP system, with a view to facilitating more diverse innovations and creations that may benefit a wider range of communities. As Canada embarks on a national IP Strategy aimed at helping *all* Canadians harness IP, we are interested in hearing the views and experiences of other Members, with regard to how IP and innovation systems can reach and involve a broader range of groups, for the benefit of all. We would again like to thank other Members for the discussion today, and look forward to engaging further on this issue.

11.8 Switzerland

243. Switzerland would like to thank the previous delegations for their gripping interventions and presentations. We welcome the opportunity to exchange experiences and views on how intellectual property has practically contributed to improving our lives – a topic which is broader than previous topics under the IP and innovation theme. It is not only directly relevant to all of us here in this building, but to all human beings.

244. We believe that intellectual property serves as an important engine for fostering creativity, innovation, and technological progress for the benefit of society. The intellectual property system plays a major role in providing incentives to the development of solutions to current challenges and enriches lives thanks to more diverse literature and art. Since the early modern era, IP rights have contributed to technological and cultural advancement in the most diverse fields such as education, environmental protection, public health, food and agriculture, arts, and entertainment. Certain inventions have even dramatically changed the way we live or have helped improve our day-to-day lives.

245. IP rights are an important tool. They are, however, not a panacea and need to be put into the wider context of the market economy and state policies. Switzerland tries to adopt a bottom-up approach to enable innovation to flourish. This means leaving competence at the lowest administrative level as long as possible. It is an established principle, for example, in the promotion of research and innovation: The researchers' own initiative is regarded as being crucial, besides the principles of competition, qualitative assessment criteria, and international cooperation. A free competitive environment is one of the main driving forces of innovation. In addition, overall favourable and innovative-friendly conditions depend on a reliable legal framework, including a system of adequate and enforceable IP protection.

246. Let me illustrate, with a few case studies, how intellectual property protection, innovative and entrepreneurial spirit, international trade, and cooperation have contributed – and will contribute in the future – to finding innovative solutions and thereby have made, and will make, life easier.

247. The first example dates back to 1929 when financial and economic crises shook the world. Due to the Wall Street Crash, Brazil ended up with a large surplus of coffee beans. The Brazilian Coffee Institute asked a Swiss company to find a solution for the surplus of coffee beans that were sitting unsold in warehouses in Brazil. After years of research, the Swiss chemist Dr Max Morgenthaler presented a winning formula which converted coffee beans into a soluble coffee powder, while preserving the true taste and aroma of coffee. It was the world's first instant, readily soluble coffee. The invention of this breakthrough beverage helped to find a way out of the enormous surplus of coffee beans in Brazil, while preserving the traditional form of coffee production. In addition, it made coffee consumption more popular worldwide, expanding the international market for coffee producers. The availability of patent protection for this new method of producing instant coffee served as an important incentive, since it enabled the company to recoup its investments in research and development. In addition, protecting the trademark of this innovative product contributed to making the company internationally known for its original food products and processes.

248. Switzerland is convinced that the promotion and protection of intellectual property is an important element – among others – that contributes to technological progress for the benefit of humanity. Creative solutions prosper if inventors are able to commercialize their inventions in a predictable and stable legal environment. Protection of IP also encourages investors to provide the necessary funding for developing new products and technologies that increase our well-being.

249. Intellectual property has also contributed, as is well-known, to the development of new innovative drugs and treatments that have helped to ensure healthy lives and promote well-being across the globe. IP plays a key role in providing the necessary funds to cover the expensive undertaking of developing new medicines. In the last decades, significant progress has been made in increasing life expectancy as well as eradicating, curing, and improving the treatment of a wide range of diseases.

250. One example of a product, the development of which was made possible by IP and an innovation-friendly ecosystem, is Ceftriaxone. Ceftriaxone is an antibiotic which is suitable for treating organisms that tend to be resistant to many other antibiotics. It is a product which has made – and still is making – a great impact. In 1979, a Swiss pharmaceutical company discovered and filed for patent protection of Ceftriaxone worldwide. The antibiotic is used in the treatment of a number of bacterial infection diseases, such as sepsis (i.e. blood poisoning), meningitis and pneumonia. It has been available as a low-cost generic by many suppliers and has featured on the World Health Organization (WHO) model list of essential medicines for many years. This innovative antibiotic has helped to save countless human lives and continues to do so.

251. The development of new drugs and treatments is and will be instrumental in improving lives. It is also a very expensive undertaking. Few other industries are as dependent on effective patent and test data protection as the innovation-driven pharmaceutical industry. They need to recoup their massive investments in R&D costs and be able to reinvest in new and better products. By doing so, they not only supply the pipeline of innovative medicines, but in the medium term, also the pipeline of generics, as these innovative products may be copied by any manufacturer after their patent term has expired.

252. We would like to look at a last example of an interaction between innovative spirit and IP improving lives – and that is Solar Impulse, a completely solar-powered plane. In 2016, it completed the first-ever round-the-world flight without a single drop of jet fuel. It was built to carry the message that the world needs to find new ways of improving the quality of human life, which includes clean technologies and renewable forms of energy production.[4] This pioneering project was successful due to the joint efforts of individuals and many partners from the private and public sector, including the Swiss government. In this project, numerous companies and institutions from several countries contributed with their expertise and high-tech materials. It took 12 years of research and development to create an aircraft powered by dozens of environmental products and processes.

253. The technologies developed are now opening up new "markets and offering an opportunity for economic development, job creation and profit."[5] The Swiss solar plane served as a laboratory and platform for clean technology. Project partners invested money and expertise. In return, they benefited not only from the project's media impact but also from IP, such as patents for technology developed for building the aircraft. As was explained in a related article in the WIPO Magazine, the Solar Impulse team entered into a partnership with Bayer MaterialScience, which offered access to "innovative material solutions" that reduce energy consumption. Another partner, the Swiss energy company SIG, helped "optimize the energy chain and push the storage capacity of the batteries to their maximum". The project partners relied on IP protection to make their research viable, and help them administer the rights in their innovations within their partnership and with external partners. The project team itself also applied for some IP rights, despite the fact that the project itself was not commercially oriented.

254. The project fulfilled its ambition: "to contribute to the world of exploration and innovation, to the cause of renewable energies." It wanted "to demonstrate the importance of the new technologies". Beyond its contribution to the cause of renewable energies and their importance for mankind, the technology developed for the solar impulse aircraft may be used and further developed for other purposes. Take the lighter-weight and more efficient batteries that were essential for the aircraft. They can now just as well be used in cars.

255. This endeavour would not have been possible if the companies involved did not have the assurance that all of their investment in physical and human capital and knowledge, and research and development, would be protected and rewarded, including through the protection of intellectual property.

256. In conclusion, we note that intellectual property has widely contributed to the improvement of lives around the globe. We encourage Member States to continue providing the necessary framework and make all IP instruments available to encourage financing and other investments in

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[4] For further information, see: https://www.swissinfo.ch/eng/sci-tech/record-breaker_swiss-solar-plane-ends-round-the-world-tour/41329902

[5] *Available at:* http://aroundtheworld.solarimpulse.com/.

innovative solutions – solutions that improve lives. The Swiss delegation is looking forward to continuing constructively engaging in this information sharing-session.

11.9 Brazil

257. From the outset, allow me to thank the proponents of document IP/C/W/642 for the document. We appreciate opportunities for the exchange of views and experiences that enable mutual understanding.

258. The issue before us relates directly to the basic objective of intellectual property: to promote technological innovation in a manner conducive to social and economic welfare. The attainment of such goal is a constant concern of policy makers and demands an unceasing and careful analysis of the designing and application of intellectual property policies. The IP toolkit of rights, if I may use that expression, offers many options for those interested in generating a competitive edge to their services and products. Small enterprises may rely on trademarks and trade names to differentiate them from larger competitors; they may also use patents to attract investments to their industrial innovations, even if they don't have the capital themselves for making that investments. Agricultural producers are able to bring additional income and value to their regions when the protection afforded by a geographical indication is adequately utilized as part of their commercial strategies.

259. On the side of the society at large, IP also generates concrete benefits. The dramatic improvement on life standards seen in the last century is largely attributed to new and innovative medicines. The technical improvements applied to the agricultural sector have allowed food production to reach levels unheard of during and after the green revolution. Trademarks and GIs, on their hand, make it possible to distinguish one company from another, enhancing competition and increasing the quality of products in the market.

260. I would like to present two examples of innovations by Brazilians which have improved lives. A Brazilian company developed a smartphone app called "Cataki", which connects consumers to companies that recycle products. Consumers merely have to consult the app in order to find the nearest recycling company, which then may be contacted to collect the recyclable product. The app received a prize from UNESCO, due to its positive impact on the environment. Mario Adolfi Jr, from a company called Kidopi, received a prize from MIT for "Clever Care", a software that uses artificial intelligence in the form of a chatbot, which is used to exchange messages with patients. The software monitors the administration of medication, clarifies basic questions of patients and alerts their doctors if something goes out of the ordinary.

261. Allow me to stress the efforts that Brazil has been developing to provide an environment conducive to innovation. We are currently undertaking studies in partnership with international organizations to measure the concrete impact of intellectual property on our economy and on the access to technology in areas such as agriculture and health.

262. There are also ongoing initiatives to modernize the Brazilian industrial property office. We have hired 210 new patent examiners in the last two years, almost duplicating the office's capacity to process patent applications. Further, Brazil is engaged on creating an increasingly integrated and effective innovation ecosystem. In the last session of the Council, I have referred to the broader legal framework of the Brazilian innovation law. The government of Brazil also fosters innovation through financing of start-ups, and by providing, by law, that federal university professors may take temporary leave to create a start-up. Of course, IP by itself does not generate innovation and development and must be part of a broader innovation and industrial policy of countries, but its contribution cannot be reduced.

263. In this sense, Brazil will continue to support initiatives aimed at encouraging and rewarding innovation and its widespread use in the economy and society.

11.10 Korea, Republic of

264. As a co-sponsor of the document IP/C/W/642 – IP and Innovation: IP improving lives", Korea is pleased to share with the TRIPS Council its views as well as experiences with regard to this agenda item. In my intervention, I would like to briefly present some of the important

innovations that have significantly impacted people's lives - and then provide an overview of Korea's efforts to support the development of IP in other developing countries

265. As is well-known, an effective IP system plays a crucial role in enhancing our daily reality by incentivizing innovation and technological development. There are countless examples of inventions in the history of humankind that have brought significant improvements in human lives. To give a few examples, the telephone, which was, as you know, invented by Alexander Graham Bell, has brought a revolutionary change in communication. Cars brought great advances in transportation. The milestone patent, for a "vehicle powered by a gas engine" was filed in 1886 by Benz. Benz went on to develop and patent other automotive components and this invention resulted in dramatic improvements in people's lives; people were no longer bound to one place and this meant greater flexibilities in the choice of living and working places. The semiconductor is another key example of an invention the benefits of which were far-reaching and widely felt. In 1958, Jack Kilby of Texas Instruments patented the first prototype integrated circuit Indeed, the semiconductor ushered in a revolution in technology. If it were not for the semiconductor, we wouldn't have computers, the internet, televisions and in fact most electronic devices - and it is hard to even imagine a world without these.

266. Korea is one of few countries that have succeeded in achieving economic growth in a relatively short period of time - and we believe that it was possible to achieve such a rapid economic development mainly due to intensive efforts to innovate, which have been anchored in a strong and effective IP system. Korea's experience serves to demonstrate that there is a positive correlation between effective IP and innovation, growth and indeed a better quality of life.

267. And yet, we do not believe that a strong IP system in itself automatically brings about innovation and economic growth. Other elements such as technical capability are also crucial factors. As such, Korea is working with other developing countries to support efforts to innovate and enhance our daily lives through appropriate technology (AT). The goal of appropriate technology is to promote a better quality of life in the developing world without condescension, complication or environmental damage. In AT inventions there is a special focus on the social and cultural impact on a particular community that they are intended for. We are carrying out various AT development projects in countries in need of assistance mainly with a view to improving the quality of life for low-income households. For example, a crop dryer and solar charge controller was developed for Makerere University in Uganda. The drying technology in agriculture is expected to improve the quality of feed and contribute to the income of local farmers. A coconut oil expeller was developed in Sri Lanka with the aim of addressing issues regarding the quality of coconut oil. Furthermore, relevant technology research centres have been established in both countries to promote the sustainability of such technologies.

268. Korea will continue to work with WTO Members with a view to improving lives through the further development of an effective IP system and promotion of technological innovation.

11.11 South Africa

269. This delegation would like to thank the co-sponsors for having introduced this interesting and relevant item, we have not heard any dissent to many of the statements that have been made, perhaps we can start a new trend. Increasingly, harnessing technological progress is viewed by policymakers as a key priority to boost economic growth and improve living standards. The relationship between IPRs and development is indeed quite complex from a theoretical point of view. Any attempt to quantify the impact of IPRs needs to appreciate the variable nature of the legal frameworks that supports IPRs. The context of IPRs is important: they are interwoven with other domestic laws and institutions governing competition policy and anti-trust, international trade, labour rights, privacy and many other issues.

270. The economic literature on the impact of IPRs is rather inconclusive. We have to ask whether current IPR frameworks encourage innovators to address the most pressing issues facing our global society and developing countries' needs? Do they ensure access to the products of this innovation by those who need it most? It remains ambivalent as to whether the social benefits of IPRs exceed their costs, even in relation to the developed world. The basic argument in favour of IPRs is that they are necessary to stimulate invention and new technologies. The main critique against IPRs is that they increase the cost of patented commodities which reduces welfare. This

problem is exacerbated in developing countries because they are net importers of technology.[6] Given these embedded costs, a quantification of the contribution of IPR frameworks to improving lives through social and economic growth ought to rest on development models that enable developing countries to catch up and as such the optimal IPR regime for them may be different from that for a more advanced economy. In the pharmaceutical industry, for example, pharmaceutical companies devote relatively little of their research budget towards diseases that afflict developing countries, and the incremental returns that they receive from developing countries are sufficiently smaller that they are unlikely to affect significantly the overall pace of innovation.

271. If it is argued that IPR frameworks lead to broader and stronger IPRs and that such systems may encourage more IP to be generated, or greater creativity to develop, such assumption must at the very least address the following questions: How much of the IP that is generated translates to more innovation, jobs, creativity, and productivity and greater societal benefits? Are IPRs currently calibrated to maximise innovation and inclusive growth? Some innovators avoid heavy reliance on IP because they are concerned that it could slow innovation down. In their view, most innovation is incremental and if IP rights are too strong or too widely used, IP will retard progress for subsequent inventors. This perspective originated with certain software hackers and academics and eventually helped to shape the development of open-software platforms like Linux, Android and Chrome OS.[7]

272. Furthermore, the pace of innovation in some industries is raising doubts in the minds of some stakeholders about the universal suitability of IP systems for helping to solve major global challenges such as climate change. This was illustrated by the decision of Tesla Motors to open its patent portfolio, which Tesla said was a result of its disappointment with the slow pace of adoption of electric motor technology.[8]

273. Whereas the transformational effect of new technologies cannot be denied, the diffusion and access to such technologies are not only dependent on IPR frameworks. UNCTAD's *Information Economy Report: Digitalization, Trade and Development*[9] underscores the fact that affordable access to different ICTs is essential for people and enterprises to take active part in the evolving digital economy and reap development gains from it. More than half of the world's population remains offline and the broadband divide is ever wider.

274. Proponents advance the argument that in respect of education and training, a range of intellectual property rich materials foster social and economic contributions to society. A fundamental component of the right to education is access to high quality text books and other learning materials. Yet in many developing countries, access to such resources can be prohibitive since textbook scarcity is a serious challenge affecting the quality of education. In Cameroon, there is approximately one reading textbook available for every 12 grade two students and one mathematics text per 14 students. As more and more learning is facilitated through computer access and the internet, both students and teachers are able to log onto fast amounts of information. Unfortunately, access to these technologies are both inadequately and unequally distributed between the developed and undeveloped regions in the world.[10] The disparities experienced in the physical world is often exacerbated in the online environment. Buy a book and you own it forever; pay for access to a digital book and when the period of service is over you often retain nothing.

275. A better understanding of the enabling conditions and implications of digitalization for the economy and society is urgently needed in order to maximize potential benefits and opportunities, and cope with various challenges and costs.[11] The adoption of digital technologies in global supply chains across all industries also impact on international production. In this context, we are beginning to see the disruptive effects of DT when firms re-shore investment as low-wage jurisdictions lose their cost advantages from increased use of robotics and artificial intelligence.

[6] Auriol et al. Intellectual Property Rights Protection in Developing Countries p.2 (2012), Toulouse School of Economics.
[7] OECD Enquiries into Intellectual Property's Economic Impact (DSTI/ICCP) p.18 (2015).
[8] Ibid.
[9] Information Economy Report: Digitalization, Trade and Development p.17 (2017).
[10] K. Bohma "Digital Divide Effects on Education Development in Africa." p.9 (2014).
[11] UNCTAD p.11 (2017).

There are concerns that the labour conditions may deteriorate in the digital economy and exacerbate polarised labour markets and inequality. Employment levels in many sectors appear set to decline and as the new technology augments the premium for higher skills and replaces routine jobs, workers will be forced to compete for fewer, lower-paying jobs. Where new employment is created, it is often insecure with declining levels of health, safety and unemployment benefits. The use of self-driving cars and drones may save time and money; however, the introduction of these technologies is not value neutral in themselves, aside from the IPR dimension, there are a myriad of other factors that determine their ultimate societal impact and utility.

276. Over 40,131 patents originating from all over the world were registered in South Africa between January 2005 and July 2015.[12] Only 10% of the total number of patents granted were South African patents, this translates to on average less than 400 South African patents granted per year. The South African patent landscape is characterized by the easy grant of patents of dubious quality and value, as well as the enforcement of a legal frame work that appears to be heavily skewed in favour of patentees. What this means in practice is that in exchange for very little, market exclusivity is easily granted, and maintained, ordinarily at a high cost to society.[13]

277. Intellectual property in itself has always been an integral part of general economic, social and cultural development worldwide. Whether IPRs are a good or bad thing, the developed world has come to an accommodation with them over a long period. Even if their disadvantages sometimes outweigh their advantages, by and large the developed world has the national economic strength and established legal mechanisms to overcome the problems so caused. Developing countries are far from homogeneous, a fact which is self-evident but often forgotten. Not only do their scientific and technical capacities vary, but also their social and economic structures, and their inequalities of income and wealth. The determinants of poverty, and therefore the appropriate policies to address it, will vary accordingly between countries. The same applies to policies on IPRs. The impact of IP policies on poor people will also vary according to socio-economic circumstances. What works in India, will not necessarily work in Brazil or Botswana.

278. We thank the proponents for the introduction of this very useful contribution. Much of what is presented is based on broad generalisations and assumptions. This delegation would like to invite proponents to enter in to a more focused discussion on the theme of Intellectual Property and Innovation. More specifically, we would like proponents to address some of the following issues in upcoming discussions:

- What can we learn from the economic and empirical evidence about the impact of IP in developing countries? Does the historical experience of developed countries hold any lessons for developing countries today? How can technology transfer to developing countries be facilitated?
- How does the IP system contribute to the development of medicines that are needed by poor people? How does it affect the access of poor people to medicines and their availability? What does this imply for IP rules and practices?
- How does copyright protection affect developing countries' access to knowledge, technologies and information that they need? Will IP or technological protection affect access to the Internet? How can copyright be used to support creative industries in developing countries?
- How should developing countries frame their own legislation and practice on patents? Can developing countries frame their legislation in ways that might avoid some of the problems that have occurred in developed countries?
- Are the international and national institutions involved in IPRs as effective as they could be in serving the interests of developing countries?

11.12 India

279. The history of evolution of IP rules in developed countries suggests that the design of IP rules and policies should be adaptable to the changing needs of societies. This is reflected by the fact that the levels of IP protection in developed countries increased as their industrial and technological capacities improved over time. While IPRs may provide an incentive to innovate,

[12] Jonathan Berger and Andrew Rens "Innovation and Intellectual Property in South Africa: The Case for Reform." p.15 (2018) Shuttleworth Foundation.

[13] Berger and Rens: p.44.

they are neither a necessary nor a sufficient condition and could only be effective in certain contexts;

280. We have seen firms using patents and other forms of intellectual property in anti-competitive ways. Firms may use patents as a strategic deterrent by building up "patent thickets," which make incremental or follow-on innovation by other firms a more challenging and costly process. Non-Practicing Entities (NPEs) also have been identified by many policymakers as a costly impediment to innovation and economic growth.

281. IPRs cannot boost innovation if the required conditions – skills, information, capital, market prospects – do not exist. Therefore, the strength of IP rules should be calibrated to the levels of development in country. In countries where the required conditions to benefit from strong IP protection do not exist, IP protection may be more costly than beneficial.

11.13 Norway

282. Norway would like to thank the proponents for the communication contained in document IP/C/W/642 and for including the topic on the agenda of the TRIPS Council. The societal value of IP is a topic of interest to Norway, and we take the floor today mainly to indicate our support of the discussions, which we continue to follow with interest. We see this as a good opportunity to have a balanced discussion related to IP in the WTO, focusing on both challenging and positive aspects of Intellectual property rights.

283. Norway supports effective and balanced protection of IP, which we view as an important incentive for investments in innovation and creativity. Norway is not in a position today to share specific examples or experiences. However, we have taken note of the proponents' questions and we may come back to the Council with more specific comments later this year.

284. We would also like thank other Members for their interesting presentations and interventions today.

11.14 New Zealand

285. New Zealand would like to thank all Members who have presented under this agenda item. We have found the presentations to be thoughtful and interesting. We recognize the importance of this topic, and consider that the sharing of examples, national experiences and viewpoints to be a useful exercise. We look forward to sharing this information with interested persons back in capital.

11.15 China

286. In 2017 the theme of World Intellectual Property Day was innovation and how it improves our lives, similar to the topic we discuss today. From new materials to new transportation technologies, it is no doubt that Innovation has changed our lives.

287. While the intellectual property system is a crucial part of a successful innovation system, it contributes to the protection of innovation and helps to transfer and dissemination of technology.

288. China attaches great importance to innovation. And in order to better protect innovation, China has built an intellectual property system based on the international rules. Under the protection of intellectual property, in 2017, there were 1.3 million patent applications, 5.7 million trademark registration applications, and 2.7 million registrations of copyrights. All three numbers hit a record high.

289. In 2017, China's e-commerce industry led to employment of 42.5 million people. Innovation plays an important role in changing the Chinese people living standard and stimulating economic growth.

290. But we still recognize the huge gap in the current innovation field. At present, developed country Members created more innovations. At the same time developing and LDC Members

created less. China believes that innovation should not only be the "toy" for developed Members, but also can allow more people to share the benefits of innovation.

11.16 UNCTAD

291. I would like to take the opportunity to update Members on a new element of UNCTAD's activities related to IP. Building on the results of UNCTAD's capacity building and policy advice for developing countries related to the implementation of the TRIPS Agreement, we now consider it important to assist developing countries in the support of technology-based industries and job creation, in areas such as pharmaceuticals, biotechnology, information and communication technology, and agricultural technologies. With a view to improving living conditions in beneficiary countries, avoiding brain drain and large-scale migration, it is essential to help developing countries move away from their dependence on natural resources and cheap labor. The fast-growing percentage of young people in developing country societies and the expected impact of artificial intelligence and robotics on currently existing employment in the processing industry call for a shift toward more knowledge-based economies. Technology plays a key role in this respect, and technology transfer for developing countries is crucial.

292. This is where our future activities in IP are intended to take place. In our work, we have seen that voluntary, contractual licenses may provide a key avenue for technology transfer in developing countries and may at the same time open new markets for foreign investors. Well negotiated contracts can create win-win situations for both the foreign investor and the domestic partner in a developing country. This has been demonstrated in a series of case studies on "Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries" that UNCTAD published in 2011.[14] In that context we found that contractual agreements between a foreign investor – which could be a patent holding pharmaceutical company or a generic company – and a local producer were important sources of technological know-how that assisted local producers in meeting WHO Good Manufacturing Practices (GMP). For example, we analysed a case where a foreign investor authorized a local manufacturer to use the investor's trademark to sell locally produced products in the host country, in exchange for the right to benefit from the domestic producer's distribution network. The licensor of the trademark agreed to provide GMP training to the licensee to ensure the good reputation of the trademark. We found beneficial effects in terms of contractual know-how transfer in countries at very different stages of development, for example Argentina, Bangladesh, Colombia, Ethiopia, Indonesia, Jordan, and Uganda.

293. All of this being said, we have also seen in our work that the private sector in many least-developed countries and developing countries has very little capacity in understanding and negotiating a contractual license. This lack of capacity not only concerns IP licenses, but likewise contracts on research collaboration, technology transfer, joint ventures, and other transactions involving technology. To our knowledge this problem has not been sufficiently addressed by the providers of technical cooperation.

294. In our view, this represents a missed opportunity for technology transfer and foreign investment that we intend to address. We wish to promote mutually beneficial contractual arrangements. We intend to cooperate with the Medicines Patent Pool (MPP), which in informal consultations confirmed the need to build capacities in developing countries to better understand patent licenses. UNCTAD could complement the work of the MPP in that respect. In addition, we would seek to build capacities of pharmaceutical producers based in countries that are usually excluded from MPP licenses, considering that some of these countries are seriously affected by certain diseases and at the same time provide interesting markets for foreign investors. Finally, we intend to go beyond the area of pharmaceuticals and will seek to build capacities in contracts related to other areas of technology that are important to help developing countries become less dependent on commodities, such as biotechnology, agricultural technologies, and information and communication technologies.

295. Importantly, we will not address contractual licenses in isolation. Foreign investors will only engage with local producers where the latter have acquired a certain degree of technological capacity. We therefore intend to advise developing country governments on the design of appropriate IP and investment frameworks that are conducive to the acquisition of domestic technological capacity and an improved R&D framework. One example is the promotion of linkages

[14] http://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf

between public universities and R&D institutions on the one hand and the domestic industry on the other. Other examples relate to the adaptation of domestic IP frameworks to recent technological developments in big data solutions and artificial intelligence, and the design of incentives to more effectively address technology solutions for antimicrobial resistance.

296. We would like to invite development cooperation partners to approach us for further discussion.

12 LDC GROUP PROPOSAL ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT (IP/C/W/640)

12.1 Chad, on behalf of the LDC Group

297. I am making this statement on behalf of the LDC Group. The LDC Group submitted document IP/C/W/640 with a view to facilitating discussions with developed countries on the manner in which implementation of Article 66.2 of the TRIPS Agreement could be improved. The Members have preliminary talks on this submission at the February meeting of the Council. The statement is that the contribution with a view to having a more detailed discussion on the above-mentioned submission, it does not address the issue of meaning of technology transfer. Indeed Article 66.2 of the TRIPS Agreement is a very important and substantive provision for LDCs and the Group here would like to emphasize that the links between the objective for LDCs to create a sound and viable technological base within the meaning of the provisions of Article 66.1 of the TRIPS Agreement and the provision according to which developed country Members must provide incentives to enterprises and institutions to promote and encourage technology transfer to LDCs according to Article 66.2. That is why the LDC Group would like to invite developed countries to find appropriate ways to operationalize Article 66.2 in accordance with the letter and spirit of the provision. The incentives should include the establishment of an environment that will allow for technology transfer to be absorbed and secured, and direct measures to ensure the effective and voluntary realisation of technology transfer. The consequence will contribute to the development of a sound and viable technological base and so to the strengthening of the production and export capacity of LDCs.

298. The LDC Group had several bilateral meetings with developed Member countries that reported under Article 66.2. Most of these consultations gave us ideas on which the Room Document that we are distributing today is based (document RD/IP/24). The LDC Group would like to emphasize that it would be useful to have an indicative list of what could help notifications, and provide clarifications to stakeholders in LDCs. The LDC Group has already distributed this list that is a non-exhaustive list, with some Members, partners, among developed countries. In compiling the list we based ourselves upon some of the elements of developed country Members that we considered reflected the mandate according to which incentives should be given to enterprises and institutions on their territories. We added others that would help to live up to the letter and spirit of Article 66.2 with regard to the meaning of the incentives. We hope that this list could form a basis for a for a discussion within the TRIPS Council, or for a decision in the TRIPS Council. The illustrative list contains the following elements:

- The incentives to invest in enterprises that propose technology transfer for equipment and environmentally friendly methods for LDCS.

- Systems that would provide coupons to enterprises and institutions on the territory of the developed country to acquire inputs if the project of the enterprise or institution includes technology transfer to LDCs.

- A fund that would be created to stimulate investment in low-carbon emission technologies in order to contribute to the objectives and development strategies of LDCS and in the context of calls for tenders of developed countries' governments to the benefit of LDCs.

- A rating system could be used give additional points to the total score if the tender includes a technology transfer plan, including one that would, for instance, employ local experts in LDCs.

- Issue government technology licences prepared in the context of research and development projects financed by government funds to support technology and innovation in LDCs.

- Tax exemptions for enterprises of the developed country territory if the technology is transferred to LDCs.

- Technology transfer or right to transfer to LDCs when the project financed by the government of the developed country generates technologies during the implementation of a project in a LDC.

- Subsidies for risk insurance provided to projects based on technology in LDCs.

- Development of industrial cooperation programmes between the enterprises of developed countries and LDCs in order to strengthen the technological absorption capacities and technology transfer capacity and knowledge and know-how necessary for industrialisation, economic diversification and structural transformation of LDCs.

299. The LDC Group looks forward to constructive discussions within the TRIPS Council with a view to making a decision based on the proposal of the LDC Group.

12.2 Bangladesh

300. My delegation fully associates itself with the statement made by Chad on behalf of the LDC Group. Listening to the intervention and presentation made by the proponent under the Agenda item 11 we are thinking that if the LDCs had such technological base, we could have prospered like others. But unfortunately, that is not the case, and we aspire to have this, with the support of our development partners. Implementation of Article 66.2 in the letter and spirit will help us to reach that stage.

301. We follow the technical assistance projects and programmes for creating viable technology bases in LDCs and other developing countries as reported in the submissions made by developed country Members under the annual review. We believe that if these activities are supported by the measures as recorded by Article 66.2, it will help us to gradually develop a viable technological base.

302. In this context, we request the Council to examine the list and come up with a decision. We are ready to engage in any format to help to have an outcome on the implementation of Article 66.2 in an effective way.

12.3 United States of America

303. The United States appreciates the interest expressed by the LDC Members in the Article 66.2 reports. The United States is proud of the work that US agencies have conducted over the years for promoting and encouraging technologic transfer to LDCs in order to enable the creation of a sound and viable technological base.

304. Many of the programmes that the United States funds seek to help improve the commercial, legal, and regulatory environments to attract foreign investment and promote private sector-led growth and voluntary technology transfer on mutually agreed terms. By establishing commercial environments that attract and stimulate the creation of technologies that address local needs and development goals, LDCs become more attractive to innovative foreign enterprises and institutions looking to undertake voluntary technology transfer on mutually agreed terms, while also creating conditions to stimulate the creation of new technologies.

305. It is important to the United States that the programmes are as successful as possible, and the United States would be interested in learning from the LDCs that have participated in these programmes to see what policies may have been enacted as a result of the programmes, particularly at the stage of technology absorption.

306. With respect to an indicative list, such as the one included in the room document, we are concerned about limiting the breadth of the wide range of programmes we already support.

12.4 India

307. The Preamble of the TRIPS Agreement reflects a particular balance of rights and obligation and it clearly recognizes the underlying public policy objectives, including developmental and technological objectives. Article 66.2 of the Agreement is specific and it clearly entails developed country Members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members. The Doha Declaration on TRIPS and Public Health reaffirmed the commitment of developed country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country Members. We welcome deliberations here on effective and meaningful implementation, in letter and spirit of this important provision.

12.5 Norway

308. We wish to thank the LDC Group for their proposal and willingness to engage in an open and frank discussion, both in bilateral and small group meetings and through their intervention in the Council today.

309. Norway appreciates the valuable clarifications that the LDC group has provided. We are working on improving our own reporting, and intend to take the LDC Group's comments and concerns into consideration when preparing our 2018 report, due later in the year.

310. We look forward to further cooperation and discussion with the LDC Group and other Members in order to make reports on the implementation of Article 66.2 of the TRIPS Agreement as effective and transparent as possible.

12.6 New Zealand

311. New Zealand would also like to thank the LDC Group for its proposal, and for the guidance list that it has shared, and we look forward to taking the opportunity to consider these documents further.

12.7 European Union

312. The EU takes note of the document RD/IP/24 submitted by the LDC Group. The EU and its Member States take their commitments and obligations under Article 66.2 of the TRIPS Agreement very seriously, trying to make the annual submissions on technology transfer more transparent and comprehensive. Reporting on ongoing and future technology transfer projects every year, in which LDCs are among the beneficiaries, helps interested parties to be aware and benefit from these projects. It is still crucial though that the annual reports are also circulated by the LDCs in their country to make sure that it really reaches all the interested institutions and stakeholders.

313. The EU and its Member States gave proof to promptly reacting to natural, social, health, climate and economic changes by putting in place projects specifically tailored to the current needs of LDCs and their regional organizations.

314. In the annual reports it is clear that the EU actions often target groups of countries or regions. The reason is because the EU strongly supports regional integration, which fosters better understanding and political and economic links between neighbouring countries. Even more importantly, many of the problems these projects try to address do not stop at borders. That is why many technology transfer programmes of the EU and Member States target regions including both LDCs and also other developing countries. We find it counter-productive to exclude the reporting of these joint projects, as the LDC Group seems suggesting.

315. Many of the EU's technology transfer projects have an obvious regional footprint. Projects that aim at introducing an Integrated Aquaculture based on sustainable water recirculation and sanitary system for the Victoria Lake Basin, for instance, are equally important for LDCs and developing countries around the Victoria Lake.

316. It is crucial to have a common understanding what technology transfer means and includes. If we apply the well-researched definition used by the OECD in its most recent study on international technology transfer, we can say that technology transfer refers to the ways and means through which companies, individuals and organizations acquire technology or know-how from third parties, whether such technology is IPR-protected or not.

317. Technology transfer is often one component of a more complex matter, rather than a stand-alone activity. The acquisition by LDCs of a sound and viable technological base does indeed not depend solely on the provision of technology or equipment, but also on acquisition of know-how, management and production skills, improved access to knowledge sources as well as on adaptation to local economic conditions.

318. Therefore, training and education of university graduates, exchanges of qualified staff, and joint research projects must accompany the buying or licensing of IP rights related to the transferred technology. We know that the mere transfer of technology without the training of local employees does not enable the recipients to achieve the internalization of the provided technology and to reduce the technology gap with developed countries. Several projects put in place by the European Union and its Member States are accordingly aimed at providing such training and education.

319. As the OECD rightly pointed out in its recent study on technology transfer, one of the most important pre-conditions of technology transfer is the improvement of the absorption capacity of LDCs. Absorptive capacity can be defined as availability of human capital and presence of technological capability and other factors, such as good governance, access to finance and infrastructure, which helps assimilate and replicate knowledge gained from external sources. Absorptive capacity is key for diffusion of any knowledge, originating domestically or abroad, and thus for determining how technology can contribute to economic transformation and "catching-up" of a country. Together with IP protection, it can also influence technology holders' incentives to promote transfer and diffusion of knowledge. Policies aimed at improving absorptive capacity can help to remove some of the key bottlenecks to technology transfer, particularly in least developed countries.

320. Aimed at increasing the ability to absorb, internalise and utilise new knowledge, absorptive capacity policies encompass a wide range of measures addressing workforce, organisational and adjustment deficiencies. Increasing the pool of trained workforce able to understand and assimilate technology, improving the quality of higher educational institutions and scientific infrastructure as well as of networks between these educational and research institutions and enterprises, and better access to finance and efficient institutions, can all have significant impact on technology absorption, and thus stimulate technology transfer.

321. The EU questions the need for any indicative list of what would constitute an incentive to enterprises and institutions to transfer their technologies. Governments have to remain free to decide how to incentivise their enterprises to transfer technology to LDCs and other developing countries to find the most effective means. The current model, which, among others, is based on direct financial support, results in hundreds of technology transfer projects year after year, which show that the incentives system of the EU and its Member States work well.

322. The EU would rather suggest the TRIPS Council to focus on suitable policies, such as absorptive capacity improving policies or appropriate intellectual property rights protection measures that can create the environment for companies and other stakeholders to voluntarily apply and transfer their technology generating inward investment and technology transfer to LDCs.

12.8 Canada

323. Canada would like to thank the LDC Group for its proposal on the implementation of Article 66.2 of the TRIPS Agreement, document IP/C/W/640 and room document RD/IP/24 which Canada will study carefully, and for the insightful discussion on the issue of technology transfer. Canada is always interested in hearing the views of LDCs in respect of their interests and priority needs in respect of technology transfer, particularly with a view to informing our own development priorities and the incentives that are provided to enterprises and institutions for the purposes of

promoting technology transfer to LDCs in order to enable them to create a sound a viable technological base, pursuant to Article 66.2 TRIPS.

324. On this note, Canada would like to highlight the valuable exchanges that take place during the annual WTO workshop on the implementation of Article 66.2 TRIPS, which provides a useful opportunity for LDCs and developed country Members to exchange experiences and priorities in this area. Canada views the annual workshop not only as an opportunity to present on developed countries' annual reports on the implementation of Article 66.2, but also to arrive at a clearer understanding of LDCs' specific technology transfer priorities and sectors of interest, as well as notable projects and best practices in this area.

325. Further to the LDC Group proposal to deliberate on the meaning of "incentives to enterprises and institutions", the annual workshop could provide a venue to draw commonalities and best practices from developed countries' annual reports, with a view to better informing Members of how future incentives and projects in the area of technology transfer might best respond to LDCs' evolving priorities and needs. As the annual workshop will be held on the margins of the next TRIPS Council meeting in November 2018, it would serve as a useful opportunity for further practical and evidence-based discussion on these issues. Canada is open to discussion with any interested Members on how the workshop can be enhanced in this regard.

326. Canada also takes note of the interest expressed in the LDC proposal to interpret the meaning of "incentives" under Article 66.2, such as with regard to conditions for contracts tendered by governments. Canada would like to reiterate that governments may be limited in the extent to which technology transfer can be required on a contractual basis, and that Canada's longstanding position has been to encourage technology transfer on voluntary and mutually-agreed terms. Nonetheless, and without prejudice to Canada's position on this issue, Canada would be interested in further information from LDCs on this proposal, including specific examples of how contractual requirements have been used to facilitate technology transfer, as well as any best practices in this area.

327. At the same time, while noting the interest in deliberating on the meaning of "incentives", it is also important not to lose sight of the outputs of technology transfer, specifically in how specific initiatives meet LDCs' needs and priorities. In addition to the specific incentives provided, we are also interested in getting a clearer indication of LDCs' priority sectors and technologies, in order to ensure that these priorities are integrated into the types of incentives, projects, and initiatives that Canada supports in promoting international development.

328. Canada also takes note of the LDC proposal that developed countries' Article 66.2 reports "only specify incentives provided to least developed countries for technology transfer". Canada is always open to suggestions from LDCs on how to make our annual report more targeted and clear, while also ensuring that the report provides a comprehensive overview of the range of incentives provided on this issue. We note, for instance, that Canada's annual report follows the format proposed by LDCs in the context of the 2011 document IP/C/W/561, and remain open to further discussion on the reporting format in view of providing the most useful and informative information, pursuant to Article 66.2.

329. Canada would once again like to thank the LDC Group for its proposal, and for the views shared on this issue. We remain open to discussing with any interested Members following this meeting of the TRIPS Council, including in view of the upcoming workshop on this issue in the fall in the margins of the next TRIPS Council meeting.

12.9 Australia

330. We thank the LDC Group for its proposal and its recent room document with an illustrative list of incentives. We will consider further the informal document on incentives, we note that Australia takes its obligations under Article 66.2 very seriously. With respect to the point raised in the proposal in paragraph 3, we think only including in our Article 66.2 report incentives which relate to technology transfer exclusively to LDCs would not be an accurate picture of Australia's implementation of Article 66.2. For example, we provide incentives for technology transfer to the ASEAN region, which includes both developing countries and LDCS.

331. From our perspective, even if the incentive also led to technology transfer to developing countries, it would still be relevant to co-recipient LDCS under Article 66.2. We continue to see forums, like the Article 66.2 workshop as the kind of forum more suited to questions regarding approaches to reporting on Article 66.2.

12.10 Switzerland

332. We would like to thank again Cambodia and the LDC Group for its communication in IP/C/W/640, circulated prior to the first Council this year. We take note of the background information and the proposal for the TRIPS Council to deliberate and make some decision in favour of LDCs. We also had a first look at the paper with some ideas about incentives and will need to study this in more detail.

333. Switzerland acknowledges that the implementation of Article 66.2 of the TRIPS Agreement poses a number of challenges. Over past years, this has also lead us to re-analyse our commitments under the said article and our yearly reporting following the TRIPS Council decisions in 2001 and 2003.

334. The issues raised in the LDC Group's paper are not new, and some of them have been discussed before, also on the occasion of the yearly workshops organised by the Secretariat the day before the third TRIPS Council every year. The discussions held in the workshop format between LDCs and developed country Members, including the Q&A exercise, resulted in a number of modifications and improvements of developed countries' reports under Article 66.2 over the years.

335. Responding to the proposals made in document IP/C/W/640, Switzerland does not think that it would be useful, or possible, to restrict the measures and the reporting to incentives for technology transfers which are exclusively directed at least developed countries. There are a number of significant governmental incentives and programmes for enterprises and institutions which are for the benefit of a group of countries or a whole region, which may cover both least developed countries as well as middle-income countries.

336. We do not think that such incentives and programmes should be left out of the reporting. This is probably a particular concern of smaller countries like Switzerland which do not have the capacity to engage in each and every LDC and middle-income country. For example, a number of technical assistance programmes are organised as global programmes. Tracking of funds to individual countries can be difficult in those cases.

337. It does not seem appropriate to exclude all such incentives or programmes solely because they are directed at enabling technology transfer to both specific LDCs and middle-income countries. They need to be taken into account also and should be duly reflected in the reports.

338. We agree with the LDC Group that the reports should whenever possible specify the LDCs targeted by incentives and programmes, i.e. specify the beneficiaries of technology transfers enabled by specific incentives.

339. As for the LDC Group's request to deliberate on the meaning of "incentives to enterprises and institutions", set out in document IP/C/W/640, we also have some reservation. Switzerland believes that the intention of the Member states when drafting Article 66.2 of the TRIPS Agreement was to keep the mandate rather broad and not to exclude specific incentives or entities from the mandate.

340. We are looking forward to continuing this dialogue also in the workshop prior to the next Council. There, specific concerns relating to incentives can be further discussed.

12.11 Japan

341. While not necessary to mention, the delegation of Japan recognizes the importance of Article 66.2 of the TRIPS Agreement for LDCs, taking into account their economic, financial and administrative constraints.

342. This delegation understands that incentives to achieve technology transfer include a variety of measures including such as financial support and business infrastructure arrangement and so on, because one of the major obstacles for enterprises and institutions to transfer technologies to LDCs, is lack or insufficiency of sound or comprehensive business environment in LDCs.

343. In particular, a lack or insufficiency of IP systems hinders enterprises and institutions from transferring their technologies to LDCs. Therefore, supporting the business environment of LDCs by strengthening the protection of IP is one of the effective ways to advance technology transfer by enterprises and institutions.

344. In this context, this delegation believes that activities noted in the Japanese Article 66.2 report contribute to creating a sound and viable technological base in LDCs, which will also encourage and bring further technology transfers by enterprises and institutions.

345. This delegation thanks the LDC Group for preparing the room document with ideas of incentives. We need to have time to consider it carefully. Nevertheless, at this moment, we have a general concern that the list might rather limit the implementation of Article 66.2.

346. Japan will continue to make its utmost efforts to improve business environments in LDCs so that they can become even more conducive to transferring technology. This delegation looks forward to meaningful discussions in this Council or the annual workshop designated to the discussion of Article 66.2, as opportunities for working further with LDC Members in this context.

12.12 Brazil

347. Article 66.2 is part of the delicate balance of rights and obligations reached by the TRIPS Agreement. One of the expected benefits to LDCs of becoming Party to the Agreement is precisely this clause. We thus recognize the importance of this discussion, which benefits from the insightful views expressed here today.

348. Brazil takes note of the Room Document, which will be conveyed to our capital for further analysis. We hope to come back with comments at the next session.

349. In the meantime, we urge delegations to continue their consultations in order to address the issue in the best possible way.

12.13 Nepal

350. I join the statements delivered by Bangladesh and Chad on behalf of the LDC Group. My delegation wishes to thank the developed country Members who have provided technical and financial supports to the LDCs in the areas of capacity development, trade and economic development.

351. Article 66.2 of the TRIPS Agreement clearly states that developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base. The provision is obligatory. It is very clearly written and does not bear ambiguous meaning. The three words "shall", "incentives to enterprises" and "LDCs" are very important.

352. Similarly, the Doha Declaration on TRIPS and Public Health reaffirmed the commitment of developed country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to LDC Members.

353. Since 1995, LDC Members have been continuously raising the concerns about an ineffective implementation of Article 66.2 of the TRIPS Agreement and are requesting for its effective implementation in letter and spirit. The notifications and reports of developed country Members do not provide specific information on the incentives provided to their enterprises and institutions to transfer technology to LDCs.

354. It is very important to note that Articles 66.1, 66.2 and 67 are linked to each other. If we do not implement Article 66.2 effectively and meaningfully in letter and spirit, the enhanced transition period under Article 66.1 does not yield any outcome. Similarly, Articles 66.2 and 67 have a complementary relationship. The support provided under Article 67 including training, could create the foundation and enabling environment for technology transfer to LDCs as they lack necessary capacity to transfer technology. In this context, effective implementation of Article 66.2 is fundamental.

355. LDCs, the most vulnerable segment of this august house, are the least integrated into the MTS. Sustainable development depends on mutually reinforcing actions across the social, economic and environmental dimensions of development. The technology transfer could play a significant role in achieving SDGs which are our shared commitments. Without rapidly building up capacities in Science, Technology and Innovation (STI), the goals of eradicating widespread poverty, removing structural constraints and unleashing sustained growth and achieving sustainable development in LDCs could not be achieved.

356. Finally, once again my delegation acknowledges the efforts and support provided by developed country Members so far. For the better outcome, the continuous dialogue, brainstorming and experience sharing between the LDC and developed country Members could provide specific and better ideas. Such discussions and experience sharing could be supportive in developing a framework or mechanism in technology transfer. Incentives to enterprise or institutions to transfer technology could be tax exemptions, felicitation and recognition to the enterprises and so on. We request developed country Members to consider the LDC proposal on the implementation of Article 66.2 of the TRIPS (IP/C/W/640) and to provide specific reporting.

12.14 Bangladesh

357. Thank you to all Members who have intervened on this matter. The implementation of Article 66.2 has been under discussion for the last twenty years and progress was made regarding the implementation of Article 66.2. Every year we have the annual review, we pose two questions: please inform us about the incentives you are providing to enterprises and institutions. We then find out whether these are LDC-specific or not. Every time, we are asked to submit written questions, and we are used to getting these answered in the next annual review, and we have seen that the answers are similar. That is why we have come with our proposal, to better understand what do we mean by the incentive to the enterprises and institutions in the territories of developed countries, that is, to the spirit and the letter of Article 66.2.

358. As we mentioned earlier, all these technological projects and programmes reported under the Article 66.2 Annual Review are very useful to create a viable technological base - we are not trying to limit the submission - but we want to actually focus on Article 66.2. Our understanding is that several elements are present in technical innovation, that is scientific knowledge, physical objects, production know-how, training, etc. We understand that there are several means by which we can transfer technology and you are focusing on these technical assistance projects which are very important, but Article 66.2 specifies one type of means, that is the incentive to the institution or enterprise in your territory, so that is what we want to address.

359. I understand that whatever the legal interpretation, it is said that this incentive should be specific to LDCs and that is why we have made this proposal in paragraph 3. The drafter of the TRIPS Agreement in the Uruguay Round promoted this Article in such a way that it should be directed towards LDCs and it should be the incentive to the enterprise and institution in develop country territories, that is the way it was drafted. From our understanding we thought that that should be reported, but we never ignored that technical assistance projects which have been chosen do impact on creating a technological base in our countries. We don't want to limit that one, but wish to focus on incentives. We have tried our best to identify from the reports which projects could constitute incentives to the enterprise. Every report is long, as the Secretariat has already mentioned, it has already become 5,000 pages of annual reports. We tried to identify which could constitute the incentive within the meaning of Article 66.2. If you look at our proposal, we have tried to bring some elements from those reports which we thought are incentives, that is what Article 66.2 is looking for. That is why we thought it could be useful to discuss here the illustrative list. We don't want to restrict the list with these elements, but it is our thought that through discussion we can actually modify that one or this one. We put our thoughts in our room document, and we want to discuss that one and how develop countries want to implement it. We

have an illustrative list which could support implementation and that is why actually we wanted to have a useful discussion to have an idea which we could consider that would be in line with Article 66.2.

360. What we can request to the Members is that they let us have a discussion on the list and how we could actually implement Article 66.2 in letter and spirit. But again I want to emphasize that we always allow the technical assistance projects, all these projects which are directed towards creating a viable technological base in our country. But let me say something about Article 66.1 and Article 66.2, their linkage. Article 66.1 says that LDCs should have a different period, until they develop their viable technological base. Article 66.2 then says that we need to do something so that LDCs can create a viable technological base, so this is the link. It is important that we create a viable technological base through the implementation of Article 66.2 and other technical assistance projects you referred to in your reports of the Annual review of Article 66.2.

12.15 Chad, on behalf of the LDC Group

361. I would also like to support what Bangladesh has just stated and clarified. On behalf of the Coordinator of the LDC Group I would like to thank Members for their support, and we can clearly see the importance of Article 66.2 of the TRIPS Agreement for LDCs as Members have all recalled, the significant challenges and restrictions that LDCs face. I think the effective implementation of this Article could help us to reduce these obstacles for LDCs. The Group of LDCs really does take note of the questions and observations raised by the Members, Canada, Australia, the European Union, United States, Switzerland and other Members. We will come back as soon as we possibly can to provide even further clarifications with regard to the concerns expressed. The group of LDCs remains always open, flexible and constructive in its approach.

13 INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: PROMOTING PUBLIC HEALTH THROUGH COMPETITION LAW AND POLICY

13.1 South Africa

362. On behalf of the co-sponsors in respect of IP/C/W/643 and Add.1, we are honoured once again to introduce this very important *ad hoc* topic, which we have been able to sustain over the last few TRIPS Council meetings. Today's discussion focuses on Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law and Policy. Members will recall that when we first addressed the issue, we had done so through the introduction of the High-Level Panel Report on Access to Medicines which investigated the relationship between intellectual property, access to health technologies, incentives for research and development and the opportunities to the strengthen governance accountability and transparency. In the process, we have looked at various flexibilities that are imbedded in the TRIPS Agreement, I will not go through all of it, the paper was circulated to Members (documents IP/C/W/643 and IP/C/W/643/Add.1) but I want to concentrate for a few minutes on the purpose of today's discussion, and that is competition law.

363. Competition law is one of the least-discussed flexibilities within the WTO TRIPS Agreement. The fundamental objective of competition law is to protect the integrity of competitive markets against abusive conduct and to protect consumers from the effects of such conduct. Even though TRIPS sets minimum norms for standards of IP protection that significantly limit Members' discretion on a large number of IP rights issues, it is not the case with competition law. Members are free to design competition laws in a way so as to take account of their domestic interest and needs, including their respective levels of development, subject only to the natural limits defined by the territorial limitations of such laws.

364. Various other provisions of the TRIPS Agreement are relevant to competition law including Article 6, Article 31(k) and Article 40. As such, these provisions leave broad discretion to Members in how they apply competition law in respect of the acquisition and exercise of IP rights. Article 6 of the TRIPS Agreement authorizes Members to allow parallel importation of health technologies, a major pro-competitive form of activity that can be used to secure the lowest priced products available on international markets. Article 31(k) of the TRIPS Agreement confirms the right of Members to use such licences as anti-competitive remedies. The only condition required by

Article 31(k) for the grant of this type of compulsory licence is that anti-competitive practice needs to have been determined through a judicial or administrative process.

365. The possible use of compulsory licences to deal with anti-competitive practices as explicitly recognized in Article 31(k) of the TRIPS Agreement is of particular importance to protect public health in cases, for instance, of excessive pricing of health technologies or refusal to grant licences on reasonable commercial terms. The sponsors of this communication urge Members to share their national experiences and examples of how competition law is used to achieve public health and related national objectives.

366. The debate and information exchange could serve to enhance understanding of Members' various approaches to the use of competition law and policy to prevent or deter practices such as collusive pricing or the use of abusive clauses in licensing agreements that unreasonably restrict access to new technology, prevent the entry of generic companies and may result in higher prices for medicines. The issue of abuse of IP rights remains relevant in the context of the application of national and regional law regimes. We have framed the debate by posing certain questions, such as: what grounds are available in national laws to pursue competition law and policy to achieve our public health outcomes; what are the difficulties faced by WTO Members when using competition policy to prevent or deter abusive practices; whether unreasonably high royalties may deter the transfer of technology; what policies of Members established to deal with the technology pricing and other aspects of transfer of technology transactions; and whether or not compulsory licences have been used by competition authorities in some countries to restore competition in cases involving the exercise of IP rights.

13.2 South Africa

367. I will continue in my capacity as the representative of South Africa, and share some experiences from the viewpoint of South Africa.

368. South Africa has a proud history of robustly engaging with issues that concern the intersection between IPRs and public health. Indeed, the South African government's stance in the case between the Pharmaceutical Manufacturers Association versus the President of South Africa (the late President Nelson Mandela) in 1998, was a key factor leading to global dialogue around the potential negative impacts of intellectual property rights on public health, culminating in the Doha Declaration on TRIPS and Public Health.

369. South African law reflects the principles embodied in the TRIPS Agreement and the Doha Declaration in particular with regards to the measures that Members may implement in domestic legislation to protect the public against the abuse of patent rights and monopolies. However, the practical implementation of the provisions that give effect to the TRIPS Agreement, have not been effective in protecting the public against patent monopolies and ensuring that the public has access to essential medicines, at affordable prices.

370. Competition policy in South Africa, as reflected in the preamble to the Competition Act 89 of 1998 (Competition Act) seeks to address, amongst other things, inadequate restraints against anticompetitive trade practices and unjust restrictions on full and free participation in the economy by all South Africans. It thus aims to open up the economy to greater ownership by a larger number of South Africans in order to attain an efficient, competitive, economic environment, one that balances the interests of workers, owners and consumers, and focuses on the development of all South Africans. This is accomplished by preventing cartels aimed at price-fixing, limiting output or otherwise restricting competition, by preventing firms from gaining market power in unjustified ways, including through anticompetitive mergers, thus raising barriers to market entry by new firms. Competition policy is also concerned with preventing firms with market power from abusing their dominant positions, including by charging excessive prices to the detriment of consumers. The role of competition authorities is therefore to ensure markets function efficiently and to the benefit of both consumers and producers.

371. South Africa has a well-developed competition regime based on best international practice. Even though our economic system is mainly based on free market principles, competition is regulated by statutory-created competition authorities, namely the Competition Commission, the Competition Tribunal and the Competition Appeal Court. The Competition Act became effective on

1 September 1999. It fundamentally transformed South Africa's competition legislation and substantially strengthened the powers of the competition authorities. Unlike some foreign jurisdictions, South African competition law focuses not only on pure competition law matters, but also addresses pertinent public interest and social objectives.

372. Both competition law and patent law together can be used to implement competition-related TRIPS flexibilities and advance consumer welfare. Chapter 2 of the Competition Act covers practices such as horizontal restrictions, vertical restrictions, and abuse of dominance, and various licensing provisions in the Patents Act. Horizontal agreements such as price fixing, market division and collusive tendering are prohibited *per se*, without requiring a showing of actual harmful effect or permitting a showing of net efficiency.

373. The Competition Act also prohibits price discrimination: in relation to prices broadly, discounts, rebates, allowances, credits, services, or payment terms, for products or services. Again, market power is a prerequisite – only a dominant firm acting as a seller can be liable. Liability is subject in all cases to a competitive effects test: is the discrimination likely to have the effect of substantially preventing or lessening competition?

374. In line with the general approach to South African competition law and policy, it is accepted that certain anti-competitive conduct may be required to achieve broader industrial and macro-economic goals which is set out in Section 10(3)(b) of the Competition Act. The Competition Act therefore provides a mechanism whereby a party or parties can apply for an exemption from prosecution in certain cases. What is inferred from section 10(4) is that the legislator intended for the current Competition Act to extend to the exercise of intellectual property rights and that an exemption is required for certain intellectual property rights in order to achieve these broad industrial goals.

375. The South African Competition Commission has not issued specific guidelines on the application of the Competition Act to IP. However, it has explained its general approach in that firms are not automatically exempted from the rules of the Competition Act as a result of the rights granted in terms of laws like the intellectual property laws. This means that firms cannot be allowed to automatically continue with a particular prohibited practice as outlined in the Competition Act because that practice is allowed by another Act. It has taken the view that conflicts between intellectual property rights and competition mandates should be resolved according to the extent to which the "long-term pro-competitive benefits" of a practice outweigh its "short-term 'anti-competitive' effects." The Competition Commission has thus analysed this conflict by considering the following factors:

a. Competition law should recognize the basic rights granted under intellectual property law. The creation and maintenance of innovation markets are necessary for economic progress and development.

b. Intellectual property does not necessarily create market power.

c. A practice involving intellectual property should not be prohibited if the practice leads to a less anti-competitive situation than without the said practice.

d. The long-term pro-competitive benefits should outweigh the short-term 'anti-competitive' effects of intellectual property rights.

376. I leave it at this and would invite other proponents to share their perspectives, as well as, other Members of this house.

13.3 Brazil

377. I would like first to thank China, India and South Africa for co-sponsoring document IP/C/W/643. The communication builds on document IP/C/W/630, with the goal of expanding the discussions on the complex interplay between intellectual property and public interest. The debate of the relation between intellectual property and competition lies at the heart of the IP system and is certainly of interest to this Council.

378. In economic terms, the temporary exclusivity on the market granted by a patent is expected to generate long-term dynamic pro-competitive innovation at the cost of short-term anti-competitive effects. Considering this theoretical background, policymakers strive to design an efficient and balanced patent system, avoiding a situation in which patents or other intellectual property rights lead to inefficiencies, high prices or the under-provision of goods.

379. The Brazilian Constitution establishes an explicit foundation for competition policy. Article 170 states that the "economic order" of Brazil shall operate with "due regard" for certain principles, including "free competition," "the social role of property," "consumer protection," and "private property."

380. One way to pursue competition law and to achieve health outcomes is to prevent illicit conducts such as cartels and illegal unilateral conducts. Another way is to prevent the formation of undue mergers in the pharmaceutical sector.

381. Our competition authority is CADE, the Administrative Council for Economic Defence. It has recently concluded an investigation of a cartel in the segment of implantable cardiac pacemakers. The companies involved were being accused of facilitating and promoting the adoption of anticompetitive practices, including through price collusion. Due to the violation of the economic order, fines totalling approximately R$ 6 million were imposed.

382. By investigating and punishing cartels, CADE prevents this kind of practice, decreasing the price of medicines and medical products that were artificially high due to anticompetitive practices. This helps to achieve public policy goals by making health services more accessible.

383. Specifically to intellectual property, I would like to provide an example of how IP rights may be used in an anticompetitive way. The case was initiated during the years 1990s but only concluded in the 2000s due to the complexity and the tactics of the company. The defendants were accused from abusing exclusive market rights in relation to a medicine called Gemcitabine. Gemcitabine, sold under the brand name Gemzar, is a chemotherapy medication used to treat different types of cancer. These include breast cancer, ovarian cancer, non-small cell lung cancer, pancreatic cancer, and bladder cancer.

384. The patent was initially filed in the United States in 1983 and was approved for medical use in 1995. The company filed the patent in Brazil in 1993 for the production process of the substance, as the compound itself was not novel by then. Since our pre-TRIPS legislation did not provide for the protection of pharmaceutical products, the company requested that the mechanism provided in Article 70.8 TRIPS be applied. However, the patent did not relate to a product, only to a process, thus being outside of the scope of Article 70.8.

385. After Brazil's patent office had rejected the patent application, the company tried to transform its limited "process patent" into a "product patent" application, through an amendment to the original patent application.

386. Additionally, the company requested to one federal judge the suspension of the INPI decision process. To a second federal judge (who was unware of the first request), the company complained that INPI was excessively delaying a final decision in her case. Because of that, it asked for protection under Article 70.9 TRIPS, which provides that, until a product patent is granted or rejected by the procedure established in Article 70.8, the company or the individual has, for the period of 5 years, exclusive marketing rights. The only problem, in this case, was that the delay was caused by the company itself.

387. Unaware of the request to suspend the processing of the patent application, the second federal judge granted exclusive marketing rights for Gemcitabine when used to treat a specific kind of cancer. Not satisfied with this result, the company went to a third judge and claimed unrestricted exclusive marketing right for all kinds of cancer, well beyond the scope of the original decision. An injunction was granted, extending the protection for eight additional months, blocking a generic competitor from offering the drug in the meantime. The result is that during that period the price of the drug in public bids was more than double the price offered by the same company when the injunction was rejected (from 540 reais or US$144 to 189 reais).

388. That is why CADE understood that the company abused her exclusive rights and was liable for "sham litigation". CADE imposed a fine of 36.6 million reais or US$10 million dollars. There was no need to issue a compulsory license in this case, as the defendant did not have any legal and valid patent. This Antitrust Law decision is important not only for this case, but also to signal to other enterprises that this kind of illicit strategy will be punished in the Brazilian Juridical System.

389. In this respect, it is important to underline that Brazil never used Article 31(k) TRIPS as a remedy for an anticompetitive practice. While the single case of a compulsory license issued in Brazil did involve a medical product, its issuance was based on public non-commercial use to treat HIV patients.

390. 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 of the TRIPS Agreement contain clear language regarding the relationship between public interest and the protection and enforcement of intellectual property rights. Further, Articles 31(c), 31(k) and 40 of the Agreement recognize that the exercise of intellectual property rights may entail anticompetitive effects.

391. In the field of medical products, it is of particular importance to assure that the exclusive right granted to the patent, trademark or other right holder does not become itself a hindrance to technological innovation and access to medicines.

392. Past government reports in the pharmaceutical sector have shown that the anticompetitive use of patents not only reduces the welfare of society by restricting access to off-patent medicines, but also affects innovation activities in the pharmaceutical sector, impacting the generation of new life-saving medicines. Regardless of each Member's level of development, it must be stressed that competition law is essential to ensure that the intellectual property system works properly and fulfils its goals.

393. We hope this document fosters the debate about TRIPS and its relationship with competition law. The cases and examples mentioned today are part of a non-exhaustive list of what happened in Brazil, in relation to competition law and public health outcomes. We invite other delegations to join the debate, allowing us to have a rich exchange of views and experiences.

13.4 China

394. During the meetings of the TRIPS Council in 2017 and 2018, Members were actively involved in the issue of intellectual property and the public interest and good results have been achieved. China believes the protection of intellectual property rights should contribute to the mutual advantage of producers and users and to a balance of innovation and public interest.

395. With regard to the relationship between intellectual property and competition, China's anti-monopoly law clearly stipulates that this law is applicable to the conduct by undertakings to eliminate or restrict market competition by abusing intellectual property rights.

396. We believe that the scope of the use of intellectual property rights is not borderless. Intellectual property right holders shall not use intellectual property to restrict or hinder competition.

397. But we also make sure that intellectual property rights are well protected within the scope of the laws and regulations. In the anti-monopoly of China, it is also clearly stipulated that this law is not applicable to conducts by undertakings to implement their intellectual property rights in accordance with relevant intellectual property laws and administrative regulations.

398. China thinks that competition and the protection of IP rights do not oppose each other, instead they have common goals. These are promoting competition, enhancing innovation, protecting consumers and safeguarding public interest.

399. In 2015, the former State Administration for Industry and Commerce formulated the "Regulation on the Prohibition of Conduct Eliminating or Restricting Competition by Abusing

Intellectual Property Rights". This regulation is more detailed and is made to implement principles of the Anti-Monopoly Law.

400. Finally, China believes the discussion on intellectual property and public interest should be open and inclusive. Members could exchange views and experiences on how to take advantage of flexibilities in the TRIPS Agreement, including the competition law and policy.

13.5 India

401. I would like to support the statements made by South Africa, Brazil and China. In India, we have specific IP legislations (namely Patents Act 1970, Trademarks Act 1999, Copyright Act, GI Act etc.) where anticompetitive concerns have also been dealt with. In addition to this, the Competition Act 2002 as a general act keeps track of every market-unfriendly activity cropping up in Indian markets. As both sets of legislation (IP legislations and Competition Act 2002) have the jurisdiction and power to deal with IP cases, therefore, both laws determine the manner in which the anticompetitive issues relating to IP are to be resolved.

13.6 Indonesia

402. Indonesia welcomes the inclusion of this agenda item in the TRIPS Council and supports the discussion in the Council for TRIPS of the relationship between IP and Public Interest, especially with regard to the issue of public health and competition policy. As Members are all aware, the TRIPS Agreement sets minimum standards of IP protection, including the issue of competition related to public health. Members have the right to design their own policies in accordance with domestic needs and interests.

403. The legal basis to deal with monopolies and unfair competition Indonesia has Law No. 5 of 1999 concerning the prohibition of monopolistic practices and unfair business competition. It states that this is an unfair business competition and contains specific and comprehensive rules governing competition among business actors.

404. Article 3 states that the basic objective of Law No. 5 is to safeguard the public interest and improve the efficiency of the national economy in order to better the welfare of the public. Indonesia has an independent enforcement agency to enforce the law, i.e. the Commission for the Supervision of Business Competition, Komisi Pengawas Persaingan Usaha (KPPU). Related to intellectual property, Law No. 5 provides exemption from its scope concerning intellectual property rights, trade secrets and franchises.

405. The provision is not an absolute exemption from the existing prohibition. The exemption provision must be viewed in the context of the following:

- intellectual property licence agreement is not automatically leading to monopolistic practices and unfair business;
- monopolistic practices and unfair business arising from the implementation of intellectual property licence is a condition which can be prevented through competition law;
- in order to apply the competition law to the implementation of intellectual property licence agreement, it must be proven that 1) the intellectual property licence agreement is consistent with the law and 2) that there are conditions indicating a monopolistic practice and unfair business.

406. Finally, Indonesia will take the opportunity to support South Africa, China and India as the proponents of this agenda item. Therefore we propose that this agenda item be maintained for the next meeting of the TRIPS Council, especially with regard to the session on IP and Public Interest, including the sharing of experiences regarding the utilisation of flexibilities of the TRIPS Agreement by Members.

13.7 United States of America

407. The United States welcomes the opportunity to participate in this discussion and share our views on intellectual property, competition, and the importance of prudently applying competition law in appropriate circumstances.

408. The United States has long held that IP 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 maximize these benefits. We are concerned, based upon the cosponsors' concept paper and some interventions, that this agenda item could discuss "public interest" in a way that fails to account fully for the benefits of protecting IP.

409. One potential negative consequence of an insufficiently nuanced discussion could be to discourage Members from striving towards and upholding robust domestic IP regimes, harming incentives for critical future innovations that would greatly benefit the public.

410. The United States fully believes that "the intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare."[15] We also recognize that intellectual property and competition are distinct disciplines implemented and overseen by different administrative authorities. The TRIPS Council is not the ideal venue to have detailed discussions of competition law and policy concepts.

411. As we will describe in more detail below, the misapplication of competition law is particularly concerning in IP disciplines because it runs the risk of forestalling future innovation. As such, antitrust enforcers should strive to eliminate as much as possible the unnecessary uncertainties for innovators and creators in their ability to exploit their intellectual property rights, as those uncertainties can also reduce incentives for innovation. Innovative firms pay close attention to both IP and competition laws in foreign markets when determining where to invest and partner. If competition law is misapplied in the IP context it runs the risk of discouraging the high-value R&D and manufacturing that many Members seek to attract and promote.

Co-sponsor references to outside research

412. The belief that intellectual property and competition laws can coexist and share common purpose is not unique to the United States, and, in fact, can be found in the trilateral WTO, WIPO, and WHO study on IP and Public Health cited by the cosponsors.

413. I would like to draw your attention to two points in the Trilateral Study that are not included in the cosponsors' submission:

- "Openness to international trade generally promotes competition, and offers improved affordability and access. By enabling a wider range of suppliers to serve the population, it can also enhance security of supply."

- "In the area of innovation, the aims and effects of IP protection and competition policy can be complementary: both are aimed at fostering innovation by creating incentives to develop new products as an advantage over competitors. IP protection for novel medical technologies is generally considered to be an important means of promoting investment in R&D of new medical technology. This leads to competition between different originator companies with regard to the development of valuable new medical technologies, and therefore with regard to their earlier production and availability. This form of competition is generally not hindered by IPRs, rather it is enhanced by them."

414. The cosponsors also invoke the 2030 Agenda for Sustainable Development, in particular Sustainable Development Goal 3. It is important to note that nowhere in the 2030 Agenda is competition law or policy prescribed as a way to achieve the SDG targets. In fact, misapplication of competition law to IP cases could make it more difficult to achieve certain goals, such as ending communicable diseases, promoting newborn and infant health, and supporting the research and development of vaccines and medicines, as we do not currently have all of the health technologies needed to fully address these challenges.

415. With respect to the UNSG High-Level Panel Report (HLP) on Access to Medicines, as the United States explained in previous statements, we were deeply disappointed by the Report, which detracts from, rather than advances, the critical objectives of identifying practical ways both to increase access to safe effective, affordable, and lifesaving medicines around the world and to support policies that drive the development of new medicines. I remind the Council that the HLP

[15] "Antitrust Guidelines for the Licensing of Intellectual Property" (DOJ, FTC), 1 December 2017.

Report lacked consensus among panelists and note that the Report included the following statement from one panelist that is relevant to today's discussion: "without innovation, there will be no new tools for public health needs, new pandemics, and AMR. There are already precious few diagnostics, vaccines, and medicines that can address these menaces and limited sources to support research into basic biology that underpins them. It would be unwise to set into motion activities or policies that further choke innovation, placing large populations at risk and contradicting the core principles under which the HLP was convened."

416. As the United States and many other Members have explained during past TRIPS Council interventions, the vast majority of medicines on the WHO's Essential Medicines List are not patented, yet remain out of reach for many patients.

417. By focusing on IP-related competition issues, China, South Africa, India, and Brazil have asked the TRIPS Council to focus on governmental tools that, if misapplied, could threaten innovation, while ignoring the barriers that affect medicines that are without patent protection.

US policy on IP and competition

418. The United States believes innovation is key to sustained economic growth. It benefits consumers through the development of new products, processes, and services that improve lives and address unmet needs. At the same time, innovation is complex and risky. Intellectual property rights are necessary to promote innovation in the face of that risk. Likewise, competition drives firms to create new or better products in these complex environments. As a result, the US believes in strong intellectual property rights and market-based competition to promote economic development.

419. It is important to keep in mind what patents can do and what they cannot. The granting of a patent does not confer automatic commercial success or market share—in fact the vast majority of patents in the United States are either never commercialized or fail to achieve a profit for the patentee. A patent may exclude others from making or selling the same invention, but does not prevent others from finding novel ways to achieve innovative solutions to common problems. It is for this reason that there are not one, but several, patented medicines on the market to cure or treat certain illnesses, such as heart disease or arthritis.

420. Furthermore, one of the important benefits of the patent system is the disclosure of a written description of the invention and manner and process of making and using it, so as to enable any person skilled in the technological area to which the invention pertains to make and use the same. This disclosure helps to ensure that upon expiry of a patent, others have the means to quickly enter the market, which, in turn, provides consumers with more, and often cheaper, products.

421. Given these and other benefits of the patent system, of particular concern to the United States is the possibility that competition laws could be used as a means to gain access to desirable intellectual property rights or regulate royalties in order to advance broad social or political goals that could undermine free market competition. When a competition authority favours one competitor over another through the forced sharing of IP rights, or the regulation of royalty payments, it can diminish or remove crucial incentives to innovate because exclusive property rights or the benefits of being first-to-market are eroded. This innovation disincentive can hurt consumers, who will no longer benefit from newer and higher quality products or services. We believe that reliance on market-based pricing and unilateral freedom to choose whether to license IP, and if so, to whom one will license, leads firms to efficient investment in R&D because they know there is a chance of recoupment. Therefore, we disagree with the cosponsors' submission as to where it suggests that excessive pricing provisions of competition laws should be used to gain access to medicine.

422. The competition issues raised in the submission, such as liability for excessive pricing and the use of compulsory licensing remedies, have been debated in more competition-focused international organizations such as the OECD and the International Competition Network (ICN). As these raise competition, not IP issues, those are more appropriate venues than the TRIPS Council to address such issues.

423. The United States does not regulate "excessive pricing" under US antitrust law and we have encouraged jurisdictions that have excessive pricing laws to refrain from applying them to IP rights, which are designed to promote innovation through, among other things, investment in R&D. Antitrust enforcers who impose liability for pricing "too high" may deter R&D investment because they supplant market-based forces with an artificial cap.

424. We believe it is also important to consider that it is not illegal merely to have market power or a monopoly; many monopolists obtained their position by creating better, cheaper, more attractive products. This system promotes innovation because it incentivizes first-entrants to develop the best product. It also creates incentives for rivals or new entrants drawn by the lure of large rewards.

425. A related point is that the US Antitrust Agencies do not rely on a presumption that an IP asset conveys market power. The exercise of an IP right does not necessarily create market power or a monopoly. There will often be sufficient actual or potential close substitutes for a product, process, or work to prevent the IP owner from obtaining market power. This point has been recognized by the US Supreme Court. Many jurisdictions recognize this fact and have adopted this principle that IP ownership does not necessarily create market power in their own IP-competition guidance (including China).

426. As China, South Africa, India, and Brazil point out, TRIPS acknowledges the application of competition law in Article 40. The US Antitrust Agencies' focus is on evaluating whether specific conduct harms competition. Firms might, for example, engage in anticompetitive exclusion through collusive agreements that unlawfully limit entry into a market, which may result in higher prices than would have been the case in a competitive market. The focus is not on whether a drug's price is too high or particular royalties for a pharmaceutical patent are unreasonable, but rather on evaluating the effect of conduct. This keeps the focus of competition enforcers where it should be—on protecting the competitive process.

427. In addition, the US Antitrust Agencies have also urged caution in the reliance on compulsory licensing remedies. We recognize that the core right to exclude (as discussed in Article. 28) promotes innovation. Indeed, choosing not to share an intellectual property right is a form of exercising that exclusive right. Thus, the US Antitrust Agencies ordinarily will not require the owner of intellectual property to create competition in its own technology. And we believe the "antitrust laws generally do not impose liability upon a firm for a unilateral refusal to assist its competitors, in part because doing so may undermine incentives for investment and innovation."

428. As we have demonstrated in the United States, IP and competition polices can and should coexist and complement one another. The United States is committed to achieving public health goals in a way that upholds IP rights and promotes competition. For example, by accelerating Food and Drug Administration (FDA) reviews of generic drugs, the United States approved over 1,000 generic drugs in 2017, which is the most in FDA's history in a calendar year by over 200 drugs.

429. We urge China, South Africa, India, and Brazil, as well as other WTO Members, to find responsible ways to carry out domestic IP and competition laws, so as to contribute to the innovative ecosystem that is made possible by IP incentives.

13.8 European Union

430. The EU views critically a number of issues discussed in the Communication from China, South Africa and co-sponsors. To start with and as previously stated, the work conducted by the United Nations Secretary-General's High-Level Panel on Access to Medicines started from an assumption that there was "policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health". As the European Commission already indicated in its written contribution to the Panel and in various interventions at this Council, it does not share that assumption.

431. This is why in its written contribution to the Panel, the Commission encouraged it to adopt a holistic approach to the problem of access to medicines that could result in a valuable contribution to the wider debate. However, due to its limited mandate, unfortunately, the High-Level Panel has focused its proposals exclusively on addressing an alleged conflict between a research and

development model that (partially) relies on intellectual property rights and the possibility of providing affordable medicines. In doing so, it has missed an opportunity to advance more balanced, comprehensive and workable solutions to the problem of access to health. As we all know, IP protected medicines are only a very small fraction of the medicines that patients in need in many developing countries lack access to.

432. While there are a number of issues in the Communication the EU disagrees with, we would like to particularly voice concern over the mentioning of "refining the criteria for grant of a patent (patentability criteria)" as a TRIPS flexibility. The TRIPS Agreement is very clear and unambiguous on patentability criteria. TRIPS Article 27(1) states very unmistakably that: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." We see with growing concern that misinterpretation of this Article has led many jurisdictions to apply practices in the patent grant process which could be interpreted as amounting to additional patentability criteria not mentioned in the TRIPS Agreement. The EU urges those Members to reconsider their practices.

433. In the general, the EU would also be cautious to consider the use of competition policy as a TRIPS flexibility. Without doubt, the TRIPS Agreement is compatible with the application of competition policy measures. However, as clearly provided for in Article 28(1) and (2), as well as in Article 40 (2), these measures have to be consistent with the provisions of the TRIPS Agreement and cannot be used as tools in avoiding the obligations under the Agreement.

434. If applied in a compatible manner with TRIPS, competition policy has a role in regulating and controlling unlawful market behaviour in any sector, including the pharmaceutical sector.

435. Taking into account the sensitive balance between encouraging, incentivizing and ensuring continued innovation in the sector, on the one hand, and competitive generic medicines, on the other, the EU's antitrust enforcement seeks to promote open and competitive markets in the sector.

436. In the pharmaceutical and health services sector, the European Commission's Directorate General for Competition has investigated a number of anticompetitive agreements between companies (pursuant to Article 101 Treaty on the Functioning of the European Union (TFEU), which prohibits agreements restricting competition) and abuses of a dominant position by dominant market players (Article 102 TFEU). It also reviews proposed mergers and intervenes where market concentration would significantly impede effective competition and lead to less innovation.

437. For example, the EU Commission has adopted decisions against pay-for-delay agreements. A landmark case was the 2013 Lundbeck decision, which concerned citalopram, Lundbeck's blockbuster antidepressant medicine. After the basic patent expired, Lundbeck still held a number of related process patents with limited protection. Lundbeck paid significant sums, purchased generic's stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement, in return for agreements from generic producers not to enter the market with generic product. These agreements were found to infringe Article 101 TFEU.

438. The EU Commission fined Lundbeck (€93.8 million) and generic competitors (€52.2 million) for delaying market entry of generic citalopram. In September 2016, the EU General Court basically upheld the Commission decision. Appeals are currently ongoing before the European Court of Justice.

439. In another example, the EU Commission is currently investigating, for the first time ever, pricing practices for life-saving medicines in the Aspen investigation. Aspen is a global pharmaceutical company headquartered in South Africa, with several subsidiaries in the EEA. The investigation concerns Aspen's pricing practices for niche medicines used for treating cancer, such as hematologic tumours. The medicines are sold with different formulations and under multiple brand names. Aspen acquired these medicines many years after their patent protection had expired. Hence, we are talking here about generic drugs.

440. The Commission is investigating allegations suggesting that Aspen has imposed very significant and unjustified price increases of up to several hundred percent, so-called 'price

gouging' in violation of Article 102 TFEU. To impose such price increases, Aspen may have threatened to withdraw the medicines in question in some EU Member States and may have actually done so in certain cases. The investigation covers all of the EEA except Italy, where the Italian competition authority already adopted an infringement decision against Aspen in September 2016.

441. The EU Commission has not pursued a case involving unreasonably high royalties for a technology transfer. Nor has it ordered an originator company as the IP holder to grant a licence for its proprietary technology to remedy a competition law infringement. Such interventions would only occur under very strict conditions and in exceptional circumstances, which are typically not associated with conditions of competition between the innovator and the generic companies.

442. In addition to the obligations under the TRIPS Agreement, with respect to compulsory licencing under Article 102, the test developed by the EU courts sets out very strict criteria which are usually met in highly exceptional circumstances:

(i) licensing is indispensable for the exercise of an activity in a neighbouring or related market;

(ii) the refusal is capable of eliminating any effective competition on that market;

(iii) the refusal prevents the introduction into the market of a new product for which there is potential consumer demand; and

(iv) the refusal has no objective justification.

443. It has never been applied as a remedy against excessive pricing (i.e. a licence to generics to bring down the price) or to otherwise remedy patent barriers to generic entry.

444. Compulsory licences to pharmaceutical patents as a remedy to excessive pricing would have a negative impact on innovation incentives and appear to be superfluous, because a competition authority, once it has established unlawful market behaviour, has the normal toolbox of competition policy remedies.

13.9 Switzerland

445. It is with interest that we have studied the communication from China, South Africa, and co-sponsors. This topic at the intersection of competition law and IP is a challenging one, it is only to some limited extent relevant in the TRIPS context.

446. However, we think it is important to include an economic point of view in this discussion. Both competition law and IP law start from the premise that government intervention can be justified to redress the effects of a market failure. The promotion of public health and the development of new and better treatment for unmet medical needs in particular is a textbook example of where you need to redress the market failure. Without the patent law and test data protection, you would have a lack of incentive for investing the massive funds required for R&D.

447. Depending on the characteristics of the market failure, there are different means to fix the problem. We can distinguish between three kinds of market failure:

a. Firstly, relating to goods with public good characteristics; examples of such goods are "inventions" or "creative works": this market failure can be fixed with IP such as patents or copyright.

b. Secondly, a market failure relating to information asymmetries between buyer and seller, e.g. concerning the quality of a good: this market failure can be fixed by introducing another IP right, namely trademarks or geographical indications.

c. And last, but not least, in the case of abuse of market power, for example if you have the power to control market entry: in this situation, antitrust law can be used as a fix.

448. The challenge we face with respect to IP rights such as patents or copyright is that they explicitly provide for a temporary monopoly/exclusive right. As for patents, the idea is to incentivize investments in R&D. Granting such monopoly/exclusive right is considered to be a precondition for innovation and future wealth. The patent right as well as all other IP rights are a deliberate restriction on free competition, which provides a necessary incentive.

449. Just like any other legal right or title granted by a legal system, patent rights can be abused and there are several means in place to prevent this. Competition law is one legal means to prevent such abuse. The intellectual property system itself provides a number of its own measures to safeguard against abuse, which are also reflected in the TRIPS Agreement.

450. Submission IP/C/W/643 mentions some aspects of the wider framework to be considered. Switzerland only partially agrees with the reference points set out in the co-sponsors' paper. We would like to recall that the UN High-Level Panel on Access to Medicines was a process that was not driven by the member states. The Members of the High-Level Panel did not reach consensus and the Member States did not endorse the recommendations.

451. Switzerland believes that building on voluntary and inclusive efforts (such as the Medicines Patent Pool), instead of denouncing the intellectual property system, is the way forward. This approach also corresponds with the collaborative spirit of the 2030 Agenda for Sustainable Development.

452. But how do the two legal institutes, antitrust and IP law, relate to each other? In Switzerland, the Antitrust Act, or so-called "Cartel Act", states that it does not apply to effects on competition that result exclusively from the legislation governing intellectual property. Conversely, we can say that the Antitrust Act may apply in cases where the effects on competition *also* arise from the Patents Act. IP and competition law are considered not to be contradictory, but complementary.

453. Having said that, any strong measures taken under the antitrust act or the intellectual property legislation, such as compulsory licences, should be considered solely as a policy tool of last resort. They are measures that may not necessarily reinstate competition, but may rather have a far-reaching, negative impact on the investment climate, particularly on investments in R&D of innovative medical products in a market. They should thus be applied with utmost restraint.

13.10 Korea, Republic of

454. Korea would first like to thank China, India and South Africa for their proposal (IP/C/W/643) to discuss how to promote public health through competition law and policy in the Council. As mentioned by the delegates from the US and the EU, Korea is also of the view that the TRIPS Agreement and competition law can co-exist in a mutually supportive manner. Misapplication of competition law in the name of public health could run the risk of unduly hindering the IPR and forestalling the invention of new, innovative medicines and health technologies.

455. However, we also think that there exist some explicit anti-competitive behaviours in the pharmaceutical industry and that proper implementation" of competition policies can serve as an effective tool to tackle those behaviours and achieve public health by regulating abusive exercise of IPRs.

456. Without prejudice to Korea's position on the elements in document IP/C/W/643, I would like to share Korea's experience of tackling abusive exercise of IPRs through the implementation of competition policy.

457. The case I would like to mention is similar to the first of the two cases presented by the EU. Although the EU delegate used a different terminology, the essence is the same- i.e. reverse payment, a common form of collusive behaviour in the pharmaceutical industry. Unlike the usual practice where a patent owner of a new drug receives licensing fees from a generic manufacturer, a patent owner provides the latter with economic benefits, what is known as "reverse payment", to deter the entry of generic drugs into the market. Reverse payment settlement has a significant anti-competitive effect: a patent holder maintains a monopoly status in the market even after the

expiration of the patent rights by forestalling the selling of generic drugs, while consumers pay higher prices than they would otherwise.

458. The Korean Government has been exerting tremendous efforts to eradicate such anti-competitive practices in the pharmaceutical industry. In 2011, the Korea Fair Trade Commission, the government agency responsible for the enforcement of competition law, took remedial actions with regard to reverse payment. The FTC issued an injunction and fined a patent holder of a drug, a multinational pharmaceutical company who engaged in the practice of reverse payment in return for the exit of a generic drug manufacturer from the market. This marks the first case in which reverse payment was regulated by a government agency in Korea.

459. The Korean Government will even further strengthen its efforts to promote public health by ensuring a fair and competitive market environment in the pharmaceutical industry, in a manner that is consistent with the TRIPS Agreement and does not hamper the necessary innovation in the health sector.

13.11 Australia

460. Australia notes the communication regarding Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy. Australia has a number of policies and procedures in place to achieve public health outcomes, including in relation to intellectual property and competition law and policy. For example, Australian law provides statutory provisions to allow free access to patented inventions for the purpose of research and experimental use, introduced through the Intellectual Property Laws Amendment (Raising the Bar) Act 2012. The introduction of this measure provides researchers with a freedom to experiment and maximises the potential for research in Australia, including to support public health outcomes.

13.12 Japan

461. For the purpose of having meaningful discussions under this agenda item, the delegation of Japan would like to ask other Members to note that it might be better to take a more thorough and cautious approach, taking into account not only the interests of third parties but also those of patent rights holders. As this delegation reiterated, the HLP report should not constitute the basis for this discussion.

462. In this context, this delegation would also like to point out that provisions such as those in Article 31(k) and Article 40 of the TRIPS Agreement, rest on an intricate balance. Therefore, Japan believes that we should be cautious in discussing this agenda item. And these provisions should not be interpreted too broadly. Any measures taken under these provisions should be fully consistent with the TRIPS Agreement. From this perspective, this delegation shares the concern generally expressed by the United States delegation about document IP/C/W/643.

13.13 South Africa

463. On behalf of the proponents, I would like to thank Members who have intervened on this particular topic. I believe the objective of having entered into a discussion on competition does not undermine the application of IPRs as recognized under the TRIPS Agreement. The proponents demonstrated that there are various pro-competitive provisions in the TRIPS Agreement. Four provisions specifically refer to competition law issues: Article 6, Article 8.1, Article 31(k) and Article 40. There is no doubt that these provisions leave WTO Members broad policy space to apply competition law in respect of acts related to the acquisition or exercise of IP rights. Outside of these provisions there are several other provisions, as demonstrated, that give context to these rights. Whereas our paper does not advocate the use of competition policy to violate rights recognized under the TRIPS Agreement, it reminds all of us that the granting of intellectual property rights recognize inherently the balance between the rights holder and the vested rights that society have in this particular process.

464. Article 8 of the TRIPS Agreement sets out a very important parameter for the application of appropriate measures and requires that they be consistent with the Agreement. Nowhere in our paper do we make the statement that rights recognized under the TRIPS Agreement should be unduly impeded by application of competition law principles. The proponents also indicated that

competition law should recognize the basic rights granted under intellectual property law and that intellectual property does not necessarily create market power. As a result, to determine the effect of any restrictive practice, some sort of rule of reason should be applied to assess the effect of such a practice, short of such a practice essentially being deemed inherently illegal. The facilitation of universal access to health, including access to medicines and medical technology is not only a function of the IP system, it requires a much broader approach, as pointed out by the US and several other delegations. This cannot be disputed. In previous contributions proponents recognized this fact, the interplay between the domains of health, trade and IP affect medical innovation and access to medical technologies, so focusing merely on IP as one of the modalities may be misplaced.

465. In closing, we would also reiterate that the expression of competition law is generally used to describe a set of rules aimed at addressing anti-competitive behaviour associated with the existence of market-dominant positions and restrictive business practices. What we can see is that some competition laws focus on the effects of regulated conducts on competitors, while others focus on competition as such. Consumers (and not just competitors) are protected to a different extent under various national regimes. For instance, the approaches of the United States and the EU differ in the treatment of dominant firm conduct. The US representative indicated that US antitrust statutes have no equivalent to the excessive pricing prohibition under EU rules. This is essentially an indication that all of us apply to a certain extent different rules when it comes to competition. We hope that this clarification puts the discussion of this topic on an even keel. We are happy to reach out to any delegation that needs further clarification on any of the points that we have made.

13.14 Brazil

466. I would like to support the statement made by South Africa, I think we have all learned a lot about this topic, with our discussions here at the TRIPS Council. As mentioned by my colleague from South Africa, competition law does not endanger IP rights, in fact, it reinforces them when it provides a level playing field among competitors. I would like to comment on two topics that were mentioned by the delegations of the US and the EU. The first is on the effect of patents on access to medicines. The patent issue, as argued in this and other fora, is one of the central elements to broader issues regarding access to medicines. The broader approach on access to medicines is rightly done by WHO, but the mandate of this Council is intellectual property, so I think this is fully under the purview of the TRIPS Council to discuss this.

467. The second comment that I would like to make is about the WHO Essential Medicines List. It is factually correct to say that the number of non-patented medicines or the Essential Medicines List is much higher than those benefiting from patent protection. But despite this fact, governmental, cooperative and out-of-pocket expenses are proportionally much higher for the patented medicines on the Essential Medicines List. On top of that, WHO has historically preferred the inclusion of non-patented medicines with equivalent therapeutic value, precisely because they are cheaper. In conclusion, I would like to thank all the delegations who have made statements under this agenda item. We hope to revert to it at the next session of the TRIPS Council.

13.15 New Zealand

468. New Zealand thanks all Members who have presented under this agenda item. We recognize the importance of this topic and consider the sharing of examples and national experiences to be a useful exercise. We look forward to sharing this information with interested persons back in capital.

13.16 South Africa

469. Just on a point of process, there has been one or two delegations that have indicated that they may want a continuation in discussion of this topic after referring back to their capital for further analysis. From the side of the proponents, we would wish to request that this item be entered as a continuation at the next TRIPS Council.

13.17 United States of America

470. The United States wishes to object to a continuation of this agenda item and recommends that, if the proponents would like to continue to discuss it, to follow the rules of procedure and submit it as an *ad hoc* agenda item at the appropriate time.

13.18 South Africa

471. We note the intervention of the United States and as may be the case, we will follow such rules, and notify for the next TRIPS Council meeting an *ad hoc* item that continues a discussion, but with a different focus in respect to competition law.

13.19 European Union

472. We would briefly like to reiterate what we also mentioned earlier in the intervention, that only to the extent that competition policy is relevant to the TRIPS Council, we should also discuss competition policy on a continuous basis, because many of the cases for example which we, as an information point mentioned here clearly show that the issue is not necessarily only related to IP, or probably to a large extent not related to IP, but simply to anti-competitive behaviours. I do not think that the TRIPS Council should venture into long and detailed discussions of competition policy, so we would urge the Members who request an *ad hoc* item for the next TRIPS Council to duly reflect also the clear linkages if they make that point.

13.20 South Africa

473. We note the intervention from the European Union. I think firstly, as we indicated, competition-related provisions are squarely within the ambit of the TRIPS Agreement. Secondly, we believe that, as many delegations indicated, the IP and competition-related issues are complementary to one another. As a result, this is a topic which is useful. Of course, competition law in its general meaning perhaps is broadly applied, but when it comes to the application and exercise of IP rights, there may be certain abusive practices that may be regulated by the application of competition law norms. As a result, the proponents believe that there is more scope to discuss national experiences and will formulate a focused discussion, bringing out some more examples of how IP and competition law can co-exist and how the application of these norms in a complementary way will lead to increased societal benefits.

13.21 United States of America

474. The United States would just like to support the EU and its position, and remind the Council that the TRIPS Agreement, the officials present in this room, represent largely IP agencies. There are already organizations and international organizations such as the OECD and the International Competition Network that discuss these types of concerns from an anti-trust and competition perspective. There are more likely to be the appropriate forums to discuss these issues.

13.22 Brazil

475. We are enjoying very much this interactive discussion. Brazil would like to support what was mentioned by South Africa on the importance of bringing this topic to the discussion here at the TRIPS Council. Unfortunately, not all WTO Members are part of the organizations that were just mentioned by the US, therefore I think it is useful to have a broader discussion here at TRIPS Council.

13.23 UNCTAD

476. Referring to the communication from Brazil, China, India and South Africa on "Promoting Public Health Through Competition Law and Policy" (IP/C/W/643/ and Add.1) and based on our experience in providing technical cooperation in intellectual property and health in developing countries, UNCTAD would like to confirm the need to build capacities in the use of competition law and its interface with intellectual property rights and technology transfer in developing countries.

477. In our technical cooperation activities, we emphasize the use of competition law and policy to strike a balance between innovation and access. For instance, we discuss cases where competition authorities in developed countries analysed abuses of IP and of drug regulatory laws to prevent market entry of generic competitors after patent expiry.

14 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

Dispute Settlement Consultations

14.1 European Union

478. As a point of information, last Friday, the EU has formally submitted a request for consultation with China on *Certain Measures on the Transfer of Technology*. We understand a document number is currently attributed and the document will be circulated shortly.

14.2 China

479. China does not think that it is the appropriate time or place to talk about this issue.

TRIPS Amendment

480. No statements were made.

IPR-Related Issues in Trade Policy Reviews

14.3 WTO Secretariat

481. Since the last TRIPS Council Meeting in February, the Trade Policy Reviews of the Philippines, Montenegro, Guinea and Mauritania have taken place. In the interest of time, we will not attempt to summarize the full range of IP issues covered in each of these reviews; we will limit the update to those matters on which other Members actively registered an interest by posing questions during the review process. The issues that were of particular interest in this concrete sense included:

- The exhaustion regime;
- Administrative capacity in national intellectual property offices;
- Protection of copyrights;
- Geographical indications;
- Patent protection for inventions related to computer software;
- Compulsory licensing regime, including preventing diversion of pharmaceutical products imported through a special compulsory license;
- Supplementary protection certificates for patents;
- Registration and protection of partial designs as industrial designs;
- Government agencies involved in enforcement;
- Enforcement of intellectual property rights at the border and in transit;
- Specific legislation on parallel imports and customs treatment of goods suspected of infringement;
- Existence of policies to allow or prohibit importation of goods and services containing any form of intellectual property rights;
- Definition of "infringing goods" and visits to businesses suspected of engaging in intellectual property violations;
- Ratification of the Protocol amending the TRIPS Agreement and of the 2015 Bangui Agreement; and

- Accession to WIPO Conventions (Hague Agreement Concerning the International Registration of Industrial Designs International Convention for the Protection of New Varieties of Plants 1991; Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled).

482. Additionally, we have contributed with to the TRIPS-related section for the G20 and WTO-wide Director-General's Monitoring Reports, which should be circulated the coming weeks. On this occasion, the section highlights certain trade-related IP policy initiatives undertaken by Canada, the Kingdom of Saudi Arabia, Moldova, China, Mexico, Seychelles, Singapore, Thailand and Turkey.

15 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

15.1 India

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

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

15.2 United States of America

485. The United States position remains the same, and we are unable to support any other observer requests at this time and have no new developments or updates to report to the Council.

15.3 Ecuador

486. The delegation of Ecuador would like to take this opportunity to reiterate its support for the granting of observer status to the South Centre and the CBD Secretariat, or at least grant them the status of *ad hoc* observers.

15.4 South Africa

487. This delegation would once again call on Members to support the granting of permanent observer status to the South Centre, the International Vaccine Institute and the CBD Secretariat.

15.5 Venezuela, Bolivarian Republic of

488. We do not need to recall our position, but we would like to reiterate our support for the South Centre as a permanent observer.

15.6 China

489. China supports that the CBD Secretariat and South Centre should be granted observer status.

15.7 Brazil

490. We all know that Brazil supports the South Centre and the CBD Secretariat to become permanent observers to this body, but we also invite the delegation currently opposing these organizations to present a reason behind their position, so that we can perhaps start a negotiation. So far we have not heard this. I have been following TRIPS Council for nine years, and we have not heard a concrete reason for this opposition.

15.8 Bangladesh

491. We would like to support the South Centre to be granted permanent observer status to this Council.

16 OTHER BUSINESS

16th Annual Review under Paragraph 2 of the Decision on the "Implementation of Article 66.2 of the TRIPS Agreement"

16.1 Benin

492. We would like to briefly intervene on this item, recalling that, during past reviews of Article 66.2 reports, the LDC Group has often highlighted the importance for developed country Members presenting these reports to kindly follow the model that has been proposed in order to make this easier to use and easier to read in terms of determining the different actions that have been implemented or are under way. Furthermore, the Group has highlighted that it is important that the report is consistent with Article 66.2 which concerns actions and initiatives undertaken in favour solely of LDCs. We have had the opportunity to highlight that several reports have mixed initiatives targeting other developing countries, even with higher income. This makes it more difficult to determine the actions undertaken.

493. To conclude, Chair, on this item, we have noted that the reports are in the majority only available in English and do not allow francophone countries to be able to send the reports back to capital in order to get feedback prior to the meeting. This in some way places countries with French as an official language at a disadvantage. Yesterday we discussed the document that the LDC Group has submitted with regard to the implementation of Article 66.2. This is an additional contribution to facilitate the discussion, putting forward a list of actions and initiative which could be undertaken in order to better encourage the provision of incentives to companies and enterprises so that these could voluntarily try to transfer technology to LDCs. We were not able to achieve consensus on that yesterday, and the Group would like you to hold consultations with the different parties that are involved or are interested, particularly developed countries, as this proposal is addressed to developed countries. We hope that we can hold consultations with those developed countries that have expressed reservations so as to quickly find a common understanding around this document. It is not a binding, but an indicative document, a guide in order to allow developed countries to meet their obligations.

16.2 European Union

494. This is to respond to the intervention of Benin with regard to the choice of language of reports. We must note that in the European Union there are 28 official languages among Member States. All administrations working in their own language must translate their contributions into English, which is a lot of work for them. We have administrative procedures, descriptions and all project documents which are in their own languages, so it would be very difficult to then produce versions in several languages beyond that. I am not sure it would be possible to transmit this information in other languages than that we can read here in Geneva, namely English.

16.3 Bangladesh

495. Listening to the intervention made by Benin and the European Union I was thinking whether the Secretariat would be in a position to translate the document for French-speaking Members. I also support Benin's proposal to have more consultations on the list we have provided so that we can have some ideas where we are heading.

16.4 WTO Secretariat

496. Just to clarify that, as working documents of the Council, these reports, when prepared in English, are translated into the official working languages, i.e. into French and Spanish. Unfortunately, because of the length of these reports and the tight time-frame, often we receive them very close to the meeting itself. This unfortunately means that the translations are delayed. I do very much respect the concerns of Benin and other francophone delegations. It is an acknowledged difficulty, but unfortunately the translation task is a very significant one. There are two practical solutions I can mention, apart from the overall challenge we have with translations. One is to ensure that this a continuing dialogue about the content of these reports. That is what we have been trying to do through the workshops and through the follow-up questions and answers. But perhaps in a more informal setting we can discuss with delegations how to reach out

more effectively, particularly with the LDC Group, so that it is not 'all or nothing:' either there is a chance to speak at that session of the Council or it is finished. We do have opportunities for continuing the dialogue which all delegations have supported. The second point is that we do hope that the use of the e-TRIPS system that we outlined yesterday, particularly the notifications submission system, the NSS, will speed up the processing of this documentation and make it easier to access it. It does not translate automatically - translation will also remain a sensitive professional task - but at least some of those delays will be reduced. That is one reason why we have worked on that system. While this is not an entirely satisfactory situation, and we certainly express regrets to francophone and hispanophone delegations who do have to wait for those translations, there are some partial solutions and we will work to enhance those in dialogue with the delegations concerned.

16.5 United States of America

497. Just as we are heading into a very busy time for preparing our reports for the next TRIPS Council, we want to caution against entering into consultations that may detract from that work. We do want to make sure that our reports are as comprehensive and helpful as possible, and we have taken into account and will continue to review the documents that you have submitted, but at this point in time it would be too great of a burden to enter into separate consultations before the next workshop.

16.6 Benin

498. We take note of the suggestion of the United States. We know that drafting reports obviously takes time and involves a lot of energy and resources. However, these countries have already taken these initiatives and actions. We are not asking for additional research to find something that does not exist, or that is very difficult to find. This should not prevent consultations taking place on a document which may enable these countries to contribute more than what we are accustomed to receiving from them already. We want to be more specific. For several sessions, we have been raising this question, but there has been no progress on this. We now want to make progress, to move towards an effective implementation on this issue. We need incentives and encouragement perhaps, so that a viable and lasting technological system can be set up for the economies of our countries. This means that our countries have to be involved in international trade. We want to include countries in this category. Time must be found to have these consultations. These are not endless consultations: they are not going to take up so much time We are just talking about consultations which will make it possible to see how we can re-orient a document, which elements can be taken into account to give more encouragement and incentives. That is all we want, so we strongly encourage the United States and other developed countries to commit themselves so that we can finalise this certainly very useful document as early as possible.

16.7 Bangladesh

499. I have listened carefully to the statement made by the United States. It is our understanding that this consultation, and the preparation of these documents should be mutually supportive. It would therefore be better to have the consultations taking place so can we can better prepare for the review. I suppose that everyone will agree that the consultations are needed and that they will support the Annual Review.

Work Programme on E-Commerce

16.8 Bangladesh

500. My delegation would like to thank you for your effort. We are of the opinion that Ministers at MC11 gave us the mandate to continue the work under the 1998 Work Programme on Electronic Commerce. We understand that this Council is one of those four bodies which has been entrusted to examine specific issues. We strongly believe that we have the responsibility to carry out the mandate. Moreover, the TRIPS Council has the requirement to report to the General Council for the upcoming review in July. However, it is frustrating to observe that the Council has nothing to report to the General Council due to the fact that the e-commerce Work Programme was neither included on the agenda of the February session nor on the agenda of our current session. My delegation is convinced that e-commerce has been evolving rapidly and many issues have come into the debate, for example data, where the intellectual property right is an important subject to discuss. In addition, there has been a continuous innovation in the digital economy. Therefore, we need to better understand the importance of innovation and access to technology for spreading the benefit of e-commerce to all.

501. Against this backdrop, my delegation proposes to include the Work Programme on e-Commerce as a standing agenda item of this Council until the next Ministerial Session and to update the background document by the Secretariat, document IP/C/W/128/Add.1, in order to have a fruitful discussion at our next session. My delegation looks forward to a positive consideration of our request by the Council.

16.9 United States of America

502. The United States objects to establishing any new standing agenda items, including the one proposed by Bangladesh.

16.10 Brazil

503. We thank the delegation of Bangladesh for the request. As you have mentioned, Ministers at MC11 issued the Decision emphasising the need to re-invigorating our work on the e-Commerce Work Programme. It mandates the four bodies which are referred there to examine and report on aspects of e-commerce pertaining to their activities. It therefore only makes sense to include this item on the agenda of our session, perhaps on an *ad hoc* basis, to continue to discuss this on a sustainable basis. We would also like to support the proposal by Bangladesh on updating the background document.

504. While Brazil has no new document with regard to IP and e-commerce, I would like to take this opportunity to recall that we circulated document JOB/GC/113 dated 15 December 2016, co-sponsored by Argentina. It's goal is to launch a comprehensive discussion of copyright management in the digital environment. The key motivation is to ensure that the fruits of the online environment are fully enjoyed by those who lie at the core of the copyright system, namely, authors and performers, and whose legitimate demand for a fair remuneration for the use of their works needs to be addressed by Members.

505. We look forward to continuing these debates about e-commerce in order to find a common understanding and to provide the General Council with information necessary to consider the way forward on the matter.

16.11 Benin

506. We thank Bangladesh for making this proposal. As Brazil reminded us previously, our Ministers in Buenos Aires called for the work under the 1998 Work Programme to be reinvigorated. This was the outcome of consensus. And yet Members that were present at the Ministerial Conference now object to the inclusion of this item on the agenda. We do not find it very comfortable to have to have a discussion on this again. Ministers have already decided this. We are meant to continue with this Work Programme: it is set forth already, that is our mandate. It is up to the Council to take the necessary measures in order to accomplish this mandate. The Council is one of the WTO bodies that was selected to look at specific aspects of electronic commerce that

were relevant in the context of the Work Programme. Therefore, it goes without saying that this item is and has to be on the agenda. Our delegation strongly recommends that this item be included on the agenda in conformity with the existing mandate.

16.12 Venezuela, Bolivarian Republic of

507. We also want to thank Bangladesh for its proposal. In this connection we wish to support both of the proposals made, we feel that they are in line with the mandate received by our Ministers in Buenos Aires as to the need to revitalise the Work Programme on E-Commerce.

16.13 Bangladesh

508. I have a question: what prevails, decisions taken by Ministers or by Geneva-based delegations? What actually is the rule of the WTO? If Ministers have given us a mandate, is it our responsibility to carry out this mandate or not, or is it up to us to decide whether we will carry out the mandate or not? This Council has the requirement to carry out the mandate of the Ministers. We think that there is the requirement by the Council to have electronic commerce on its agenda.

16.14 Benin

509. I was asking myself questions about your conclusion. For our part, we wonder whether delegations have higher status than Ministers who took the decision, because in the organisational chart of the WTO the highest body for taking decisions is the Ministerial Conference, and the Ministerial Conference took a decision. One delegation says no, I object to the decision taken at the Ministerial Conference. This is a systemic problem and it is harmful to our work. I believe we should draw some lessons from this, we should be aware that we have a mandate, irrespective of the interests of one party, we cannot call that decision into question, unless we have another Ministerial Conference at which Ministers declare that they no longer agree on the decision that they took before. In that case, Members do not have to put this on the agenda of the Council any more. Otherwise it should be done automatically. We do not even have to have consultations on it. If Members have interests to raise and concerns and do not want to discuss this, well these Members do not have to discuss it, but they cannot prevent others from raising points that they wish to discuss within the Council in conformity with the existing mandate. It is important to stress this: "in conformity with the existing mandate". The delegation of Benin stresses that this arises systematically and it is harmful. We should not fall into this trap.

16.15 Brazil

510. We appreciate your efforts and we look forward to the consultations. In the meantime, I would just like to ask for a clarification. We have heard a proposal to update the background notes, and we have not heard any opposition to it. I would therefore like to clarify whether the Secretariat will be instructed to update the document.

16.16 United States of America

511. Just to confirm, we do not support updating the note at this time, and would need further information on what is intended.

16.17 European Union

512. We also see no need to have a standing item on the agenda of the TRIPS Council. However, I would like to remind the Council that in one of the previous Council meetings, the European Union, and I think also Canada, updated the Council on our initiatives in the context of the services discussions here at the WTO, where this work is obviously taken forward. I therefore wonder whether there is a real need for having this as a standing item. We can obviously continue to update the Council if needed. I do not remember the relevant delegations all intervening at that time.

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