



**Council for Trade-Related Aspects of
Intellectual Property Rights**

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 8-9 NOVEMBER 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 8-9 November 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 NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1.1 Colombia

1. Law No. 1915 of 2018 (IP/N/1/COL/9) amends Law No. 23 of 1982 and establishes other provisions on copyright and related rights, clarifies and updates the general copyright regime in areas such as presumption of authorship, protection of first publication or fixation abroad, the scope of certain authors' rights in their works including digital media storage, the term of copyright protection for legal persons, the rights of performers to their performances, etc. The law entered into force on 12 July 2018, repealing articles 58 to 71, 243, and the other contrary provisions of Law No. 23 of 1982.

2. Law No. 1835 of 2017 amending Article 98 of Law No. 23 of 1982 on copyright and providing for the remuneration of authors of cinematographic works (IP/N/1/COL/C/10) is also known as the "Pepe Sánchez" Law in honour of a well-known Colombian director, screenwriter and actor. This law amends the general copyright regime and recognizes the right to fair remuneration of authors of cinematographic works for acts of communication to the public of their works, without prejudice to the presumption of transfer of copyright and economic rights to the producers.

3. Decree No. 670 of 2017 partially amending the Single Regulatory Decree for the Trade, Industry and Tourism Sector No. 1074 of 2015 (IP/N/1/COL/C/11; IP/N/1/COL/I/5) explains the procedure for the declaration of the existence of reasons of public interest for compulsory licensing. Compulsory licensing is referred to in Article 65 of Andean Decision 486 of 2000. Decree No. 670 of 2017 provides for an Interinstitutional Technical Committee made up of the competent authority (i.e. the authority that initiated the procedure), the Ministry of Commerce, Industry and Tourism, and the National Planning Department. This Committee has to examine the application submitted, request any further information that may be required, and seek opinions and technical support from other entities and natural persons. Following its assessment, the Committee makes a recommendation to the competent authority on whether or not to declare the existence of reasons of public interest. It is important to note that the Decree establishes a clear procedure with a specific time frame to ensure the participation of all interested parties.

4. Law No. 1834 of 2017 promoting the creative economy (Ley Naranja, or Orange Economy Law, IP/N/1/COL/I/6) is an initiative that seeks to promote the development and growth of creative industries in Colombia. Creative industries include the sectors that combine creation, production and marketing of goods and services based on intangible cultural content, and those that generate copyright protection. The Law seeks, *inter alia*, to create a strategy to improve interinstitutional coordination, support for the formalization and adaptation of the creative industry, and the promotion of international instruments to ensure greater and better access to foreign markets.

1.2 Japan

5. This delegation is pleased to inform the Council that Japan recently amended its Acts of Patents, Designs and Trademarks. The amendments have been notified to this Council in accordance with Article 63.2 TRIPS in documents IP/N/1/JPN/P/13, IP/N/1/JPN/D/8 and IP/N/1/JPN/T/8. We would like to briefly explain some points about the amendments.

6. First, the amendments to the Patent Act and to the Design Act were made in order to expand the "grace period" from six months to one year, in regard to the exception to lack of novelty of inventions. This delegation firmly believes that this expansion will make the Japanese IP system more user-friendly, and will promote innovations through appropriately protecting inventions and designs.

7. Second the amendment to the Trademark Act added a requirement of divisional applications to improve the trademark filing procedures.

8. The Government of Japan will continuously fulfil its obligation to ensure the accessibility and the transparency of the Japanese intellectual property system.

1.3 Moldova, Republic of

9. The Republic of Moldova has submitted the notification of laws and regulations under Article 63.2 of the TRIPS Agreement, announcing the new Government Decision Number 741 of 18 July 2018 amending Decision 541 of 18 July 2011 which establishes the legal framework for the activity of the authorized intellectual property rights attorneys (IP/N/1/MDA/O/3 and IP/N/1/MDA/O/4).

10. The notified document regulates the fundamental principles and rules of professional conduct for the authorized intellectual property attorneys both in relations with customers, national and international authorities, non-governmental organizations and in relations with other authorized authorities. The operated amendments take over the best practices and the international standards of professional conduct for IP lawyers.

11. The principle of transparency and the notification obligations remain at the core of the well-functioning of this Council, to which we attach great importance. We thank the delegations that have submitted notifications prior to the meeting and encourage other Members to do so.

1.4 Ukraine

12. The first notification, circulated in document IP/N/1/UKR/C/4, concerns the new legislation of Ukraine regarding collective management system (CMO) and, in particular, the Law of Ukraine "On Efficient Management of Property Rights of Rights holders in the Sphere of Copyright and/or Related Rights" Number 2415 of 15 May 2018, which entered into force on 22 July 2018.

13. The Law provides that collective management of copyright and related rights is exercised in a form of voluntary, extended and mandatory collective management.

14. The main principles of CMO are:

- a. Strict compliance with the interests of the rightsholders;
- b. Equality;
- c. Transparency, accountability; and
- d. Efficient management.

15. The Law determines clear requirements for the Statute of CMO, membership conditions, the powers of General Assembly, and Supervisory and Executive Bodies of CMO. I also include a provision on transparency of operation of CMOs, requirements for annual reports on activity of CMOs, and rules of declaration and withdrawal of rights. The new legislation provides for clear and transparent procedures of collection, distribution and payment of rights revenue.

16. According to this Law, the current system of CMO will be reloaded. All certificates of registration and of authorization of CMOs, issued before the entry into force of this Law, shall become invalid.

17. The Law strictly determines the sphere of extended and mandatory collective management. The accredited CMO shall be designated by an open competition organized by the Ministry of Economic Development and Trade (MEDT) and conducted by the Accreditation Committee in the manner prescribed by this Law.

18. Ukraine's second notification (IP/N/3/UKR/3) provides new information regarding its contact points. Specifically, it informs Members that the MEDT of Ukraine is established as a contact point for the exchange of information and cooperation on all intellectual property matters. Ukraine previously notified its updated contact points, which were established in the State Fiscal Service of Ukraine for the law enforcement purpose.

19. To conclude, we would like to note that work in the IP sphere is one of the key priorities of the Government of Ukraine. We do our best to create a modern transparent, effective and efficient CMO regime in Ukraine that ensures that right holders will receive fair compensation for their creative works consumed in Ukraine.

20. Ukraine wants to reassure Members in its intention to fulfil its commitments under the TRIPS Agreement. The MEDT of Ukraine as the central body of executive power will put its best efforts within its competence for ensuring efficient protection and enforcement of IP rights. The delegation of Ukraine will actively participate in addressing all challenges jointly with all Members of the World Trade Organization.

1.5 United States of America

21. The United States appreciates the notifications made for the meeting and will follow up with delegations.

1.6 European Union

22. The European Union takes note of the questions from the Indian delegation (on enforcement of IP rights regarding goods in transit, circulated in document IP/C/W/636/Add.1). Since we received the document only a couple of days ahead of the TRIPS Council on a subject involving several services of the European Commission, the European Union is not in a position to provide replies at this meeting.

23. The European Union is compliant with its TRIPS obligations, including those related to enforcement. We are not aware of a single recent case in the European Union were there was an issue of seizure of legally transiting pharmaceutical products not destined for the European Union internal market.

24. As India is aware, there is an ongoing bilateral consultation process on matters of transit between India and the European Union. The European Union remains committed to that bilateral process.

1.7 India

25. India takes note of the European Union's response and will wait for their response.

1.8 WTO Secretariat

26. The work on the e-TRIPS project, particularly the notification submission tool, is at a very advanced stage, and we have reported extensively on this project in the past, so our report will be very brief.

27. The WTO Secretariat is fine-tuning the IT aspects of the project, with the aim of opening to Members for trial usage in the new year. Current work includes cleaning, tagging and confirming the integrity of legacy data, and improving the IT to make it clearer and more user-friendly for Members. We are currently introducing specific refinements in the light of the direct experience of Members in preparing and submitting notification and reporting material. We are conscious that it is much easier and more cost-effective to refine the system now rather than returning to it subsequently after it is released; hence the emphasis on fine-tuning it now.

28. The WTO Secretariat would welcome any further feedback, comments and suggestions, in particular through informal consultations and demonstrations with delegates. This would help us to shape the final version which would then go online for Members to use directly when providing notifications and other reports relating to the work of this Council.

29. The Secretariat is also developing a comprehensive step-by-step guide on how to use e-TRIPS, which also provides information on the various categories of material – notifications and regular reports - that Members may wish to submit as part of their ongoing contribution to the transparency function of this Council. The Secretariat will be in touch with Members with further details in due course, and again will refine this material in the light of feedback received. Our technical assistance work will also include advice on notifications and, in particular, how Members can make use of e-TRIPS to track their existing notifications and to keep them up to date and complete.

30. This work has concerned an improved notification and reporting submission tool – the input side. We are also working on the improved gateway for access to and easier searching of this

material. This, too, will be the subject of consultations with Members to ensure that it corresponds with the practical needs of Geneva-based delegates and capital-based officials seeking better access to the TRIPS-related material contained in the system. Again, we will be in touch with delegations to arrange for informal consultations to facilitate this stage of work.

31. I conclude by thanking delegates for their guidance and cooperation in the development and implementation of this new system. This has been indispensable for the efforts made to ensure that this will be a tool that is practical to use and efficient and timely in the processing and dissemination of the key working materials for this Council. We therefore place strong emphasis on this continuing feedback from Members in taking this project forward.

2 REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

32. No statements were made under this agenda item.

3 REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

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

5 PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

5.1 India

33. The WHO report on Traditional Medicine Strategy 2014-2023 notes that demand for traditional and complementing medicines has been growing at a fast pace. The extent of economic value contained in herbal medicines is evident from the fact that the output of Chinese medical material was estimated to amount to USD 83.1 billion in 2012, an increase of more than 20% from the previous year.

34. The Trilateral Study (WHO-WIPO-WTO) on Promoting Access to Medical Technologies and Innovation (2013) acknowledges the fact that traditional medicines and medical knowledge provide leads for the development of new treatments. It goes on to mention that many existing modern medicines are originally based on herbal products.

35. 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.

36. In more recent years, with the establishment of the Traditional Knowledge Digital Library in India, more than 1000 patent applications could be identified in a short period of time where a patent was being sought for knowledge that already existed in codified traditional knowledge systems such as Ayurveda, Unani, Siddha and Yoga.

37. Countries have adopted various methods to protect traditional knowledge and associated genetic resources at the national level. However, it is important to note that what can never be addressed by the domestic/national regimes is misappropriation of existing knowledge in foreign patent offices. Absence of an international regime therefore is a major gap in addressing the problem of biopiracy.

38. It has therefore been a long-standing demand that there should be an international regime that makes the patent office the check point to contain misappropriation. Patents should not be granted for existing traditional knowledge and associated genetic resources. Further where genetic resources and associated traditional knowledge form the basis of scientific development, it is important that patent applications must disclose source or origin of the resource and also disclose whether the access was on mutually agreed terms. Disclosure is important not only to address information asymmetry at the Patent Office but also to enable a better assessment of the inventive step. The TRIPS/CBD linkage is therefore important for developing countries because it seeks to address biopiracy.

39. 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.

40. The Nagoya Protocol of the Convention on Biodiversity (CBD) entered into force on 12 October 2014. 105 Countries, including India, have ratified the Protocol, till now.

41. The Doha Ministerial Declaration in Paragraph 19 mandated that the TRIPS Council examine the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore.

42. We also need to take note of the recent developments of the 2030 Agenda for Sustainable Development to which we are all committed. It 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.

43. It would also be useful to the delegates of the TRIPS Council if the CBD Secretariat were 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, to which 105 Members have acceded. We reiterate our demand for a formal briefing by the CBD Secretariat in the interest of the large majority of Members. We also support updating the three factual briefs by the Secretariat.

44. I conclude by stating that we hope to continue our efforts in building momentum on the issue of the TRIPS/CBD linkage, taking into account the new developments, such as the finalization of the Sustainable Development Goals and the ratification of the Nagoya Protocol by more than 100 countries.

5.2 Egypt

45. With regard to agenda items 3, 4, and 5, the delegation of Egypt would like to reiterate its position that the protection of biological resources, traditional knowledge and folklore presents an important developmental issue. In view of the importance of these implementation-related issues, we believe it is important to continue discussions of these issues by the TRIPS Council in order to find solutions in light of the existing mandates.

46. We also would like to support the proposal to invite the CBD Secretariat to brief the TRIPS Council on the latest developments in the implementation of the Nagoya Protocol, and we support Ecuador's proposal for updating the three factual notes by the Secretariat on these three agenda items in order to facilitate future discussions in the TRIPS Council.

5.3 China

47. The relationship between the TRIPS Agreement and the CBD is an important issue in this Council. Over years, Members have conducted useful discussions on this issue. China attaches great importance to the TRIPS Agreement and the CBD and hopes that Members could be constructively involved in this discussion.

48. Regarding the substantial issues, in order to ensure the mutual support of the TRIPS Agreement, the CBD and the Nagoya Protocol, the majority of Members are supportive to amend the TRIPS Agreement, to include a mandatory requirement on disclosure of genetic resources and traditional knowledge in patent applications.

49. As to the issue of disclosure, China has provided detailed suggestions on negotiation model, improving the transparency on genetic resources utilization, preventing the misappropriation of genetic resources and traditional knowledge, and preventing the grant of erroneous patents in documents TN/C/W/52 and TN/C/W/59 that were co-sponsored by Members.

50. We also believe the prior informed consent and benefit sharing could bring better protection for genetic resources without adding extra burden to patent applicants. The benefit arrangements on a

contractual basis and the database solution could not serve the purpose of sufficient protection for genetic resources.

51. With regard to procedure, we consider that the discussion and negotiation on this issue in WIPO does not form any obstacles for WTO Members on finding solutions. The Ministerial Meeting has instructed the TRIPS Council to examine the relationship between TRIPS and CBD. Members should follow this mandate to work on solving this issue. 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, and IP/C/W/370/Rev.1). China believes that the discussion and negotiation in WIPO's IGC should not hinder Members to find solutions in the WTO, as Ministers have given the Council the mandate to examine the relationship between the TRIPS Agreement and the CBD.

5.4 Brazil

52. 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.

53. The introduction into the TRIPS Agreement of a mandatory requirement for the disclosure of origin of these resources in patent applications is an important objective for Brazil. A multilateral and mandatory disclosure would be the most effective way to address the misappropriation of genetic resources and traditional knowledge. This would require patent applicants to disclose the country of origin of a biological resource and provide evidence of compliance with prior informed consent and benefit-sharing. It would also contribute to patent examinations by providing additional information to patent offices. These, however, would not be overloaded with extra work since they would be just checking points in the new system.

54. A mandatory disclosure requirement in patent applications will also contribute to enhance transparency about the utilization of associated traditional knowledge. This will not only ensure compliance with the CBD, but also accomplish one of the primary purposes of any intellectual property regime, namely, providing appropriate incentives and rewards to knowledge holders in acknowledgment of a benefit to society as a whole.

55. In the past, we have heard some Members stating at this Council that WIPO is conducting negotiations on genetic resources. However, those same delegations have consistently blocked any textual advances in WIPO and negotiations there have been ongoing for the last eighteen years, without any concrete result. This leads to a frustration on the part of countries hosting a rich biodiversity and there is a need of a concrete answer from the multilateral IP regime.

56. There were great, recent developments at the CBD level, with the entering into force of the Nagoya Protocol, which already has 109 Parties, more than half of all UN Members. The majority of WTO Members are likewise parties to both the CBD and Nagoya Protocol. More recently, the UN Sustainable Development Goals have given us a clear mandate to safeguard biodiversity and to promote compliance with the Nagoya Protocol.

57. Therefore, Members would greatly benefit from an update of the factual notes, as proposed and supported by Ecuador and South Africa, India and other countries. This update does not prejudge positions of delegations, as those documents are restricted to facts. We also support inviting the CBD Secretariat to provide us a briefing on recent developments at the CBD level.

5.5 Bangladesh

58. Under these triplet agenda items, the position of Bangladesh, as well as that of the LDC Group, is well-known. Although there is no change in it, I would like to reiterate our position for the sake of record.

59. On the issue of the Review of the Provisions of Article 27.3(b), my delegation does 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.

60. 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 a view to requiring applicants of patent relating to biological materials to provide information on the source and country of origin of biological resources and traditional knowledge used in the invention.

61. In addition, 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.

62. We believe that traditional knowledge should receive legal recognition as its protection could as well contribute significantly to the achievement of development goals.

5.6 Bolivia, Plurinational State of

63. We would like to emphasize the importance of keeping this item under discussion and on this Council's agenda. The Plurinational State of Bolivia wishes to reiterate the relevance of document IP/C/W/545 of 26 February 2010, in which it submitted a contribution to this Council. The review of Article 27.3(b) is an issue within the mandate of the Doha Development Agenda under Paragraph 19 of the 2001 Doha Ministerial Declaration. Article 27.3 must be clarified in order to prohibit the patenting of all life forms and to protect all the rights of farmers, genetic resources, traditional knowledge and traditional practices in developing countries.

64. There is no reason why microorganisms, microbiological processes and non-biological processes for obtaining plants and animals should be singled out for patentability, while Members are given the discretion to prohibit patents on plants and animals, and on essentially biological processes. The patenting of life forms promotes an imbalance in the current intellectual property system. The TRIPS Agreement, while granting private monopoly rights, does not explicitly recognize the collective rights of indigenous peoples and local communities over their biological resources and traditional knowledge, farmers' rights or the sovereign rights of States.

5.7 Ecuador

65. Ecuador would like to reiterate its position regarding agenda items 3, 4 and 5 and calls on the Council to consider encouraging discussion on the review of Article 27.3(b) of the TRIPS Agreement and the adoption of new rules on the patentability of all life forms or parts thereof. Ecuador has stated that it is imperative to prohibit this type of patents because life or parts thereof should not be considered a tradeable good.

66. It is important for Article 27.3(b) to be in line with the themes of the Convention on Biological Diversity: countries have sovereign rights over their biodiversity and the benefits resulting from its use should be distributed equitably.

67. This takes us to the second item, regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity. As we have said, the two are related and complement each other.

68. The CBD, the objectives of which are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, recognizes that systems of intellectual property protection may have an influence on its implementation. In that regard, its Contracting Parties undertake to cooperate in order to ensure that such rights are supportive of and do not run counter to its objectives. Additionally, in many cases these genetic resources represent traditional knowledge.

69. This leads to the third item on the protection of traditional knowledge and folklore. Ecuador has noted the importance of having multilateral legal instruments that can improve the use of genetic resources, associated traditional knowledge and traditional cultural expressions and give them

effective and adequate protection. It has also noted the need to establish legal mechanisms to allow disclosure of the source of origin, prior informed consent, access and equitable benefit sharing.

70. With respect to these points, we would lastly like to refer to the updating of the factual note on the relationship between the TRIPS Agreement and the Convention on Biological Diversity, which was last updated in 2006.

71. Ecuador must insist that the aim of this update is to provide Members with greater input in order to enrich the discussions and help move them forward, and stresses that each Member's position would remain intact.

72. As we have said, we acknowledge the small gains that have been made to date in achieving this objective, which will certainly be of benefit to the Council, and we call on the delegation of the United States to show flexibility in its position.

5.8 Chinese Taipei

73. On the issue of the relationship between the TRIPS Agreement and the CBD, the delegation of Chinese Taipei believes that there are still some important technical issues that need to be clarified, such as the definition of associated traditional knowledge and the trigger for the disclosure requirements and so on.

74. My delegation would not oppose the request by Members for a briefing on the current work by the CBD Secretariat, provided that the briefing would be helpful in clarifying technical issues and the mode is acceptable to Members.

5.9 Chile

75. The delegation of Chile would like to reiterate its position regarding these agenda items, which it has expressed on previous occasions before the TRIPS Council.

76. Chile believes it is important to maintain the flexibilities contained in the TRIPS Agreement. Each Member has the sovereign right to define and take into account the ethical, social and economic aspects that it considers relevant when developing its intellectual property system, so as to promote areas such as access to health, access to cultural heritage, and innovation development.

77. In Chile's view, intellectual property systems are not an end in themselves, but are tools for promoting innovation, development and the transfer of knowledge, while also facilitating access to health. We therefore believe that a country's decision regarding the creation of monopolies over life forms must be made in accordance with the situation existing in that country. In the case of Chile, plants and animals are excluded from patentability under Law No. 19.039 on industrial property.

78. Chile, like other delegations, agrees that the TRIPS Agreement and the CBD are complementary instruments and that there is therefore no need to amend the TRIPS Agreement to ensure consistency between the two texts. We feel it is appropriate to highlight the work being done at the World Intellectual Property Organization on genetic resources, traditional knowledge and traditional cultural expressions, and we reaffirm Chile's commitment to continue working and facilitating discussion in that forum.

79. Lastly, we would like to express our support for the proposal that the CBD Secretariat provide a briefing to this Council. We believe that a factual description could shed light on this topic for Members and provide further elements for discussion.

5.10 South Africa

80. South Africa would like to recall its previous interventions on the substantive items that constitute the triplets. Specifically, on the issues of the relationship between the TRIPS Agreement and the CBD, we recall Paragraph 19 of the Doha Declaration. Document TN/C/W/59 constitutes an approach that a large number of developing countries have supported. This document 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 CBD and has ratified the Nagoya

Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

81. The issue of unauthorised use of biological resources and traditional knowledge remains a serious problem internationally. The failure to ask permission or acknowledge the origin or source of the invention or creativity, failure to share benefits, culturally offensive use, and grant of patents or other forms of IP rights in error remain unaddressed. Given the international dimension of bioprospecting and patenting activities, national legislation is insufficient to address misappropriation and misuse of genetic resources and traditional knowledge. Strong multilateral disciplines are required in this area. Given the continued impasses in the WIPO IGC, the most appropriate forum to address these issues would be the WTO.

82. 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 characterized by persistent restatement of long held positions. We further support a briefing by the CBD Secretariat on the Nagoya Protocol and subsequent developments.

5.11 Indonesia

83. Indonesia would like to reiterate its view that the relationship between the TRIPS Agreement and the Convention on Biological Diversity should be reflected in this Council by ensuring and maintaining the cohesion, coherence, and consistency between the two. These two internationally agreed instruments must be implemented in manner that is mutually supportive with respect to their objectives. Since the Convention on Biological Diversity and the Nagoya Protocol have formed the basis for the protection of genetic resources and/or associated traditional knowledge with provisions on prior informed consent for access and fair and equitable benefit sharing, the TRIPS Agreement needs to reflect the said provisions to avoid misappropriation and obliges Members to take necessary measures to ensure fair and equitable benefit sharing.

84. The protection of genetic resources is of paramount importance to Indonesia and we consider that a legal obligation to establish a mandatory disclosure of origin as a requirement for patent applications will not only prevent misappropriation and enhance transparency on the utilization of genetic resources and/or associated traditional knowledge, but will also provide greater legal certainty as to the rights and obligations of the providers and users of genetic resources.

85. We would also like to add that we should not delay substantive discussions in this Council for reasons that it is being negotiated in other fora, such as WIPO. The discussions to take place in this Council should reinforce what has already been agreed at the multilateral level, such as CBD, and should complement negotiations/discussions in other fora. We believe that parallel discussions will enhance effort and understanding of achieving a fair and balanced trading system with regard to intellectual property.

86. In this regard, Indonesia would like to support the briefing by the CBD Secretariat in this Council.

5.12 Canada

87. 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.

88. 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 continues 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 upcoming session of the IGC this December.

89. 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 and communications 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.

90. With respect to procedural matters at the TRIPS Council, as Canada has previously noted, and without prejudice to our position on substantive matters, Canada can support from a procedural standpoint 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 three factual notes on the TRIPS Agreement and the CBD (documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1, and IP/C/W/370/Rev.1) by the WTO Secretariat. Canada remains of the understanding that this would remain an information collating exercise, and in both cases, this is without prejudice to national positions on these issues.

5.13 Thailand

91. The Doha Ministerial Declaration in 2001 instructed the Council for TRIPS to examine the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. Since then, this is one of the long-standing issues that has been discussed in the TRIPS Council.

92. Despite the fact that some proposals were tabled to the TRIPS Council with the intention to move forward the discussion on the relationship between the TRIPS Agreement and the CBD, no significant progress has been made.

93. Biopiracy, including misappropriation of genetic resources, could happen in any corner of the world. The CBD is put in place to ascertain that utilization of genetic resources shall be based on key principles such as prior informed consent and fair and equitable benefit sharing. It is noted that misappropriation of genetic resources and associated traditional knowledge can be prevented in the intellectual property regime on the basis of a "disclosure requirement".

94. In addition to the discussion in the TRIPS Council at the WTO, aspects of genetic resources in relation to intellectual property have also been discussed in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) at WIPO. Due to the significance of genetic resources, it is believed that both international fora should pursue their works on this matter in parallel and in mutually supportive ways.

95. Last but not least, I wish to repeat Thailand's support for the briefing by the CBD Secretariat.

5.14 Australia

96. Australia believes that the WIPO IGC is best placed, with appropriate technical expertise, to consider the complex issues relating to intellectual property, genetic resources and associated traditional knowledge and cultural expressions. We hope WIPO Members will build on the momentum in the IGC process when the issue of genetic resources is next considered in 2019.

97. Australia believes the TRIPS Agreement and the Convention on Biological Diversity are fully consistent, and that the TRIPS Agreement therefore does not need to be amended.

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

99. In relation to 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.

5.15 Japan

100. We have discussed this agenda at length during a series of meetings of the TRIPS Council. The delegation of Japan, therefore, believes that our position is well-recognized among Members, so we would like to make our intervention brief, highlighting some major points.

101. The delegation of Japan would like to reiterate our position that the Convention on Biological Diversity is by nature not relevant to the intellectual property system. Therefore, we need to seek appropriate ways to deal with the misappropriation of genetic resources. This means that 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.

102. This delegation is firmly convinced that the disclosure requirement would discourage industries from conducting research and development activities on biological materials. This is the very consequence of the disclosure requirement that Japan has been concerned about. The same holds true for not only developed country Members but also emerging and developing countries. Therefore, Japan believes that the disclosure requirement is not an adequate means for dealing with such misappropriation. Therefore, we have to avoid including it in the intellectual property system.

103. In addition, this delegation believes that the WIPO IGC is the most appropriate forum for holding technical discussions on genetic resources, traditional knowledge and folklore from IP aspects. This delegation has been actively contributing to the discussions at the IGC meetings, making various proposals, and remains willing to contribute to evidence-based discussions on these issues in a constructive and effective manner.

5.16 United States of America

104. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues. The WIPO IGC is looking at addressing unresolved issues and working on a common understanding of core issues, using an evidence-based approach and examples of national experiences.

105. 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.

106. With respect to the various requests made, the United States is not in a position to support these requests, but remains open to discussions, including bilaterally with delegations in between and at the margins of the TRIPS Council meetings.

5.17 Switzerland

107. The TRIPS/CBD issues, including the question of a disclosure requirement for genetic resources, have been on the agenda of the TRIPS Council as outstanding implementation issues for many years. Switzerland recognizes that these are important concerns for many biodiversity rich countries. Switzerland being a Party to both the CBD and the TRIPS Agreement, we remain open to continue exploring ways to further enhance the mutual supportiveness of both international agreements.

108. In relation to patent applications for inventions that are directly based on genetic resources, as for example in certain inventions in the field of biotechnology, or if an invention is directly based on associated traditional knowledge, disclosure of the source of such genetic resources and traditional knowledge provides additional transparency. Such additional transparency may be particularly relevant for patent examiners to facilitate "prior art searches" and to avoid the granting of erroneous patents, as well as for providers of genetic resources and traditional knowledge to facilitate the implementation of access and benefit-sharing obligations. Transparency is a core value of the patent system. For these reasons, Switzerland remains open to the TRIPS Council looking into how a disclosure requirement for genetic resources and traditional knowledge in patent applications can further enhance transparency under the TRIPS Agreement.

109. We are aware that here, as everywhere, the devil is in the details. This should not discourage the TRIPS Council or prevent the WTO from undertaking the necessary efforts to work out solutions, which are adequate, practical, non-burdensome and non-prejudicial to an expeditious and effective patent application, examination and grant procedure. My delegation is confident that this can be achieved. This is why Switzerland is a co-sponsor of TN/C/W/52 which proposes draft modalities for such a disclosure requirement in the TRIPS Agreement, as well as for the other two outstanding implementation issues in the field of geographical indications.

110. In our view, the fact that work is under way in the IGC of WIPO on an international legal instrument for the protection of genetic resources and traditional knowledge and traditional culture expressions does not discharge the TRIPS Council from its duty to work out a solution for the specific context of the TRIPS regulatory framework. We thus support technical discussions under this agenda item in the TRIPS Council and we remain open to work on a solution in the TRIPS Agreement. In our view, the basis for such work should be document TN/C/W/52, while taking into account that, in the meantime, the international legal environment has advanced, with some of the concerns now being addressed by the Nagoya Protocol on Access and Benefit-Sharing.

6 ANNUAL REVIEW OF THE SPECIAL COMPULSORY LICENSING SYSTEM (PARAGRAPH 7 OF THE ANNEX TO THE AMENDED TRIPS AGREEMENT AND PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH)

6.1 Brazil

111. The entry into force of the Protocol Amending TRIPS was an important signal for the multilateral trading system that the protection of IP can go hand in hand with measures to ensure access to medicines. The Protocol provides a legally secure and predictable option for those countries wishing to use the TRIPS flexibilities to get affordable medicines. We would like to highlight the importance of this periodic review of the implementation of the System, which became even more necessary after the Protocol entered into force.

112. While we reiterate our concern that the Special Compulsory Licensing System was used only once so far, it would be important to reflect on ways to improve it. According to reports provided by participants in the single case of use of the System, it is considered too complex and administratively unwieldy. In 2017, Brazil, India and South Africa organized a side event to the TRIPS Council in order to receive the assessment of the System from representatives of industry, Government, non-governmental organizations and academia. Future discussions in the Council could benefit from additional information that can be provided by stakeholders other than Members.

113. We believe it is important that this Organization continues to provide technical support to Members, including through the provision of legal assistance, awareness-raising activities and capacity building. This will ensure that the System becomes a practical option for the procurement of medicines in countries without industrial capacity, allowing that the fruits of the IP system are enjoyed in an inclusive way. The regional event held last year in Brasília for Latin American countries was considered a great success by participants and we will continue to support those actions by the Organization, including through the provision of experts from Brazil. We also support that the Secretariat continues its efforts to reach out to those Members not yet parties to the Protocol. Members could also act through the periodic Trade Policy Review mechanism.

114. We have always been of the view that the Doha Declaration on the TRIPS Agreement and Public Health constitutes a major landmark in the history of the WTO, because it recognized the primacy of public health needs and the preparedness of the Organization to take up the problems faced by the poor and developing countries. The recent agreement on the United Nations' Sustainable Development Goals clearly reinforces that agenda, as its Goal number 3 mandates the global community to ensure healthy lives and promote well-being for all at all ages. To attain the goals of reducing child mortality and end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases, access to medicines is a fundamental part of that. The global community needs to act together through a multitude of ways, including through the Special Compulsory Licensing System before us.

6.2 India

115. India attaches high importance to the Doha Declaration on the TRIPS Agreement and Public Health, the Paragraph 6 System as established under the 2003 Waiver Decision and the Protocol Amending the TRIPS Agreement. India is one of the first countries that notified its acceptance of the Protocol in March 2007.

116. India has always been of the view that the Doha Declaration on TRIPS and Public Health constituted a major landmark in the history of the WTO because it recognized the primacy of public health needs and the preparedness of the Organization to address the problems in access to medicines faced by the poor in developing countries. The 2003 Waiver Decision was expected to address the public health concerns faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. It may have sounded prophetic at that time when India voiced certain apprehensions in the General Council meeting of August 2003 by stating: "the results accruing from this mechanism should not be negated by the creation of cumbersome systems that would lead to huge delays in getting medicines across at reasonable cost to those that needed them or discourage Members from using the System for the benefit of the people. In order to make this System successful, a sincere collective effort is required on the part of all Members and the entire pharmaceutical industry". Regrettably, we have been proven right. The export of HIV/AIDS medicines by the Canadian pharmaceutical company Apotex to Rwanda in September 2008 has been the first and only use of the System so far.

117. The UNSG High Level Panel on Access to Medicines, in its report released in September 2016, also recognized that the Paragraph 6 System is complex and cumbersome.

118. My delegation urges Members to constructively engage on improving the Paragraph 6 System for making it more workable and effective, so that it can benefit Members with insufficient or no manufacturing capacities in the pharmaceutical sector.

6.3 Japan

119. The delegation of Japan would like to express our gratitude to the Secretariat for preparing a draft report so we can review the Special Compulsory Licensing System. We welcome this work, hoping that it will encourage all remaining Members to notify their acceptance of the Protocol.

120. This delegation would like to reiterate the importance of access to medicines, which needs to be discussed in a broader context, taking into account not only the Special Compulsory Licensing System, but also various other relevant measures and factors, such as procurement and tariffs. Japan supports the Paragraph 6 System as established under the 2003 Waiver Decision and the 2005 Protocol Amending the TRIPS Agreement. The very objective of the System is to support WTO Members in obtaining greater access to medicines, specifically Members that have either insufficient or no pharmaceutical manufacturing capacity. Compulsory licenses are, whether granted under the System or not, just one of the potential means that can be utilized for this objective under an exceptional circumstance and, therefore, the System should not be considered as the only solution, but rather as just an option we could consider.

121. In addition, this delegation would like to mention that voluntary efforts to streamline access to medicines have been increasing. For example, in September WIPO and IFPMA collaboratively launched a new medicinal patent information database, Pat-INFORMED, to help procurement agencies better understand the global patent status of medicines. We believe such a voluntary and collaborative effort will be one of the possible ways forward to respond to better access to medicines.

6.4 Canada

122. The Government of Canada considers access to medicines to be a key priority in our ongoing efforts to promote global health and prosperity. Canada recognizes that improving access to medicines needs to be achieved through the promotion of health equity, stronger health systems, and universal health coverage. Indeed, Canada's international development priorities and significant investments in strengthening health systems and the health and rights of women and children are contributing to improved access in this regard.

123. Canada is a global leader in supporting partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Drug Facility; and Gavi, the Vaccine Alliance, which strengthens health systems and provides targeted programming to increase access to medicines and vaccines.

124. In September 2016, Canada hosted the Fifth Replenishment Conference of the Global Fund and pledged CAD 804 million, which is roughly USD 613 million for 2017-2019. Canada is also the sixth largest donor to Gavi, having pledged CAD 520 million for 2016-2020.

125. Canada's Access to Medicines Regime (CAMR), which implements Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, is another measure Canada uses to promote access to medicines. Canada continues to believe that CAMR is a useful and effective tool to enhance access to medicines in the specific circumstances the System was designed to address. In 2015, Canada amended the list of medications covered by CAMR to add three new antiretroviral drugs. Canada notified this Amendment to the TRIPS Council in June 2016.

126. Canada also recognizes the 2017 entry into force of the Protocol Amending the TRIPS Agreement. The Amendment provides countries with another important tool to improve access to affordable medicines. As the only country to have exported medicine pursuant to the temporary waiver, Canada has always been a strong proponent of the Amendment, and would be pleased to share our experiences and lessons learned in implementing our own system with any Members who wish to learn more.

127. It is also important to recall that no single factor is responsible for preventing access to medicines. As the Doha Declaration emphasizes, the WTO is part of wider action required to improve access to medicines. This is why Canada relies on a variety of measures to promote access to medicines. Our view is that only by addressing all of the factors affecting access to medicines can we end the tragedy of people suffering from treatable illnesses. To this end, Canada is open to discussing how best to promote access to medicines that considers all relevant factors and effective tools to promote access. Canada looks forward to learning more about the views of other Members on this issue, including with respect to Members' experiences, challenges, and other considerations.

6.5 United States of America

128. The United States thanks the Secretariat for the update regarding the status of notifications of acceptance of the 2005 Protocol Amending the TRIPS Agreement contained in JOB/IP/32.

129. We congratulate the Members that have accepted the Protocol since last year's review.

130. We welcomed the entry into force of the Protocol Amending the TRIPS Agreement in January 2017 and are pleased that the amended TRIPS Agreement applies to 126 Members, as of September 2018.

6.6 Switzerland

131. The delegation of Switzerland would like to first thank the Secretariat for circulating the draft annual report; for the helpful, detailed information and the Guide to Notifications facilitating the use of the System offered on the dedicated WTO web page; as well as for the technical assistance it has provided, throughout last year, relating to the functioning of the Special Compulsory Licensing System and its effective use.

132. Incorporating the System into the TRIPS Agreement by way of adding Article 31bis and the Annex provides welcomed transparency, clarity and legal certainty. The System is there and ready for use by eligible beneficiary Members.

133. The Secretariat's draft annual report indicates that no notifications for the use of the System have been received in the year under review. No quick conclusions should be drawn from this fact with regard to the workability of the System. It has not been conceived for frequent use.

134. Its purpose is to extend the TRIPS flexibility of Article 31 of the TRIPS Agreement to eligible beneficiary Members without relevant manufacturing capacity in the pharmaceutical sector. The System applies to a certain number of WTO Members, in a specific case and under particular

circumstances. There are many instances where the lack of access to needed medicines in potential beneficiary countries is not related to patent protection. In such cases, recourse to the System will not and cannot provide a remedy.

135. Should eligible beneficiary Members meet concrete problems when actually making use of the System, then it would be the Council's duty to examine these specific difficulties in its reviews and look into how they can be addressed best in a practical manner. Until we have heard in this Council of such concrete problems from eligible beneficiary Members, it is not helpful for the Council's review of the System if some delegations claim in the abstract that the System is not workable or should be amended.

7 NON-VIOLATION AND SITUATION COMPLAINTS

7.1 India

136. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged.

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

138. 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 intellectual property right holders versus the legitimate exercise of regulatory policy choice by governments. Introducing non-violation and situation complaints into the TRIPS Agreement is unnecessary and inconsistent with the interests of 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.

139. We look forward to continuing working with like-minded Members in making non-violation complaints inapplicable to TRIPS.

7.2 Ecuador

140. With respect to this item, our delegation would like to reiterate its position that complaints of the types provided for under Article XXIII:1(b) and (c) of the GATT 1994 should not be applicable to dispute settlement under the TRIPS Agreement.

141. As the Council is aware, our position is reflected in document IP/C/W/385/Rev.1, which Ecuador co-sponsored together with other countries.

142. Our delegation will, accordingly, continue to participate actively in the Council's deliberations so as to reach a definitive solution on this matter.

7.3 South Africa

143. The issue of modalities for non-violation and situation complaints has been discussed in the TRIPS Council for the longest time. Article 64.2 of the TRIPS Agreement imposed a moratorium on the application of such complaints to the TRIPS Agreement for a period of five years. Furthermore, Article 64.3 of the TRIPS Agreement instructed the TRIPS Council to examine the so-called scope and modalities under which such complaints could be made. It required the TRIPS Council to make recommendations to the Ministerial Conference in 1999. Since then the moratorium has been extended various times, most recently at the Ministerial Conference in Buenos Aires, Argentina (MC11) in 2017. The Ministerial Decision instructs the TRIPS Council to continue its examination of scope and modalities and to make recommendations to the next Ministerial Conference.

144. We recall our last intervention in this house. I will briefly recall the elements of the intervention:

145. 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.

146. 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. 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.

147. There remain several other possible modalities that may be applied to non-violation and situation complaints, including some suggestions that TRIPS flexibilities should not be subject to such complaints.

148. This delegation once again invites Members that have an interest in discussing this matter to contact us. South Africa is not a proponent of the application of draft modalities but would nonetheless have an interest to ensure that the matter is discussed.

7.4 Bangladesh

149. My delegation's position on the proposed lifting of the moratorium on non-violation and situation complaints is well-known. We registered this on many earlier occasions, and would like to reiterate our position in favour of establishing a permanent moratorium.

150. Bangladesh, however, invited the views and ideas of our friends who are proponents of the application of the non-violation and situation complaints on the scope and modalities of the proceedings as required by Article 64.3 of the TRIPS Agreement. The Council needs to be better informed, and only then it will be in a better position to examine and consider the proposal.

151. The concept appears to be still an unknown territory, and unless the scope and modalities are outlined first we cannot go any further in this discussion. 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.

152. We reiterate our readiness to engage on this issue further.

7.5 Egypt

153. Egypt continues to firmly believe that non-violation and situation complaints (NVSCs) are not applicable to the TRIPS Agreement. The application of NVSCs to IP disputes would generate systemic imbalances and reduce the legal certainty of multilateral IP law. In light of the above, Egypt reiterates its understanding that non-violation and situation complaints should not be applied to the TRIPS Agreement.

154. We urge Members to engage in discussions towards reaching an acceptable and permanent solution to this issue before MC12. Egypt stands ready to participate in a constructive manner in such discussions.

7.6 Brazil

155. The debate on the applicability of non-violation complaints to the TRIPS Agreement has been part of the Council 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 continued its 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. Having carefully analysed statements made in past sessions of the Council by proponents of applying NVSCs to TRIPS, we continue to hold the view that the dispute settlement mechanism as currently applied to the TRIPS Agreement is sufficient to guarantee effective and adequate protection of intellectual property rights. Claims that the availability of NVSCs would prevent Members from evading their TRIPS obligations are not supported by evidence, and proponents have not once provided a concrete example of the envisaged use of NVSC.

156. In fact, the extension of NVSC to the TRIPS Agreement could pose an additional and unnecessary burden on the dispute settlement body. The DSB is already in a worrisome state caused by one country blocking the launch of the process to fill the vacancies of the Appellate Body.

157. To automatically apply GATT cases without addressing TRIPS specificities – and there are many – does not seem the best way ahead. Any discussion about scope and modalities should ensure that the policy space of Members to define their level of protection be preserved, in accordance with TRIPS Article 1.1. Brazil remains attentive to any proposal that may be brought by proponents.

7.7 Argentina

158. 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 for the reasons explained 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.

7.8 China

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

160. China reaffirms its position that non-violation and situation complaints are not applicable under the TRIPS Agreement, as has been elaborated in document IP/C/W/385/Rev.1 submitted by us and 15 other Members. Also, we welcome the discussion on this issue in accordance with the decision and the mandate given by the Buenos Aires Ministerial Meeting.

7.9 Canada

161. Our position on this issue is well-known, and remains unchanged. Canada continues to have concerns regarding the applicability of the non-violation nullification and impairment (NVNI) remedy to the TRIPS Agreement.

162. Recognizing that the current moratorium exists based on consensus, Canada wishes to express its continued interest in participating in any consultations that take place on this issue amongst other interested Members.

7.10 Chinese Taipei

163. My delegation understands that there are concerns among Members over the applicability of non-violation and situation complaints to the TRIPS Agreement. We are looking forward to more in-depth substantive discussions among Members on the scope and type of the said non-violation and situation complaints applicable under the Agreement.

7.11 Indonesia

164. Indonesia's position on the issue of non-violation and situation complaints under the TRIPS Agreement remains unchanged.

165. As stated in the last meeting, it is our view that the application of non-violation and situation complaints to the minimum regulatory standards for protecting private property rights remains unclear. The application of non-violation and situation complaint will disrupt the delicate balance of

rights and obligation in the TRIPS Agreement. In this regard, we believe that introducing NVSCs into the TRIPS Agreement is unnecessary and inconsistent with the interests of WTO Members.

166. We are also concerned about the impact of NVSCs on the regulatory policy space of Members including on using TRIPS flexibilities. We view that NVSCs will have an effect not only on Members' exercise of their IP regime, but also severely restrain the ability of Members to achieve public policy objectives. Based on the statement made by the proponents under this agenda item, we are still unconvinced of the necessity to provide NVSCs under the TRIPS Agreement.

7.12 United States of America

167. The United States's 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 such complaints in the future, as appropriate.

168. 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 the drafters intended for non-violation complaints to constitute an additional obligation for 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.

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

170. 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.

171. Further, non-violation complaints will only be successful if they could not have been foreseen when the Uruguay Round negotiations were under way. Because of this, 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.

172. 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 the 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.

173. 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.

174. 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.

7.13 Switzerland

175. Switzerland's position under this agenda item is, I assume, well-known and I will thus not take your and delegates' time to repeat it in full.

176. The distinguished colleague from Brazil in his intervention inquired what the scope and modalities are that proponents envisage to apply to NVSCs under the TRIPS Agreement. My delegation has explained this repeatedly in earlier discussions of this Council under this agenda but

I will confirm that the modalities we consider sufficient and applicable to such complaints in the TRIPS context are those contained in the WTO's DSU and those contained in past rulings of the dispute settlement body.

177. I also wish to confirm that my delegation stands ready to examine and constructively discuss any proposal that a Member may have on scope and modalities of NVSCs in the TRIPS context, whether in formal or informal mode. We listened with interest to the intervention and thoughts of the distinguished delegate of South Africa in that respect and look forward to continuing this dialog.

7.14 Russian Federation

178. The Russian Federation's position on the issue remains the same. We consider that non-violation and situation complaints shall not be applicable to TRIPS Agreement for the reasons outlined in document number IP/C/W/385/Rev.1 circulated in 2015.

8 REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.1

179. 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 Ukraine

180. Ukraine has submitted its answers to the Checklist of questions IP/C/13 and IP/C/13/Add.1. We believe that such exercise could enhance the transparency of our domestic system for the protection of geographical indications and we invite WTO Members to have a look at the document IP/C/W/117/ADD.35 that contains Ukraine's answers. We also encourage other WTO Members to provide their answers to the mentioned checklist.

9.2 Switzerland

181. Switzerland thanks Ukraine and Mexico for submitting their responses to the checklist of questions under this agenda item, respectively up-dating their set of responses submitted earlier.

182. Geographical indications are a field of IP in which there have been considerable developments over the last 20 years, both at the international and national level. Many WTO Members have put in place new protection systems or considerably adapted and improved their existing regulatory framework for the protection of GIs.

183. Therefore, to make the Council's discussion under this agenda item reflect the reality, it should be based on up-to date information from Members on their national application of the TRIPS provision on geographical indications.

184. We thus join you in your call to Members not having done so yet, to submit their responses to the checklist or, if applicable, to up-date the information they provided in the past, if changes in their national system have been introduced since. On this basis, we should resume the Council's substantive discussion under this agenda item in the Council's meetings next year in a meaningful and inclusive manner.

10 SIXTEENTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

10.1 European Union

185. The European Union and its Members take their commitments and obligations under Article 66.2 TRIPS seriously and try to deliver technology transfer programmes to least developed countries (LDCs) in a way that reacts to natural, social, health, climate and economic changes. The programmes are specifically tailored to the current needs of least LDCs and their regional organizations and concern mainly public health, environment, sustainable agriculture, water-management and water-sanitary systems. The programmes listed in the report are provided

by the European Commission or other European institutions or the European Union Members. The main incentive for the European Union companies to voluntarily transfer technologies to LDCs is that they get funding from the European Commission or the European Union Members for these activities. The high number of programmes shows that this incentive proved to be very effective.

186. 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. The majority of the technology transfer programmes in the report put in place new technologies, which in most cases will be managed by the local communities after the completion of the programme. Many of the technologies are not protected by patents, trade secrets or any IP right; therefore, local Governments are encouraged to replicate them in their countries, using the know-how and management and production skills acquired through these programmes.

187. Technology transfer is often only one component of a more complex project and not a stand-alone activity. The acquisition by LDCs of a sound and viable technological base does 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.

188. 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. Relevant literature has proven 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 country Members. Several projects put in place by the European Union and its Members are accordingly aimed at providing such training and education.

189. One of the most important pre-conditions of technology transfer is the improvement of the absorption capacity of LDCs. Absorptive capacity relates to the availability of human capital and presence of technological capability and other factors, such as 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. The improvement of the absorption capacity of LDCs generates voluntary technology transfer and attracts foreign direct investment in certain sectors of the economy that are vital for sustainable development in LDCs.

190. Policies aimed at improving absorptive capacity can help to remove some of the key bottlenecks to technology transfer, particularly in least developed countries. Inward technology diffusion to LDCs could be the primary source of technical change and productivity growth. This technology diffusion directly affects production capacities and increases consumer access to new innovative goods. This technology diffusion raises local productivity through various spillovers as domestic firms learn improved technologies and standards. The most effective strategy for LDCs to attract technology transfer is to reach out to multinational companies, initiate dialogues with them about the conditions, under which these companies would be willing to move some of their capacities to these countries and embark in further technology transfer.

191. 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, thus stimulate technology transfer.

[Second European and Developing Countries Clinical Trials Partnership Programme \(EDCTP2\) 2014-2024](#)

192. The successful Second European and Developing Countries Clinical Trials Partnership Programme continued also this year and keeps contributing to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for poverty-related diseases (vaccines, drugs, microbicides, diagnostics),

including neglected ones, in partnership with sub-Saharan Africa. This partnership targets 32 LDC Members. The allocated budget is around 1.9 million euros. The goals are to maximize the public health impact of interventions to control malaria in pregnancy through the translation of EDCTP-funded evidence-based global policies to country level policies, improving the impact of existing Malaria Products as well as improving HIV prevention and sexual and reproductive health care in high risk women, etc.

Environment

Dhaka Environmentally Sustainable Water Supply Project

193. Dhaka in Bangladesh has been relying heavily on groundwater as a source of water supply, but the current abstraction is beyond sustainable yields and an urgent intervention was needed. The Dhaka Environmentally Sustainable Water Supply Project is helping to provide reliable and improved water supply in Dhaka by developing a new surface water supply scheme for supply augmentation. This will include the development of a water intake at Meghna River, a raw water transmission pipeline, a water treatment plant at Gandharbpur with capacity of 500 million litres per day, a treated water transmission pipeline to the existing water supply network and distribution reinforcements. The project will also improve distribution networks to reduce nonrevenue water (NRW) and will improve the quality of water supply services, including support to low-income communities. The project will help provide sustainable water supply to a growing population in service areas - including improved access, convenience, and reliability of water supply, as well as increased quantities of water and improved water quality. Other indirect benefits arise from the employment of skilled and semiskilled workers in the construction works. The project will last until 2020 and the Commission's contribution is EUR 5.2 million, but also the European Investment Bank contributed around EUR 130 million.

194. The project will support organizing community based organizations in order to make sure that the transferred technology is used by the local communities of Dhaka. Households in low-income communities, including those headed by women, will have access to water supply through new water connections.

FRESAN – Strengthening Resilience and Food and Nutrition Security in Angola

195. South Angola's population have been suffering from the impact of climate change, which increases their vulnerability and affects their livelihoods. This programme aims to contribute to the reduction of hunger, poverty and vulnerability to food and nutrition insecurity, in the provinces of Angola most affected by climate change, namely Cunene, Huila and Namibe.

196. The programme has four distinct but complementary components:

197. Component 1 is to strengthen resilience and production of smallholder farming in the context of climate change through adoption and use of technologies, practices and innovative solutions to reduce vulnerability.

198. Component 2 is to improve households' food and nutrition security, increasing consumption and availability of more diversified and nutritious food.

199. Component 3 is to enhance institutional capacity and mechanisms for multi-sector food and nutrition security information management and data analysis, planning, coordination, monitoring, and reaction in areas of food insecurity, malnutrition and climate change. Prediction and early-warning systems and monitoring tools for risk management will be developed to cope with climate-induced crisis and the occurrence of natural disasters.

200. Component 4 is to find evidences and knowledge on the utility of different nutrition-sensitive actions that are effective, in the context of Angola, to curb undernutrition in children and reduce under-five mortality. It will also encourage scientific and technical knowledge transfer and exchange of experiences in the three target regions of Angola.

201. The European Union's contribution is EUR 68 million and the project started in 2018 and will last until 2022.

SafeWaterAfrica project

202. SafeWaterAfrica Project already started in 2016 but continued also this year and will continue until 2022. The key objective of the project is to improve access to clean water in Africa through research and development of an autonomous and decentralized water treatment system for rural and peri-urban areas. The project will develop new types of autonomous low-cost and solar powered water sanitation systems tailored for the specific needs in the rural areas of Mozambique and operated independently by local communities. Access to safe water through this project will reduce health risks. The total requested EC contribution is slightly less than EUR 3 million.

VicInAqua project

203. VicInAqua Project aims at integrated aquaculture based on sustainable water recirculating system for the Victoria Lake Basin, which would mainly benefit Uganda. The project is developing a sustainable combined sanitation and recirculating aquaculture system for wastewater treatment and reuse in agriculture in the Victoria Lake Basin area. VicInAqua project follows an integrated approach in order to develop a sustainable aquaculture fish pond system and simplified recirculation aquaculture systems combined with a domestic sanitation system and agriculture activities for the Victoria Lake Basin.

204. The project is developing a novel and robust membrane bioreactor (MBR) system for a recirculating aquaculture system (RAS), fish ponds and sanitation. Moreover, this will contribute to the development of a sustainable energy supply system based on photovoltaics and biogas (generated from the sludge of the recirculating aquaculture system) which will be integrated to the system for autonomous operation.

Rift Volcanism: Past, Present, Future – United Kingdom

205. Rift Volcanism Programme, is a research and technology programme which is funded by the Natural Environment Research Council (NERC) of the United Kingdom. The programme's results will be used to integrate volcanic hazard and risk into policies for long-term planning and short-term emergency management, mostly in Ethiopia. A contribution to this is the real-time connection of seismic stations to the responsible local institution to facilitate early warning of volcanic unrest and eruptions.

206. The programme will focus on the volcanoes of the Main Ethiopian Rift in central Ethiopia. The aim is to understand their past behaviour, look for subtle signs of present-day activity and assess the threat posed to the infrastructure and people on and around them. RiftVolc will involve scientists from many disciplines working together to produce an integrated view of the past, present and future of the volcanoes in this region and compare it to other parts of East Africa and volcanoes elsewhere. Experts in hazard assessment will model possible scenarios and create a long-range eruption forecast for Ethiopia.

Conclusion

207. This overview could only give a couple of examples of the many technology transfer projects and incentives that the European Union and its Members have put into place. The European Commission remains committed to work with LDCs and to finance technology transfer programmes and if LDCs have questions and suggestions, we are ready to provide replies.

10.2 Canada

208. As part of its ongoing commitments under Article 66.2 of the TRIPS Agreement, Canada is pleased to report on its work in providing incentives to enterprises and institutions 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.

209. Canada's 2018 report on the implementation of Article 66.2 of the TRIPS Agreement (document IP/C/W/646/Add.4) provides a comprehensive update on the range of projects and initiatives undertaken by Canada in recent years. Before discussing some of the more noteworthy projects included in this year's report, it is noted that Canada's report on Article 66.2 TRIPS focuses primarily on non-market projects, as financed by Canadian departments, agencies, and institutions, through official development assistance (ODA), grants, and other concessional financing. For

instance, the development branch of Global Affairs Canada provides financial incentives in partnership with Canadian educational and research institutions in key development areas like agriculture and food security, public health, sustainable development, as well as business development and capacity-building for small and medium-sized enterprises (SMEs).

210. For instance, as part of the Canadian International Food Security Research Fund – Phase II, Global Affairs Canada has allocated CAD 50.5 million (or approximately USD 38.37 million) over five years, to multiple countries, including Benin, Ethiopia, Nepal, Tanzania, and Uganda, towards the development of more productive, sustainable, and gender-sensitive agricultural techniques for women subsistence farmers. Project activities under this initiative include developing farming methods that can better withstand the effects of climate change, as well as reducing post-harvest losses through adaptable and affordable technologies.

211. As well, under the Canadian International Food Security Research Fund (CIFSRF), Global Affairs Canada and the International Development Research Centre (IDRC) research in agricultural innovation and fosters collaboration between Canadian experts and partner countries. Notable projects under the CIFSRF include Scaling Up Improved Legume Technologies in Tanzania, which aims to make legume technologies accessible to 100,000 small-scale farmers across Tanzania, including through farm-level trials and farmer-to-farmer demonstrations. Another notable project, Enhanced Preservation of Fruits Using Nanotechnology, will extend and optimize the use of post-harvest applications, including through improved packaging systems for transporting fruit in multiple countries, including Tanzania.

212. In 2017, Global Affairs Canada also launched Canada's Feminist International Assistance Policy, which supports targeted investments, partnerships, innovation and advocacy efforts to close gender gaps and improve everyone's chance for success. Canada's feminist international assistance will help protect and promote the human rights of all vulnerable and marginalized groups and increase their participation in equal decision making, and will help women and girls achieve more equitable access to and control over the resources they need to secure ongoing economic and social equality. Notable examples of technology transfer-focused project in this area include Improving Market Opportunities for Women Producers, which supports access to credit, inputs, market linkages, and new technologies for women in Myanmar, for instance, by providing matching grants to small and medium-sized enterprises (SMEs) for technology upgrades, as well as designing new and improved financial products for women producers in partnership with financial institutions.

213. Global Affairs Canada also supports programmes that encourage technology transfer and related technical assistance in the area of information and communications technology (ICT) Global Affairs Canada provides support for a number of ICT-related projects, such as Entrepreneurship and Business Growth for Youth, which uses ICTs to provide business development services and capacity-building to deliver entrepreneurship programmes for youth in Ethiopia. As of March 2018, 40,398 youths (60% of which were young women) have completed training through this initiative.

214. Multilaterally, Canada continues to actively contribute to several international institutions which, in turn, provide incentives for technology transfer to LDCs. On environment and climate change, for instance, Global Affairs Canada works with the World Bank on a number of technology transfer-related investment funds and initiatives, including the Clean Technology Fund. Global Affairs Canada has allocated CAD 200 million (or approximately USD 152 million) in financing to support the use of clean, low-carbon technologies, as well as investment in energy efficiency in the power and transport sectors, in multiple countries in Asia, Africa, and the Americas. As well, through financial support to the Global Environmental Facility, Canada supports the accelerated adoption of innovative technologies and management practices in areas such climate change, biodiversity, land degradation, and sustainable forest management.

215. Canada would be pleased to provide further information on these and other technology transfer projects and programmes, upon request. Canada also invites interested delegations to consult Global Affairs Canada's searchable "International Development Project Browser" for further information on these and other initiatives.

216. Canada also looks forward to the upcoming workshop on the implementation of Article 66.2 TRIPS, to be held on the margins of the next TRIPS Council meeting in February 2019, and to exchanging further information and views on Canada's annual 66.2 report in that regard.

Canada would also be interested in hearing more about some of the priorities and best practices that LDCs might identify in the incentives for technology transfer under Article 66.2 TRIPS obligation, including notable examples that Members might identify from developed country Members' annual reports.

217. We also take note of the recent TRIPS Council discussions on Article 66.2 TRIPS, including the LDC proposal document IP/C/W/640. Canada remains of the view that the workshop provides a useful venue to draw commonalities and best practices from developed country Members' 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. The workshop also provides 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, and to discussing with any interested Members intersessionally in advance of the February 2019 session.

10.3 Japan

218. Even though it is not necessary to mention again, this delegation recognizes the importance of Article 66.2 of TRIPS for LDCs, taking into account their economic, financial and administrative constraints and so on. From such a perspective, Japan is earnestly engaged in improving the business environment for technology transfer to LDCs

219. This time, this delegation would like to briefly describe this year's report on our implementation of Article 66.2 TRIPS, IP/C/W/646/Add.3. The report consists of four sections, namely, I) Activities Undertaken by Technical Cooperation Organizations, II) Activities in the field of Climate Change, III) Activities in the Pharmaceutical Sector, and IV) Activities in the Field of Intellectual Property Rights.

220. Furthermore, this report has an annex in a spreadsheet format, which provides detailed information on each activity involving technology transfer. In this annex, participating LDCs are shown in bold where they are included as parts of beneficiaries.

221. Japan understands that incentives to enable technology to be transferred include a variety of measures such as financial support and business environment support, because one of the main obstacles for enterprises and institutions in developed country Members to transfer technologies to LDCs is the lack or insufficiency of business environment in LDCs. Furthermore, improving the business environment helps create incentives that are stable and self-sustainable, which is especially important considering that technology transfer often takes time.

222. Japan believes that activities in the report contribute to creating a sound and viable technological base in LDCs, which will bring about further technology transfer by enterprises and institutions in developed country Members.

223. Japan will continue to make its utmost efforts to improve the business environment and make it even more conducive to transfer technology. In the coming Workshop to be held next February, this delegation is willing to introduce our report in detail, and strongly believes that the workshop will be a good opportunity to enhance mutual understanding, which will lead to greater cooperation in the future.

10.4 Australia

224. Australia was pleased to submit its Article 66.2 TRIPS report to the Secretariat on 12 October.

225. We take our Article 66.2 TRIPS reporting seriously, and are careful to submit our reports using the template preferred by LDC Members.

226. Australia is committed to implementing Article 66.2 of the TRIPS Agreement. Australia is also committed to sharing information with other WTO Members about incentives and support it offers enterprises and institutions to promote and encourage technology transfer to LDCs.

227. We are always happy to discuss our technology transfer activities with interested Members, and we look forward to detailed discussions at the Article 66.2 TRIPS workshop scheduled for February next year.

10.5 United States of America

228. The United States attributes great importance to this review with respect to the obligations under Article 66.2 TRIPS.

229. Our submission this year, IP/C/W/646, is a new report, detailing the intellectual property, trade capacity, training, development assistance, educational, financing, entrepreneurship, and infrastructure-related programmes, aimed to support LDCs in fostering the necessary environment to encourage the effective, voluntary transfer of technology to LDC Members. This year's submission also includes comments from host countries regarding the value of several of the programmes listed in the report.

230. The United States continues to believe that the effective functioning of Article 66.2 of the TRIPS Agreement's requires a robust dialogue between developed country Members and LDC Members in order to target incentives in a way that is most responsive to the self-identified technology transfer interests and needs of LDC Members.

231. We welcomed the 7 November logistical discussions with LDC Members and the Secretariat and we look forward to Article 66.2 Workshop on 11-12 February 2019 which will provide an opportunity to continue to exchange views and to further address important questions.

232. Please allow me to mention some elements contained in our 2018 report, highlighting a few programme updates.

233. The United States Agency for International Development (USAID) works with the Ministry of Health in Liberia to improve its ability to communicate priority information with frontline health workers. Communication during the Ebola outbreak was a critical challenge. To address this, USAID worked with the Ministry to integrate a text message platform, mHero, into their existing health information systems. This allows the Ministry to send information to health workers in specific counties in a matter of minutes. Today, mHero is used on a regular basis by a variety of departments within the Ministry of Health to inform health governance and service delivery.

234. Also, in Togo, MoLab is the United States Embassy's mobile S.T.E.M. (science, technology, engineering and math) learning lab. Built by young Togolese inventors, it is a vehicle filled with science, engineering, chemistry, and math activities. The United States Embassy and Contour Global, an American energy company with a plant in Togo, financed MoLab. Its mission is to bring STEM education to under-resourced rural schools, and it has a full calendar of activities. By next year, it expects to be fully financially independent through private sector and crowd-sourced donations.

235. We look forward to further discussing our report in greater detail with LDC Members at the February workshop.

10.6 Norway

236. Norway submitted its annual report on the implementation of Article 66.2 TRIPS after the deadline, due to unforeseen delays in capital. We apologise for the inconvenience this has caused in terms of shorter time for translation and studying of the document.

237. We will come back with a more detailed presentation of our report at the workshop that will take place in the margins of the next TRIPS Council meeting.

238. The report contains information on the same two agencies that we have reported on in previous years, with funding for private sector development and technology transfer: 1) Norad's industrial and commercial support schemes; and 2) Norfund's risk capital for investment in private business in Developing Countries. The report, of course, focuses on the incentives that were provided to least developed countries in 2017.

239. This year we have made use of the agreed format for reporting preferred by the LDC Group. We have shortened the main text somewhat, and separated the disbursements into a set of separate tables - specified by programme incentive, policy objective, funding agency, type of support, and recipient LDC.

240. This being the first time, we will also be pleased to receive feedback on our use of the format when we present the report in the forthcoming workshop.

10.7 Switzerland

241. Switzerland's new detailed report (IP/C/W/646/Add.1) reflects all latest relevant developments in Switzerland.

242. We reviewed the content and format of our reports from previous years, also taking into account the room document submitted by the LDC Group for the last TRIPS Council (meeting of 5-6 June 2018), RD/IP/24.

243. The major concern of the LDC group that solely projects which include LDCs as beneficiaries be listed in the report has been taken into account. Switzerland updated its list of projects accordingly, also further specifying which LDCs can benefit from which projects.

244. To take just one example, the new phase of the successful project "Medicines for Malaria Venture (MMV)" is open to 26 LDCs, mainly in Sub-Saharan Africa. The report now specifically lists each of the beneficiary LDCs. For more detail and substance, we would like to refer to our report.

245. We anticipate the workshop and the exchange with the LDCs scheduled on the margins of the next Council meeting.

246. This delegation remains committed to actively engaging in the discussion and further promoting the transfer of technology.

10.8 Central African Republic, on behalf of the LDC Group

247. Central African Republic, on behalf of the LDC Group, do have a few questions we would like to pose on some of them. However, before doing so we would like to reiterate our intention to pursue further discussion of our proposal in IPC/C/W/640 and the room document found in RD/IP/24, which we request to be placed on the agenda for the next TRIPS Council. In addition, the LDC Group intends to hold further bilateral discussions with the Members obligated under Article 66.2 TRIPS, in order to explore possible convergence on a way forward.

248. On the reports, we can say that some Members have provided new and interesting incentives that we might wish to explore further with the relevant named LDCs. However, the reports still contain information that appear to fall more appropriately under TRIPS Agreement Article 67, technical assistance and capacity building, than as incentives toward technology transfer.

249. Questions we would like to pose for the time being, without prejudice to the LDC Group coming back seeking more clarifications or individual LDCs doing so are the following.

250. The LDC Group appreciates the comment made in the United States submission that "the United States continues to believe that the effective functioning of Article 66.2 of the TRIPS Agreement requires a robust dialogue between developed country Members and LDC Members, in order to target incentives in a way that is most responsive to the self-identified technology transfer interests and needs of LDC Members. The United States encourages the efforts of the TRIPS Council Secretariat and Members to organize discussions among the Members regarding Article 66.2 TRIPS implementation." In this light we also hope that our proposal found in IPC/C/W/640 will be considered.

251. We note that Papua New Guinea is specifically reported yet Papua New Guinea is not an LDC. Article 66.2 TRIPS is only available with respect to LDCs.

252. Regarding item 13.1, which is read as for Nepal, there is a reference to a workshop in PhnonPhem. Can the United States clarify the relationship to Nepal?

253. The LDC Group appreciates where the United States has referred to specific transfer or dissemination of technology for example, in items 3.5.4 for Togo, 10.4 in Cambodia, 11.8.25 for Zambia, and others.

254. Regarding the other country specific programmes for LDC countries, can the United States further summarize for us where an incentive was provided for technology transfer?

255. The LDC Group also wonders if in future the United States can use the template which would help the LDC Group better identify the application of United States programmes to the specific elements of Article 66.2 TRIPS.

256. The LDC Group thanks Switzerland for their submission and we continue to examine further the programmes with the relevant LDC Members.

257. The LDC Group appreciates Switzerland's use of the template and also where it has provided clear information on specific benefitting LDCs and on technology transferred or incentives for technology transfer.

258. Regarding those programmes identified in the submission as "open to all LDCs" can Switzerland inform us of which LDCs have benefitted from the programmes or there have been none as yet?

259. Regarding Japan, Australia, Canada and Norway, and we also thank them for using the template and request if they could highlight for us specific technology transfer or incentives that resulted in more than know-how and training, but included for example dissemination or transfer of software, equipment or methodologies retained by the LDC? In the case of Canada, where references are made to LDC transferees being to only "multiple countries" in sub-Saharan Africa or just multiple countries, can Canada elaborate any specific countries? Where Norway refers to technology transfer as "risk capital" can Norway elaborate further?

260. The LDC Group would like to thank all the delegations having submitted reports and we have made these comments without prejudice any comments by any individual LDC.

10.9 Cambodia

261. Cambodia associates itself with the statement made by the Central African Republic on behalf of the LDC Group.

262. On behalf my delegation, I would like to express our appreciation and thanks for the reports submitted by the United States, Switzerland, Australia, Japan, Canada, Norway, European Union and its Members and New Zealand with respect to the implementation of Article 66.2 of the TRIPS Agreement. In particular, we would like to thank Members for providing incentives, technical assistance and capacity building as listed in its reports.

263. Taking this opportunity, I would like to reiterate that the transfer of technology is very important for LDCs including Cambodia. In this context, we call upon Members to further assist LDCs in transferring technology know-how along with assistance and making available projects for our countries.

264. Together with the LDC Group, we will make examinations and assessments of the reports to verify with our proposal contained in documents IP/C/W/640 and RD/IP/24. We will get back to Members in forms of comments, questions or consultations for the matters under Article 66.2 of the TRIPS Agreement.

265. Finally, we are look forward to the workshop in February 2019 for this issue.

11 TECHNICAL COOPERATION AND CAPACITY BUILDING

11.1 Canada

266. Pursuant to Article 67 of the TRIPS Agreement, Canada is pleased to submit its annual report on the implementation of Article 67 TRIPS, which provides an update on Canada's activities concerning IP-related technical and financial cooperation for developing and LDC Members, covering the 2017-2018 period (IP/C/W/647/Add.4).

267. Canada has undertaken a number of technical cooperation activities at the multilateral, plurilateral and bilateral levels. For instance, at the multilateral and plurilateral levels, Canada works in close collaboration with WIPO, as well as with the Asia-Pacific Economic Cooperation Intellectual Property Rights Expert's Group (APEC-IPEG), where Canada participates in regular discussions aimed at sharing information and best practices on IP rights. Canada also provides a number of technical cooperation activities administered by the Canadian Intellectual Property Office (CIPO), Global Affairs Canada, the International Development Research Centre (IDRC), and the Royal Canadian Mounted Police (RCMP). Other Canadian institutions that receive funding from the Government of Canada, such as the Centre for Trade Policy and Law and the University of Ottawa, are also involved in international technical cooperation efforts.

268. For instance, as noted in this year's report, CIPO hosted and delivered its annual CIPO-WIPO Executive Workshop for senior officials from developing countries on management techniques in the delivery of IP services in June 2018. This workshop, which was delivered in French for the second year, benefitted from fruitful participation from Tunisia, Algeria, Cameroon, Benin, Guinea, Guinea-Bissau, Mali, Madagascar, Togo, Haiti, Belarus, and the Organisation Africaine de la Propriété Intellectuelle (OAPI). CIPO also made available online a number of pre-recorded webinars on IP and patents in collaboration with the Trade Facilitation Office of Canada. These webinars, which were available for embassies, consulates, and businesses from developing countries, covered topics such as the basics of Canadian IP, registration of patents and trademarks, and IP foundations for women entrepreneurs. Moreover, CIPO provided research and examination reports for patent examinations upon the requests of Madagascar and Djibouti, through WIPO's programme of International Cooperation in the Search and Examination of Inventions (or ICSEI).

269. Canada's 2018 report on Article 67 TRIPS also includes a number of IP-related technical assistance projects funded by the IDRC. These include the Copyright and Innovation in the Developing World Project in India, Colombia, Brazil, and Chile, which provides evidence to support Governments on copyright and innovation issues in the digital economy. This project has worked to develop a transnational index of changes in copyright laws in fifteen countries, studying the impact of copyright laws on the behaviour of firms, and is developing sector-specific case studies. The project has also examined new forms of payment and reward for developing country-creators seeking to distribute their content.

270. Canada also contributes to the work of the Open African Innovation Research Network (Open AIR), which aims to investigate how IP regimes in Africa can be harnessed to facilitate innovation through collaboration, and to make processes more participatory, knowledge more accessible, and benefits more widely-shared. Open AIR is engaged in several research areas. For instance, Open AIR's work on high-technology hubs examines the role of formal IP rights in African tech initiatives. As well, Open AIR's work on informal sector innovation is examining, among other things, whether there are IP-related solutions or challenges in scaling up informal businesses.

271. With respect to discussions on technical cooperation in the TRIPS Council, Canada remains interested in hearing Members' views on some of the successes and challenges in seeking technical assistance and cooperation to address their priority needs. Canada would also be interested in hearing how priority needs have changed since LDCs' initial work on TRIPS implementation, and where gaps in technical assistance might remain. As well, Canada would be interested in Members' experiences and best practices on the types of technical assistance that have proven most effective in supporting the implementation of TRIPS obligations and in using IP to support economic and social development.

272. Canada looks forward to discussing these issues further, with a view to ensuring that technical assistance continues to meet the priority needs and development objectives of its recipients.

11.2 Australia

273. Australia takes an active role in promoting technical cooperation and capacity building in the intellectual property field as we have highlighted in our 2018 Article 67 Report.

274. Australia fulfils its Article 67 technical cooperation commitment through multilateral, regional and bilateral programs and activities. Many activities are focused on developing and least developed countries in the Indo-Pacific region. Australia works closely with the World Intellectual Property Organization (WIPO), the Association of Southeast Asian Nations (ASEAN) Secretariat and other partners to assist developing and least developed countries to build their intellectual property capacity and systems.

275. Many of the technical co-operation activities implemented under Article 67 of the TRIPS Agreement align with Australia's strategic focus on using aid as a catalyst to promote economic growth and poverty reduction, including through a strong emphasis on aid for trade. This is embedded in the UN Sustainable Development Goals and our future investments, including activities under the WIPO-Australia Funds in Trust program, will in turn be influenced by these goals.

276. Since our last meeting, the ongoing work of the WIPO-Australia Funds in Trust (FIT) programme has continued to support least developed and developing countries with the development and implementation of IP systems and enhance IP capabilities.

277. We reiterate our commitment to technical cooperation and intellectual property capacity building activities.

11.3 Japan

278. The delegation of Japan would like to briefly describe this year's report on Japan's technical cooperation (IP/C/W/647/Add.3). The report consists of the main body and its annex. The main body highlights recent technical activities, while the annex lists the details of each activity.

279. This report categorizes cooperative activities into four areas, namely, industrial property, copyright, plant varieties, and border measures.

280. When it comes to industrial property, the Japan Patent Office (JPO) organized 21 training courses for both Government officials and the private sector in FY2017. More than 300 people attended in total. Moreover, based on the JPO's long history of conducting training courses, alumni associations have been established in the trainees' home countries. The Japan Patent Office continues to support the alumni associations by holding follow-up seminars in Asian countries.

281. Turning now to copyrights, in FY2017, the Japan Copyright Office, with the support of the WIPO, held seminars where around 100 people attended.

282. Moreover, Japan provided technical cooperation to developing and least-developed country Members on the protection of plant varieties and border measures.

283. Japan will continue to make its utmost efforts to fulfil its obligation under Article 67 TRIPS.

11.4 United States of America

284. The United States is pleased to highlight its report under Article 67 TRIPS, contained in IP/C/W/647 on the technical assistance programmes provided by the United States Government concerning the protection, utilization and enforcement of intellectual property rights, including patents, trademarks and enforcement for developing and least developed countries.

285. In the past year, our report accounts for more than 85 training, technical assistance, and capacity building programmes for 83 different countries, including developing countries and LDCs.

Of these 83 countries, 11 programmes were provided for ten least developed countries, including Bhutan, Cambodia, Lao PDR, Myanmar, Nepal, Rwanda, Sudan, Tanzania, Uganda and Zambia.¹

286. Technical cooperation to improve IP legal, administrative and enforcement infrastructure is crucial to countries' economic development that is directly linked to contributing to foreign investment and voluntary, private sector-led technology transfer in developing countries and for developing country innovators to capitalize on their creativity.

287. The United States Government technical assistance is driven by demand and individual priority needs of beneficiary countries. The diversity of needs and interests identified by beneficiary countries results in tailored technical assistance activities on specific areas of interest.

288. We look forward to continued discussions on reports in the Council concerning technical cooperation of governments and IGOs for the strengthening of IP systems.

11.5 Norway

289. Norway has for a number of years provided technical assistance and capacity building through two sets of activities:

- Annual one-week training courses for up to 15 participants from national industrial property offices in developing countries - a collaboration between the Norwegian Industrial Property Office and WIPO; and
- A training programme, normally every two years, on exercise and management of copyright and related rights directed towards staff of collective management organizations and government officials in the cultural sector in developing countries - a collaboration between the Norwegian Copyright Development Organisation (NORCODE) and WIPO.

290. In previous reports we have covered these activities through 2016. Unfortunately, due to budgetary constraints, the Ministry of Foreign Affairs had to suspend the cooperation with our Industrial Property Office in 2017. For this reason, we have not submitted a written report for this year. We will, however, submit a report in 2019 that covers both sets of activities through 2018.

11.6 European Union

291. The details of the European Union and its Members' technical assistance activities in LDCs and developing countries can be seen in the submission made under Article 67 TRIPS on 6 November 2018.

292. This report confirms the European Union's commitment to technical cooperation and capacity building and shows that the European Union fulfils its TRIPS obligations on the matter.

11.7 WTO Secretariat

293. Document IP/C/W/645 reports on technical cooperation activities concerning TRIPS that were undertaken by the WTO Secretariat between 1 October 2017 and 30 September 2018. The document provides a general overview of trends; details of each activity are provided in Annex I of the document.

294. Technical cooperation activities, implemented by the WTO Secretariat under the aegis of TRIPS, have the objective of assisting Members and Observers to meet their developmental and other domestic policy objectives within the framework of the IP system established by the TRIPS Agreement, and to respond to the needs and priorities articulated by the Members concerned. Activities are driven by demand from developing country and least developed countries, as well as from governments preparing to accede to the WTO. Hence, focussing on the TRIPS framework itself, this work touches on areas such as innovation and industrial policy, health, regulatory aspects, competition policy and environmental protection, through the trade and intellectual property regime,

¹ For more information about GIPA, see www.uspto.gov/gipa.

in line with domestic circumstances and priority needs. These activities also have the objective of strengthening the capacity of Members to fully participate in the WTO's work on TRIPS matters.

295. A central focus also remains on assisting Members and Observers to understand their rights and obligations under the Agreement. As we have reported under Item 1, Members and Observers continue to receive tailored assistance regarding their participation in the transparency for the work of this Council, and this will be stepped up in line with the opportunities provided by the e-TRIPS system.

296. Among the more recent developments, since the entry into force of the Protocol Amending the TRIPS Agreement in January 2017, activities have increasingly focused on implementing the Protocol at the domestic level and supporting the utilization of the Special Compulsory Licensing System as an effective procurement tool to ensure access to affordable medicines. Given the increasing interest in sharing practical experience with the implementation of certain aspects of Part III of the TRIPS Agreement, the Secretariat also organized the first WTO activity dedicated to intellectual property judges from developing countries and economies in transition. This workshop shared experience with the application of relevant TRIPS Agreement provisions in a wide range of jurisdictions and fostered a network for continuing practical dialogue.

11.8 World Health Organization

297. The overall objective of the World Health Organization (WHO) technical cooperation is to strengthen the capacity of developing countries to respond to needs in the areas of public health, health innovation, access to medicines and vaccines, and intellectual property.

298. WHO's technical cooperation is based on its mandate derived from the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA) as well as other relevant resolutions of the World Health Assembly and WHO Regional Committees.

299. The WHO Secretariat will be presenting at its Executive Board in January 2019 a Roadmap on Access to Medicines, Vaccines and Health Products, developed in consultation with Members, which outlines WHO's work in this area, including activities, actions and deliverables for the period 2019–2023. The access roadmap will include some activities on IP, which are in line with the GSPoA, including the application and management of intellectual property to contribute to innovation and promote public health.

300. This year WHO published the second edition of a global report on access to hepatitis C treatment that reviews the progress countries have made in expanding access to life-saving DAAs. The report includes the main challenges countries face. It describes recent developments in relation to five key factors that determine access to DAA medicines: affordability, quality assurance, regulatory approval, government commitment and financing. It highlights key areas for action by Ministries of Health and other government decision-makers, pharmaceutical manufacturers and technical partners. It is available in different languages on the WHO website.

301. Another issue of importance is the emergence and spread of antimicrobial resistance in all geographical areas, which is jeopardizing the effectiveness of these potentially life-saving treatments. It not only impedes the ability to treat bacterial infections in humans and animals but has broader societal and economic effects that ultimately threaten achievement of the Sustainable Development Goals. There are scientific and economic challenges for ensuring investment in R&D. The traditional profit-driven biomedical R&D model has not led to the development of new antibiotic candidates; limited potential commercial markets and consequent low profit margins compared to other investments are being cited as contributory factors. In that sense, WHO published an in-depth analysis of all antibacterial agents currently in clinical development. The report showed a serious lack of new antibiotics under development to combat the growing threat of antimicrobial resistance and found very few potential treatment options for those antibiotic-resistant infections identified by WHO as posing the greatest threat to health.

302. The seventh WHO-WIPO-WTO Joint Technical Symposium on "Sustainable Development Goals (SDGs): Innovative technologies to promote healthy lives and well-being" discussed challenges and opportunities for the international community to ensure that innovative technologies are developed and reach patients in order to realize the right to health and the health-related SDGs. Access to, and

innovation in, health technologies is essential for ensuring progress toward universal health coverage and achievement of SDG 3: Ensure healthy lives and promote well-being for all at all ages. The discussion highlighted innovative, inclusive, and multi-stakeholder initiatives and partnerships that research, develop and facilitate access to novel, needs-based health technologies.

303. Finally, WHO is organizing an inter-agency meeting at the end of November, with technical staff from UN and other international agencies working on IP and health, including the High Commissioner for Human Rights, UNAIDS, UNCTAD, UNDP, UNITAID, WIPO, WTO to exchange information on ongoing and planned activities to help avoid duplications and where possible align activities.

304. Further details about WHO technical support in framing national policies, laws and regulations to favour application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products are available in our report (IP/C/W/644/Rev.1/Add.2).

11.9 Cooperation Council for the Arab States of the Gulf

305. I would like first to thank you for allowing me to present the main technical cooperation activities undertaken by the Secretariat General of the Cooperation Council for the Arab States of the Gulf (GCC) which are relevant to the intellectual property issues and to highlight more specifically those activities aimed at enhancing awareness on IP issues, performing patent-related activities, understanding some aspects of dispute resolution when it comes to intellectual property rights, as well as contributing to strengthening innovation. These activities are organized in mutual cooperation among the GCC Patent Office, GCC national patent offices, WIPO as well as with partners from other national IP offices. They are conducted either in the form of specialized workshops, on-job training or secondment at national IP offices.

306. As part of its leading role in developing an effective regional patent system and in implementing GCC Patent Law, the GCC Patent Office continues to intensify its activities on technical assistance aimed among others at enhancing the capacity of GCC national patent offices to contribute to patent enforcement and the improvement of the IP environment in general in GCC Members.

307. In order to contribute to enhancing awareness on IP issues, the GCC Patent Office has actively participated in IP day celebration organized on 26 April 2018 respectively at Rabigh-Saudi Arabia King AbdulAziz University and Oman Scientific Research Council in Muscat, and on 29 April 2018 at the GCC-SG Headquarters in Riyadh, Kingdom of Saudi Arabia. The GCC Secretariat General has also organized a workshop at the GCC IP Training Centre in the State of Kuwait on 9 and 10 October 2018 with the objective of Strengthening Innovation through Better IP Management in the GCC Region.

308. As for patent examination, the GCC Patent Office has conducted during the last quarter of 2017 six on-job trainings at the State of Kuwait IP Office for the benefit of the examiners of that office during a period of ten to twenty days for each training. These activities have focused on a substantive examination of all patent applications filed at the State of Kuwait IP Office. Another on-job training on the same issue was conducted for the benefit of Bahraini examiners in two phases at Bahrain national IP Office respectively on 12–19 and 19–26 November 2017. The third on-job training on patent examination was organized with cooperation of SIPO (Chinese IP Office) at the GCC headquarters in Riyadh, Kingdom of Saudi Arabia, from 19 November to 18 December 2017 with the participation of examiners from the GCC Patent Office and GCC national IP offices.

309. On the same topic, a four days specialized workshop on strategic examination procedures was organized during the first week of November 2017 at the GCC IP Training Centre (the State of Kuwait) in cooperation with USPTO (the United States Patent Office) for the benefit of examiners from GCC PO and GCC national IP offices. Another workshop was conducted during the last week of January 2018 on PCT National Phase Examination and Utilization of External Examination work products at the GCC headquarters for the benefit of the same participants in cooperation with WIPO and EPO (European Patent Office).

310. On other aspects of patent, a Workshop on classification, analysis, and search of patent applications by KIPO (Korean IP Office) was organized at the GCC headquarters in Riyadh from 20 to 23 November 2017 for the benefit of Specialists from the GCC Patent Office and GCC national IP offices in cooperation with WIPO, the State of Kuwait National IP Office and KIPO.

311. On the IT aspects of patent, an on-job training was organized at Oman national IP office with the participation of IT experts from that office during the period 1–3 July 2018 focusing on utilizing GCC Patent Office E-Systems and re-designing such systems in conformity with Oman Patent Law. Another technical cooperation activity on IT aspects was conducted in the Kingdom of Bahrain for the benefit of Bahraini specialists aimed at working on developing electronic systems at the Bahrain IP Office and launching E-filing system by IT experts of the GCC Patent Office.

312. On the IP dispute resolution aspects, a Conference on arbitration in the field of IP was organized on 23 December 2017 at the State of Kuwait Chamber of Commerce & Industry with the participation of specialists from GCC Members and in cooperation with WIPO, the State of Kuwait Commercial Arbitration Centre and GCC IP Training Centre. In cooperation among the GCC IP Training Centre and the USPTO, a Training programme was conducted on the litigation on intellectual property rights at the USPTO (United States) from 30 July to 2 August 2018 with the participation of judges and consultants from GCC Members.

313. With the objective of encouraging inventors in GCC Members, the GCC Patent Office grants a yearly award of SAR 50,000 for the top three GCC inventions on the occasion of International exhibition held annually in the State of Kuwait (28 to 31 January 2018) or any other GCC Member, as well as hosting and supporting the participation therein of inventors from GCC Members. For the same objective, the GCC Patent Office has also supported the hosting and participation of one inventor from each GCC Member in the International exhibition which takes place annually in different countries (Nuremberg, 2 to 5 November 2017). On the occasion of this event, the GCC Patent Office participates along with inventors from GCC Members to open up doors for communications with those concerned around the world.

11.10 United Nations Conference on Trade and Development

314. I refer to the submission by the United Nations Conference on Trade and Development (UNCTAD) to this Council on our technical cooperation and capacity building activities (IP/C/W/644/Rev.1/Add.1). I would like to highlight a few elements of our technical cooperation programme during the reporting period.

315. Policy coherence for local pharmaceutical production and access to medicines: Considering the cross-cutting nature of domestic pharmaceutical production and access to medicines, UNCTAD with the support of German International Cooperation (GIZ) in 2018 published the "Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production". The Tool Box provides interested governments with an overview of policy tools to create a framework conducive to promoting local pharmaceutical production and access to medicines. It has been used in our technical cooperation activities, for instance in national consultations for Thailand on policy coherence in the pricing and procurement of essential medicines that was organized jointly with UNDP.

316. African regional integration: UNCTAD has been actively supporting African countries in their efforts to promote regional trade integration. In 2018, we provided technical inputs to ongoing negotiations of a Tripartite free trade area made up of COMESA, the EAC and SADC. Our inputs were directed at Tripartite efforts to develop a regional IP regime.

317. We work closely with the African Union and the United Nations Economic Commission for Africa to prepare Phase 2 negotiations of the African Continental Free Trade Area (AfCFTA), which concerns, *inter alia*, intellectual property. We are currently planning a project to assist in the implementation of Phase 1 of the AfCFTA by analysing non-tariff measures (NTMs) in AfCFTA Members' legislation. Under the same project, we also intend to build capacities of the African private sector and public research organizations to increase research and development collaborations, including with foreign investors.

318. Investment and Antimicrobial resistance/AMR: Picking up on the *ad hoc* Expert Group Meeting on New Investment Models in Health-related R&D - The Case of Antibiotic Resistance, which we

organized in 2017 and which was reported to this Council, we have continued our work on AMR from the investment perspective. In cooperation with WHO, we organized, as part of the UNCTAD World Investment Forum this year, a multi-stakeholder discussion on "Fostering Investment in the Development of New Antibacterial Treatments". The objective of this meeting was to discuss ways of increasing private sector involvement in AMR-related R&D. UNCTAD and WHO are currently discussing follow-up.

11.11 World Intellectual Property Organization

319. The document IP/C/W/644/Rev.1/Add.5 provides a detailed list of activities undertaken by the World Intellectual Property Organization (WIPO) that were relevant to the implementation of the TRIPS Agreement. The document covers activities organized during the period September 2017 to September 2018.

320. It may be seen from this document that WIPO has provided extensive legal and technical assistance to Members to support their efforts in implementing obligations arising from the TRIPS Agreement. The activities that have been undertaken have contributed to enhancing the ability of Members to use the intellectual property system for economic, social and cultural development and to promote innovation. Further, WIPO has assisted countries in integrating intellectual property in their national development and public policies.

321. WIPO remains committed to continue providing assistance to Members States to implement their obligations under the TRIPS Agreement and to leverage the IP system to promote creativity and innovation.

11.12 African Regional Intellectual Property Organization

322. The African Regional Intellectual Property Organization (ARIPO) as an Intergovernmental Organization, currently with 19 Members across Africa, was established with the purpose of pooling together resources of its Members for the promotion, development and harmonization of Intellectual Property laws and policies for the social, economic and technological development of its Members.

323. In pursuance of its mandate, ARIPO, in some cases in collaboration with its cooperating partners, undertook activities which mainly focused on IP awareness raising and capacity building.

324. On IP awareness, ARIPO continued its initiative which commenced in 2017 of engaging Universities and Research Institutions as the main generators of Intellectual Property. Six seminars were conducted with selected Universities and Research Institutions in Rwanda, Zimbabwe, Liberia, Namibia, Botswana and Mozambique, where a total of 534 participants attended. The seminars were organized on the theme "Fostering Creativity and Innovation for Economic Growth and Development in Africa". The seminars were intended to enhance intellectual property awareness in Academic and Research Institutions with a view to promoting the creation, protection and utilization of research results using intellectual property tools for the economic and technological development of our Members.

325. On capacity building, ARIPO provided ten scholarships to students to pursue the Masters Programme in Intellectual Property that is jointly offered by the World Intellectual Property Organization (WIPO), ARIPO and Africa University in Mutare, Zimbabwe in collaboration with the Japan Patent Office. The programme has so far produced 296 graduates from 26 countries across Africa since its inception in 2008.

326. It is also worthy highlighting that ARIPO in collaboration with the Ghana IP Office partnered with Kwame Nkrumah University of Science & Technology in Kumasi, Ghana and launched another Masters Programme in IP on 28 August 2018 where ARIPO has sponsored 12 students.

327. In conclusion, allow me to present highlights of other capacity building and IP awareness activities undertaken by ARIPO. In June 2018, ARIPO and WIPO jointly organized a Symposium on Copyright and Related Rights at ARIPO Headquarters in Harare on the theme: "Shaping the Copyright and Related Rights System in Africa". The Symposium brought together participants from Copyright Offices and Collective Management Organizations from 18 ARIPO Members to discuss critical copyright issues affecting Africa and explore ways to address copyright in the digital

environment for the benefit of right holders, users and other stakeholders. The Symposium also sought to promote efficiencies in the administration and management of the copyright offices and collective management organizations.

328. In July 2018, ARIPO, WIPO and the Japan Patent Office jointly organised a Regional Training of Trainers Workshop on Teaching of IP in Police Colleges of the ARIPO Members at the ARIPO HQs in Harare to build capacity of law enforcement officers to prosecute IP infringement.

329. In August 2018, ARIPO in collaboration with WIPO, organized a Regional Seminar on the Implementation and Use of Patent-Related Flexibilities, at the ARIPO Headquarters in Harare, to enhance the knowledge of available patent-related flexibilities and to develop skills in the optimal use and implementation of the flexibilities for the benefit of ARIPO Members.

330. In August again, ARIPO, WIPO and the Japan Patent Office jointly organized a sub-regional meeting on the development of a sub-regional Technology and Innovation Support Centre (TISC) Network, ARIPO Headquarters, Harare. The meeting agreed to establish a Regional TISC at ARIPO in order to share best practices in effectively using technology found in patent databases and science and technology journal databases.

331. In September, WIPO, ARIPO and Japan Patent Office organized a Patent Drafting Course at the ARIPO Headquarters in Harare, to enhance the capacity and skills of targeted participants in ARIPO Members and Observer States in drafting patent applications.

332. In promoting IP awareness and dissemination of research results, ARIPO and the Africa University in Mutare, Zimbabwe jointly launched the African Journal of Intellectual Property (AJIP) which is published twice a year.

333. ARIPO in partnership with Africa University and with financial support from JPO has published an IP Textbook titled "Intellectual Property Law, Practice and Management: Perspectives from Africa". The book is mainly intended for students pursuing the Masters in IP.

334. On 10 September 2018, ARIPO launched its Regional Intellectual Property Database, that was developed with the support of WIPO, to efficiently serve multiple purposes, including online provision of published IP data, encouragement of regional trade and IP scientific research. The database has currently more than 400,000 IP titles from ARIPO Office and 12 Members.

12 INTELLECTUAL PROPERTY AND INNOVATION: THE SOCIETAL VALUE OF IP IN THE NEW ECONOMY – IP AND NEW BUSINESS

12.1 United States of America

335. 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 and New Business." I would also like to thank Switzerland, Australia, the European Union, Japan, Republic of Korea, Chinese Taipei, and Brazil for co-sponsoring this item.

336. The day before this meeting, the Friends of IP and Innovation sponsored a side event where speakers highlighted the incentivizing role of IP in the areas of economic growth, development, societal benefits as well as a catalyst for new businesses. This featured economic perspectives and innovators who have relied on IP to produce game-changing technology. We thank everyone who came and supported the event.

337. As we have discussed during the course of the year, there is a critical nexus between business development, intellectual property, and economic growth. IP-intensive industries support at least 45 million US jobs and contribute more than USD 6 trillion to, or 38.2% of, US gross domestic product (GDP).

338. The importance of intellectual property is no less for small and medium sized companies, including start-ups, which are the backbone of the American economy. The United States' 30 million SMEs have accounted for nearly two-thirds of net new private sector jobs in recent decades. And

our youngest companies – those less than one year old – have created on average 1.5 million jobs annually over the past three decades.

339. These figures indicate that creating the conditions for new businesses and start-ups to succeed is key to America's future economic success. Entrepreneurship is critical to both the United States and the global economy.

340. The United States Government agencies support entrepreneurs throughout every phase of the business-life-cycle: in addition to promoting transparency and rule of law, they provide for patent, trade secret, trademark, copyright and other IP protections to allow entrepreneurs to protect their work and bring it to the marketplace.

341. For new businesses, IPR protection can often help determine whether a firm survives and thrives. In particular, the United States manufacturing firms that use intellectual property are a boon for the economy.

342. In the case of SMEs, trade secrets may play a critical role in the development of innovation and are among the primary forms of intellectual property that companies use to protect their innovations, as smaller firms tend to have fewer resources and limited expertise and capacity for managing intellectual assets using formal IPRs.

343. Patent protection also plays a critical role for the development of new companies. Start-ups, as compared to larger firms, may factor into their growth strategies, considerations such as the marketing advantages that ensue from being able to claim patent protection.

344. Studies have shown that SMEs tend to use their patents more actively than large firms and smaller companies generally license a higher proportion of their portfolios than do larger ones. A recent study out of the UK on the survival of new technology-based firms also concludes that patent development during firms' initial years is critical to survival.

345. Registering and maintaining relevant trademarks can also help ensure that a firm rightfully enjoys the benefits of its investment in creating a distinctive brand, including brands that feature innovative products and services. Without this legal protection, an unscrupulous competitor may attempt to usurp the goodwill that another company has worked hard to create.

346. Traditionally, research on the role of IPRs for small firms and start-ups has been patent-focused. Recently, however, research on trademarks has gained momentum and has established that trademarks are a similarly important form of IPR, particularly for start-ups.

347. Recent studies have shown that start-ups are more likely to file for trademarks instead of patents when entering markets with a higher market concentration. The same study also shows that start-ups that are primarily active in business-to-consumer markets are more likely to file trademarks than start-ups primarily in business-to-business markets.

348. Exporters are significantly more likely to rely on IPR than other firms. Firms holding patents in the United States account for over 90% of the United States exports. Similarly, innovative firms are better exporters. An examination of the performance of 1700 firms before and after acquisition of a first patent found that, whereas the number and value of firms' export transactions remained constant up to the date of the patent acquisition, the number and value of export transactions rose afterward.

349. Industries in the United States that rely on IP are ones that flourish the most. One example is the copyright industry, which as a whole, generates jobs, and produces economic growth, both in the United States, and globally. Copyright protection plays a key role in a large number of companies. Even those not engaged in content creation and distribution often have a strong need to protect important materials via copyright.

350. In the United States, copyright-intensive industries supplied 5.6 million jobs and copyright industry workers earn on average 38% higher wages than other US employees. The United States music industry specifically, supports 1.9 million American jobs and added USD 143 billion in value

to the US economy in 2016, increasing over 37% since 2012. Many creative artists are small businesses, who rely on copyright protection to improve their livelihood.

351. The United States Government wants to make sure new businesses have knowledge of, access to, and benefit from, existing government resources aimed at helping start-ups and new businesses realize international opportunities.

352. Many start-ups, in particular technology start-ups, face unique challenges, so counselling from government or private sector organizations can make a big difference.

353. The International Trade Administration (ITA) at the United States Department of Commerce launched an initiative entitled "Start-up Global" in partnership with the Global Innovation Forum to provide focused advice to small and early-stage American companies looking to grow their businesses by engaging in the global marketplace.

354. Separately, the Global Entrepreneurship Summit, sponsored by the United States State Department, aims to showcase inspiring entrepreneurs and investors from around the world creating new opportunities for investment, partnership, and collaboration; it connects American entrepreneurs and investors with international counterparts to form lasting relationships; and highlights entrepreneurship as a means to address some of the most intractable global challenges.

355. The Global Entrepreneurship Summit was held for the first time in South Asia in Hyderabad, India, last year and this year will be in The Hague.

356. These programmes aim to increase survival and success rates of technology-based start-ups. The programmes also enable technology-based start-ups to scale their growth faster. Both of these goals are achieved by encouraging start-ups to expand into international markets where there is demand for their products & services and potentially less competition.

357. Other USG agencies, such as the United States Patent and Trademark office, offer programmes for new businesses and start-ups to protect their IPR.

358. Through the Patent Pro Bono Programme, the USPTO partners with non-profit organizations and law schools to establish regional programmes throughout the country. By working with their regional patent pro bono programme, under-resourced independent inventors and small businesses are eligible for free legal advice and representation to help them file and prosecute patent applications.

359. International cooperation also plays an important role for start-up development and growth. The Americas Competitiveness Exchange, is done in coordination with United States Department of Commerce's International Trade Administration (ITA) and Economic Development Administration (EDA), in coordination with the United States Department of State and the Organization of American States (OAS), and brings 50 representatives from 24 countries throughout the Western Hemisphere to explore global and regional partnerships and economic development opportunities to establish new global commercial relationships.

360. Furthermore, the United States and the European Union work together to make sure their start-ups and small businesses share best practices about how to protect their IPR in each other's markets. The EU-US SME Best Practices Workshops are held annually and are an ongoing opportunity for small businesses to engage directly and discuss trade topics of interest with United States and European Union officials and small and medium businesses and associations from both sides of the Atlantic.

361. IP protection also plays a big role in new emerging technologies and start-ups that are quickly integrating into the global economy.

362. Marvin Caruthers, Inventor of Chemical Synthesis of DNA, and co-founder of Amgen and Applied Biosystems testifies to the importance of IPR to biotechnology development. He emphasizes that the biotechnology industry would not exist without patents, as he must have patents to protect his technology in order to attract investors, as they want to know what the company is bringing to the table.

363. Artificial intelligence is another emerging area focusing in IPR protection, used mostly in the tech industry, producing new products and services every year. Artificial intelligence (AI) will redefine how individuals think about daily life, and start-ups will need to start leveraging AI to get ahead.

364. The USPTO offers programmes and tools for businesses to learn to protect AI-related inventions, navigate the quickly evolving sector, and learn about the United States approach as well as how other major economies are addressing AI in terms of intellectual property rights protection.

365. New enterprises, start-ups, and small businesses, are the core of the United States and global economies. As we have discussed over the past year, the nexus between trade, IPR, and economic growth is profound, as intellectual property not only fosters new business, but it creates new jobs and leads to higher wages.

366. IPR is an integral part of our local American innovative economy, and through trade and investment, IPR contributes to the economic growth of the global economy, improving lives and society as whole. We look forward to hearing from other Members on this topic.

12.2 Switzerland

367. Switzerland is pleased to co-sponsor this topic in partnership with Australia, Brazil, the European Union, Japan, Republic of Korea, Chinese Taipei, and the United States. We welcome the opportunity to exchange experiences on how intellectual property contributes to creating new business. This is an important topic for the WTO, whose goals are, among others, to promote trade between and economic development of its Members.

368. For large companies, the protection of intellectual property is often a cornerstone of their business strategy. They consider IPRs key to protecting their intellectual property, investment and reputation against unfair competition, misuse and freeriding. At least in innovation-driven industries, intellectual property rights are often the most valuable assets in their balance sheet. For small companies and start-ups, the use of IP as an essential asset-building instrument is not always that obvious. There may be a lack of awareness. Or the start-up may know about the potential value of IP rights but shies away from the administrative work and financial costs associated with seeking IP protection – or falsely assume that they can deal with securing IP rights at a later stage in their business development.

369. My delegation would now like to share some experience we have made in Switzerland with regard to the three aspects addressed in IP/C/W/648 on how IPR can help new business drive their success.

370. In 2015, more than 580,000 companies were located in Switzerland. 40,000 new businesses started operations in the same year, with the majority in the services sector. The economic significance of these newly founded companies does not only lie in the number of newly created jobs. It lies also in the business momentum, the value-added for the economy and society they generate, including intangible assets such as IP. Founding a start-up may be the initiative of an independent entrepreneur. Frequently, however, they are the result of a spin-off from research institutes or universities.

371. Government activity and policies as well as the legislator can best serve research initiatives and entrepreneurs by providing favourable business conditions, i.e. lean procedures for the creation of new businesses, an attractive tax system, and not least: clear, reliable legislation for adequate and effective protection of intellectual property and for licensing IP rights. This provides a safe and effective regulatory framework for new businesses or university spin-offs entering the market and doing trade with their innovations.

372. We would like to illustrate this with two examples of new businesses that were the result of the partnership between academia and Innosuisse, Switzerland's innovation promotion agency.

373. Innosuisse, the Swiss Government's Innovation Agency supports science-based innovation in the interest of industry and society, with the aim of laying the groundwork for successful Swiss start-ups and their innovative products and services. Its long-term mission and goal is to contribute with

its activity to a prosperous and sustainable economy in Switzerland. The activities of Innosuisse involve promoting entrepreneurial thinking by providing targeted and personalised training to start-ups, by funding science-based innovation projects, by helping the internationalisation of Swiss SMEs, and by promoting networking and events in key innovation fields.

374. Part of Innosuisse's mandate is raising awareness of SMEs of the importance of protecting their intellectual property. Innosuisse promotes business ideas in accordance with the subsidiarity principle, i.e. it only supports projects if the market potential is not otherwise tapped into. Innosuisse follows predominantly a non-monetary policy, i.e. a coaching and knowledge-pooling approach rather than substituting private market funds from, for example, venture capitalists. This approach helps avoid wrong incentives and ensures sustainable use of limited public means.

375. Of course, new businesses need substantial kick-off financing from private sources. Often, however, their sheer lack of expertise and experience of how to establish and run a business are by themselves handicaps. Here, governmental institutions can lend assistance as temporary partners, trainers, coaches and intermediaries. Innosuisse especially promotes partnerships between academia and the private sector. It is also a networking platform, bringing the right partners from the academic and private sector together. Moreover, by helping to promote the market potential of innovations at an early stage of development, the agency can facilitate a start-up's entry into international markets.

376. Such cooperative assistance and support can benefit companies in all economies, whether high-, middle, or low income, of course adapted to the particular circumstances, needs and capacity of the companies in an individual country. The World Bank's research paper by Cravo and Piza on the impact of business support services for SMEs in low and middle-income countries shows how business support in these countries helps improve performance of companies and create jobs. The research paper informs policy debates with its meta-analysis on how such engagement of the public with the private sector benefits companies in a country, even if such support and engagement is limited to training courses.

377. In Switzerland, around 200 start-ups benefited from such individually tailored coaching in 2017. The projects which were mentored by Innosuisse, have contributed to the development of innovative solutions, some responding to everyday problems, others producing breakthrough innovations.

378. At the side event on IP & Innovation, Jonas Pollard, a Swiss post-doctoral researcher at the University of Freiburg in Switzerland, presented his highly innovative project Hemolytics Malaria Diagnostic for which he entered a partnership with Innosuisse. The business case of his project was to develop a highly sensitive, inexpensive, portable, robust diagnostic device for malaria parasite detection in human blood. It relies on the patented chemical amplification of a malarial biomarker, a molecule found only in infected people. When this biomarker is present, a transparent liquid containing the chemical reagents ("re-agent") turns cloudy. By recording the formation of cloudiness, one can assess the infection of a patient. Mr. Pollard explained that the BRIDGE programme of Innosuisse had been essential for developing his innovative work beyond the stage of basic scientific research. The BRIDGE programme is a joint project run by Innosuisse and the Swiss National Science Foundation. It enabled the grant of a kick-off funding (of CHF 130,000), during which Pollard had to change his scientific mindset to an entrepreneurial one. This was also possible thanks to the BRIDGE programme, which aims to help young researchers apply their research results and gain the confidence needed to enter the market. To achieve this, Jonas Pollard participated in training courses such as the Innosuisse Business Concept and soon thereafter the Business Creation Training. He considered the support from different Innosuisse mentors to be crucial in helping him carry out the business development of his venture.

379. But how do academia, doctoral students and start-ups manage to handle their intellectual assets, their IP rights? Let's look at the example of Jonas Pollard, whose new business holds a first patent filed in European countries and the USA. The patent is still owned by his employer, the Adolphe Merkle Institute, which covered the cost for the patent application under WIPO's Patent Cooperation Treaty PCT. The institute's policy is that the research group where the patent originated from covers half of the patenting costs incurred for the national filing phase. This policy applies if the invention is not licensed-out to a corporation as an external partner. Pollard is now negotiating either to obtain an exclusive license or to buy the patent from the Adolphe Merkle Institute. A second patent is already in the pipeline for an important follow-on invention.

380. Summing up his experience, Jonas Pollard States that the patent was helpful in giving credibility to his project and attracting funding from other institutions and the private sector. It also enabled the disclosure of the technology to potential partners and customers without the need for a non-disclosure Agreement.

381. Let us also briefly present a second project supported by the BRIDGE programme. It concerns a new, innovative and sustainable business model that relies, *inter alia*, on trademark protection.

382. Colombian national Catalina Jossen-Cardozo arrived in Switzerland four years ago. She prepared for a Master's degree at the Lucerne School of Art and Design. In her studies, she thoroughly analysed the footwear market and observed that this sector was not only characterised by very complex logistics, but also dominated by monopolies. Against this backdrop, Jossen-Cardozo created a smart production chain for commercialising shoes in a new and sustainable way. To do this, she uses a sophisticated online tool and is building up her brand "By Maria", a registered trademark.

383. Ms. Jossen-Cardozo has collaborated with Columbian footwear designers who create their collections using her online tool and her trademark ("By Maria") thanks to a licencing agreement. This allows them to have their designs produced in a small, high quality, handcrafted limited edition. The shoe designers earn 10% of the product's selling price – compared to the normal average of only 1%. Furthermore, the Columbian shoemakers involved also receive a larger share of the selling price than is average. The project further aims at training and equipping footwear makers, enabling them to build up an independent livelihood for themselves and a better living for their families.

384. At the end of the supply chain, consumers acquire bespoke designer footwear that addresses their specific needs, while being reassured that the brand they are buying is a sustainably produced product at a fair and transparent price.

385. Ms. Jossen-Cardozo hopes that, in the future, she will be able to apply her concept and brand to other products and in other countries. Trademark law will allow her to do so through licensing contracts. Further relevant IP rights that she may rely on are industrial designs and copyright.

386. To sum up, IP can play a key role throughout the whole process of creating a new business. IP can positively shape an entrepreneur's incentive to innovate and protect investments. It can help science-based start-ups to step into markets and it can help new businesses connect with partners and gain a foothold in the international market. We encourage Members to take part in a comprehensive discussion on this. My delegation is looking forward to hearing from other delegations about their own experience and examples of the role of IP for new business, and about their policy approaches to support and promote new businesses.

12.3 Australia

387. Australia extends its sincere thanks to Switzerland for introducing this paper, which we are pleased to co-sponsor, on an issue that is assuming a growing importance for the entire membership of the WTO.

388. As suggested by our Swiss colleagues, we have based our intervention around the three guiding questions listed at the end of the paper, which sought information on i) the local IP and knowledge based business landscape; ii) the IP regulatory environment facing new businesses; and iii) real world examples of successful start-ups and IP policy settings.

389. Turning to the first of these questions, Australia enjoys one of the highest levels of entrepreneurial activity in the world. In 2016, an estimated 48.7% of all employing firms were 'innovation active', and nearly 15% of the Australian adult population was actively engaged in starting new businesses, equating to 2.2 million early stage entrepreneurs.

390. It is difficult to determine the exact number of start-ups operating in Australia. By one measure² the total number of start-ups rose from 954 to 1,465 - an increase of 54% - between 2015 and 2018. Another report found there were 2,770 start-ups in the State of Victoria alone.

391. Despite these discrepancies, all sources agree that Australia's start-up ecosystem has grown dramatically in recent years. Access to finance is improving, and the start-up industry is becoming more mature. On average, start-ups are now surviving for longer, testament to their growing ability to develop marketable products and workable business models.

392. In keeping with global trends, Australia's venture capital market declined sharply in the wake of the Global Financial Crisis (GFC). Since the GFC, Australian venture capital investment has averaged around AUD 300 million a year, down from the pre-GFC peak of AUD 900 million. However, it increased dramatically in 2016-2017, more than doubling to AUD 463 million, while venture capital fundraising jumped from AUD 211 million to AUD 959 million.

393. While the venture capital market is well established, venture debt remains for the time being a relatively unfamiliar concept in Australia, with just three lenders operating in the local venture credit market.

394. The Australian Government offers a number of programmes aimed at supporting venture capital and investment in early stage companies, including tax incentives, and flow-through taxation vehicles.

395. We now turn to the second question, concerning the IP regulatory environment for new businesses, and the importance of international cooperation.

396. Australia's IP system seeks to strike a balance between the needs of our inventors, entrepreneurs and creative artists, who require sufficient protections to encourage them to embark on their innovative work, and the needs of consumers and producers, who wish to benefit from the products and ideas which this innovative work creates.

397. The Australia Government offers a range of programmes and support mechanisms aimed at helping local businesses bring their innovations to the marketplace. The IP Toolkit for Collaboration, for example, is designed to promote the commercialisation of IP by facilitating collaborative ventures between research organisations and industry. It offers a range of tools, including model contracts and advice on navigating difficult issues, such as confidentiality provisions and the use of existing IP.

398. Another initiative, Source IP, connects businesses with Australian public-sector research organisations that are looking to license their patented technology.

399. Australia's annual IP Summit builds understanding of our IP system by bringing together entrepreneurs, industry and government for a day long discussion on strategies for businesses looking to expand their commercial footprint, particularly overseas. In 2018, the theme was "Launch to Export – Take your Ideas Global", and work has already begun on the 2019 summit, which will focus in part on businesses expanding into China.

400. Finally, the 'Accelerating Commercialisation' initiative provides support to innovators who are looking to commercialise their intellectual property. To be eligible for an 'Accelerating Commercialisation' grant, a project must aim to commercialise intellectual property in the form of a novel product, process or service. As well as financial support, participants also receive assistance from Commercialisation Advisers who closely monitor each project and provide more detailed guidance if required.

401. Cooperation with our international partners makes a vital contribution to our broader efforts to create an IP regime that fosters innovation and creates a supportive environment for fledgling businesses. For example, we look to include commitments on IP in our free trade agreements to

² Start-up Muster 2018 report.

address developments in, and achieve a consistent international approach to, IP protection and enforcement.

402. Australia is also committed to helping developing countries, particularly those in our own region, to build strong domestic IP regimes that support local entrepreneurs and encourage innovation. Our Funds in Trust (FiT) programme, which we implement in close cooperation with WIPO, has supported the development of national IP strategies and the creation of an IP toolbox that has been translated into local languages. It has also funded training activities in the fields of trademarks, copyrights and patents, and workshops on IP marketing, commercialisation, and women and IP.

403. In a similar vein, IP Australia's Regional Patent Examination Training Programme (RPET) offers intensive competency-based patent examination training to examiners from ASEAN Intellectual Property Offices, to enable them to meet international Patent Cooperation Treaty (PCT) standards. This will in turn help create local regulatory environments that are conducive to innovation and entrepreneurship.

404. At the multilateral level, the global protection treaties administered by WIPO, such as the PCT, provide a clear demonstration of the benefits of international cooperation. While entrepreneurs and innovators have always had the option of pursuing protection for their inventions, trademarks and designs directly with individual IP offices, the WIPO-administered treaties substantially simplify the process for those wishing to market their innovations on a global scale.

405. Turning to the third and final question, there is a range of Australian businesses that have expanded into global markets thanks to the protection afforded to their intellectual property.

406. We offer the example of Win Win Parenting. Win Win Parenting, founded in 2013, provides education programmes that help working parents across Australia balance their work-life priorities. After establishing a strong business at home in Australia, working with a client list that included leading banks and universities, the company's founder set her sights on expanding overseas. Recognizing the importance of securing IP protection in foreign jurisdictions, the owner began the process of filing for trademark protection in the United States, the United Kingdom and New Zealand. Having initially secured the services of a local IP attorney, the company subsequently elected to seek protection via the Madrid Protocol, which allowed it to file simultaneously in all three countries, rather than having to deal individually with their respective IP offices.

12.4 Chile

407. Our delegation thanks the delegations of Australia, the European Union, Japan, Republic of Korea, Switzerland, Chinese Taipei and the United States for the document on intellectual property and innovation.

408. Chile views intellectual property as a tool for the promotion of technological innovation and the transfer and dissemination of knowledge, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

409. In this context, we believe that intellectual property plays a role in the creation of new undertakings that base their focus on intangible assets. The dynamic shift in trade towards a model focused on the knowledge based economy continues to heighten the importance of measures that promote the creation and sustainability of this type of undertaking.

410. In this light, and on the basis of the three questions posed in document IP/C/W/648, we would like to share with the TRIPS Council some information and statistics regarding public initiatives and policies aimed at facilitating the creation of undertakings and businesses in Chile.

411. In statistical terms, and according to information provided by the Start-up Chile programme, there are currently around 1,300 start-ups that were created under this programme, more than 50% of which are active and which are valued at USD 1.4 billion. The Start-up portfolio is a colourful one, covering areas such as big data, biotechnology and the Internet. According to the 2016 Global

Entrepreneurship Monitor report on Chile, there has been a sharp rise in innovation and development transfer from universities since 2015.

412. Regarding specific regulatory measures conducive to the creation of new undertakings, we would like to tell you about some initiatives that have been introduced:

413. First of all, we have the "Your Business in One Day" initiative (Tu Empresa en un Día), which, through a single web portal, seeks to facilitate the creation of businesses by eliminating costs and reducing the amount of time it takes to set up an enterprise. The initiative, introduced by the Ministry of Economy of Chile, has achieved excellent results. Today, entrepreneurs and innovators can set up their businesses without seeking legal advice or paying notary fees, and do not need to waste time dealing with the Internal Revenue Service.

414. The second initiative was introduced by the General Directorate of International Economic Relations of the Chilean Ministry of Foreign Affairs and is aimed at Chilean exporters. Under this initiative, exporters of goods with a high technology content and those in creative industries receive training on aspects of intellectual property that should be taken into account when exporting goods to third countries. To this end, fact sheets have been produced on the main aspects of intellectual property systems in export markets. This initiative has enabled Chilean exporters to better understand the importance of considering intellectual property related aspects when exporting.

415. The third initiative is the Start-up Chile initiative, a business accelerator created by the Chilean Government to encourage a high level of innovation based entrepreneurship using Chile as a platform. Start-up Chile is the leading accelerator in Latin America and among the top ten accelerators worldwide. It has the largest and most diverse community of start-ups in the world. Start-up Chile has changed the vision of entrepreneurship at global level. Since its creation, around 50 other countries have introduced similar programmes.

416. Lastly, a draft law has been presented to incorporate the acquisition of start-ups as a tax incentive. This measure reflects the importance of technology transfer hubs, the mission of which is to protect technologies at global level and transfer the technological developments generated in universities and centres of technology off campus, either to businesses or to generate new spin offs. The measure also seeks to boost private investment in innovation.³

417. We would like to finish by showing you a specific example of a new business that is based on intellectual property. The video you are about to see tells the story of Luis Cheul whose passion for music led him to invent the smallest electric bass guitar in the world. Thanks to his invention, he established links with the Wing Instruments company, which now sells his product throughout the world.⁴

12.5 Japan

418. This delegation would like to thank the delegation of Switzerland for its clear introduction of our concept paper. As is written in the concept paper, in the current economy "knowledge is the main driver of economic growth" and "intangible assets play an important role". In this situation, this delegation fully supports the idea that protecting IP is highly important in the process of creating a new and innovative business.

419. This delegation is of the view that strategic IP protection facilitates rapid growth of new business. In order to support the growth of new business, the Japanese Government has established various IP-related policies for start-ups in Japan. Taking this opportunity here, this delegation would like to mention what we are currently doing and show how start-ups made good use of their IP.⁵

420. First, we will show you the general situation of new business. According to statistics by our Government, the number of new business start-ups in Japan is about 200,000 a year. Since a new and innovative business is essential to drive economic growth and create jobs, the Japanese

³ Video Start Up Chile - <http://www.startupchile.org/es/sobre-nosotros>.

⁴ Video Inventando Chile - <https://www.youtube.com/watch?v=Cx511TPVQCE>.

⁵ The PowerPoint presentation is available in Room Document RD/IP/29.

Government supports the so-called "start-up ecosystem" in various ways, supporting start-ups from their beginnings, up to their mature stage.

421. Then, what kind of support programme is needed for start-ups, in particular in the IP field? According to the questionnaire conducted by the Japan Patent Office, the following three points will be addressed.

- a. Lack of awareness of the importance of developing an IP strategy;
- b. Lack of opportunities to meet IP experts familiar with the start-up ecosystem; and
- c. Need for speedy support.

422. In response to this situation, just this past summer the JPO, in collaboration with other agencies, launched a brand-new IP policy to support start-ups. Currently there are five policy keywords, which are: (1) strategy (2) expansion (3) speed-up (4) low cost and (5) information. We will talk about two out of five areas of support, which are the "Hands-on programme" and the "Accelerated Examination". In addition, this delegation will show you a model case that made use of IP as a development tool.

423. This is the "IP Acceleration programme for Start-ups", which we call IPAS". The JPO just started this programme from this July. Under this programme, the JPO sends Special Professional Teams to start-ups during their early stage of growth, for a certain period of time. The team consists of several business experts such as Venture Capitalists, Business Consultants and Attorneys. The team provides hands-on support to form and work with the start-ups' IP strategies. Based on this programme, we hope that start-ups in their early stages can expand their business quite smoothly, based on developing appropriate IP strategies and making use of professional support.

424. The next is "Accelerated Examination" which also started from this July. Speed is of the essence for start-up' businesses, so it is important to adapt patent examination to enable start-ups to strategically acquire and utilize their patent rights at the right timing. In addition, it is also important to provide fine-tuned support to start-ups that have little experience in acquiring patents.

425. Based on this, the JPO launched two programmes: "Accelerated Examination Using Interviews" and "Super-Accelerated Examination" in order to fulfil start-ups' needs.

426. Conducting "Accelerated Examination using Interviews", start-ups can meet patent examiners face-to-face and directly explain the details of their patents. And examiners give general advice on patentability and various initiatives provided by the JPO for supporting start-ups.

427. In the "Super-Accelerated Examination", start-ups can request the fast-track programme if the inventions are already being worked. This system enables start-ups to acquire patent rights much sooner compared with the standard application process. Obviously, these programmes enable them to acquire patent rights in a speedy manner, and enable them to achieve strategic business activities.

428. Finally, this is a successful case in which IP was used as a means for a start-up to collaborate with a big company and expand its business. A joint-venture in Osaka, called "Microwave chemical", developed a factory process utilizing micro-radio waves. Its IP activities are worthwhile to note, in particular the following three points.

429. First, the company regularly holds an "invention committee" to maintain a solid IP strategy. The committee Members are comprised of the CEO, staff Members in the IP division, and external IP and legal experts based on a partnership agreement. In addition, it has a good training system in IP literacy for the staff, which enables the company as a whole to raise the awareness of IP protection.

430. Second, the company utilizes its IP rights for building a collaborative relationship with a big company. It enables the company to conduct collaborative research on bigger projects.

431. Third, leveraging its IP rights, the company can easily obtain financial subsidies from the public sector. The subsidies make it possible for the company to expand its business with foreign partners.

432. This company was awarded a special prize by the JPO because it adopted a successful IP strategy. This kind of exceptional role model is included in brochures issued by JPO, in order to enhance IP awareness and show that IP strategies are highly important.

433. In summary, this delegation would like to emphasize again that in the current knowledge-based economy IP is extremely important for driving new and innovative businesses. To facilitate the growth of new business, the Japanese Government provides many programmes for start-ups. This delegation hopes that its information helps other delegations create their own domestic policies and looks forward to hearing other delegations' input under this agenda item.

12.6 European Union

434. Intellectual property rights (IPRs) 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.

435. In today's knowledge society, the European Union thinks that innovation is a key asset. For many countries, it is a more valuable source of growth and wealth than natural resources - which are increasingly scarce.

436. The impressive development and growth of many countries, relies to a large extent on innovation and technology. An effective IPR system is crucial to promote innovation, as it makes it possible to protect intellectual assets such as inventions and brands, but also music, literature and agricultural products, which are as relevant for developing as they are for developed country Members.

437. Therefore, insofar as IPR regimes are concerned, legal certainty is important in encouraging innovation and investment, which underlines the need for stable and predictable IPR regimes, domestically and internationally.

438. It is clear that IPR regimes need to be properly balanced, and this has been a central concern throughout the history of IPR, with frequent controversy regarding how exactly to achieve such balance. But ultimately, there is very broad agreement about the central role of intellectual property in a knowledge based society to ensure, competitiveness, scientific progress and access to culture.

439. It is therefore not surprising that the fostering and development of intellectual property rights has become one of the crucial areas of policy initiatives in the development of a growth conducive business climate, in particular with regards to start-ups and other forms of new businesses.

440. The key role of intellectual property in the success of start-ups and innovative new businesses has long been recognized. It allows innovative businesses to profit from the results of their creativity, inventiveness and R&D investments, and creates an incentive for further investment in innovation.

441. Given that knowledge-based parts of the economy in developing and developed country Members is made up of businesses whose most valuable assets are intangible, innovative and creative start-ups need to be aware of the advantages of using IP and the dangers of neglecting it. Among other reasons, to better assist those companies in this regard, the European Commission set up the Executive Agency for Small and Medium-sized Enterprises, which manages the vast majority of the European Union programmes designed for SMEs and new business to help them innovate and do research.

442. In the Single Market Strategy, the Commission announced in 2015 that it would come forward with European Union-level measures to support the use of IP by SMEs and start-ups. Honouring that commitment, the Commission is putting in place a package of IP-support measures for start-ups, aiming at improving coordination and consistency in addressing sub-optimal use of IP across the European Union. This package was presented together with another Communication titled "Europe's next leaders: the Start-up and Scale-up Initiative". The Communication aims at enhancing a

coordinated approach across the European Union policies through a set of pragmatic measures in order to boost innovation and research with the involvement of new businesses.

443. The measures include:

- Streamlining European IP awareness schemes for new businesses and providing a cooperation platform for European Union Members;
- Developing a European Union IP mediation and arbitration network;
- Encouraging the creation of European-level insurance schemes for litigation and IP theft, building on a common IP valuation method; and
- Improving coordination of IP support funding schemes, including by means of a possible guidance to Members and by developing monitoring methods their impact.

444. Working in partnership with all levels of Government in European Union Members, regions and cities and all stakeholders - including start-ups and scale-ups themselves - is necessary for the efficient and successful implementation of initiatives intended to help new business and allow them to approach the complex matter of IP more effectively.

445. In recent years, the European Commission and European Union Members have supported the creation of 'communities' to help start-ups connect with potential partners (e.g. investors, business partners, universities, research centres) through events, platforms, business clusters, networking and supportive local/regional 'ecosystems'.

446. At European Union level, the Start-up Europe initiative has emerged as a recognized brand for creating links between those ecosystems, focusing on connecting people, international outreach and providing information through a One Stop Shop for start-ups. Start-up Europe also helps new businesses, in particular, through matchmaking between investors, corporates and entrepreneurs as well as networking of regional decision-makers.

447. Start-up Europe's objectives are:

- To reinforce the links between people, business and associations who build and scale up the start-up ecosystem (e.g. the Web Investors Forum, the Accelerator Assembly, the Crowdfunding Network);
- To inspire entrepreneurs and provide role models; and
- To celebrate new and innovative start-ups, help them to expand their business, and give them access to funding under Horizon 2020, which is the main research and innovation framework programme of the European Union.

448. To mention one of these European Union-level initiatives particularly relevant in the context of IP, the Web Investor Forum brings together top-level Investors and Accelerators from all over Europe with the goal to foster a more scale-up-friendly ecosystem. The Investors Forum acts as an internal channel conversation for the European Investment Fund and European Commission with European and international investors. Specifically, the Investors Forum bridges investors to Corporate Development Heads, like the Start-up Europe Partnership, European Matching Funds and the European Commission.

449. Intellectual property rights play an increasingly important role in corporate strategy and financial investment. The intangible assets created through the processes of innovation represent a major share of the value of today's businesses. The IP rights associated with those assets are the legal underpinning for potential returns on investment in that innovation.

450. The European Expert Group on Intellectual Property Valuation assessed the commercialisation of innovative ideas, with the value of the IP asset acting as collateral. They looked especially at start-ups. Equity investors typically invest into companies as a unit, but not into IP assets as such.

In return for their investment investors receive an equity stake of a company which owns IP and intends to exploit the IP. Therefore, investors using this model are indirectly financing based on IP.

451. The Expert Group notes that an issue which influences a company's decision to protect its IP, especially in the case of new business, is to what extent such rights are enforceable, the time and costs involved in litigation, and the foreseeable economic results. The quality of the enforcement system has an important impact in IP protection. Companies need to be assured an accessible justice system for infringement, validity and other cases.

452. Large investment banks and private equity firms alike have raised and invested funds targeted at IP and other intangible assets. Rather than looking for entrepreneurs and start-up companies, these firms are often looking to invest in IP for development and commercialization purposes. These enterprises work with companies to either buy the IP or invest in the company for commercialization of the IP.

453. The PATLICE Survey enquired about European firms' patent licensing activities and found financial use is very important for small companies. There is a significant difference in the use of patents to obtain funding and finance by start-ups compared with larger firms. All types of finance uses are much more important for start-ups than for large firms. They particularly use patents more for raising capital through private investors and Venture Capital and private equity.

454. To conclude, we would like to underline that transparent and predictable intellectual property rules assist start-ups to engage confidently in domestic and international markets. Intellectual property rights can provide the framework for ownership, protection and the use of ideas and knowledge created in Europe and beyond.

12.7 Norway

455. Norway would first of all like to thank the proponents of the paper for their efforts in keeping this discussion on the agenda of the TRIPS Council. I will provide some answers to the questions put forward in the paper and will address them chronologically.

456. The first question asked "what country-specific information could Members share on IP and knowledge-based businesses, e.g. the number of new enterprises they have each year, an overview of the start-up landscape in their country or figures relating to their venture capital and venture debt markets, and the particular role IP plays in it".

457. The Norwegian Industrial Property Office (NIPO) conducted in 2018 an analysis of the Intellectual property rights-intensive industries and their economic performance in Norway. The analysis was performed by applying the methodology and industry ranking developed for the European Union by the European Patent Office and the European Union Intellectual Property Office (EUIPO). As outlined in the EU studies, IPR-intensive industries are those with an above-average use of IPR per employee, as compared with other IPR-using industries. These industries are concentrated in manufacturing, technology and business services sectors.

458. The results show that, as in the European Union, IPR-intensive industries pay significantly higher wages than other industries, create more export revenue per capita, etcetera. Some of the main findings:

- IPR-intensive industries generated 25.9% of all jobs in Norway in the period 2011-2013 (EU: 27.8%). This corresponds to 655,000 jobs.
- IPR-intensive industries generated on average more than 51% of total economic activity (GDP) in Norway in the same period, corresponding to EUR 196 billion.
- IPR-intensive industries paid much higher wages than other industries, with a wage premium of 53% over other industries (2013 figures).

459. We have also started to bring IP data into our standard statistical framework. A few years ago, Statistics Norway established a regular database on patenting, design protection and trademarks by enterprises. The enterprises in the database are organised by regular organisational numbers rather

than by name. By using these numbers, information from other administrative registers with patenting information can be linked to each enterprise.

460. For example, we can now easily study enterprises by specific indicators, such as patents, size, age and the patenting enterprise's statistical industry rather than the patent's technology area. Given our extensive and digital administrative registers, we can look at such issues as ownership or financial structure and patenting activity. However, these are still time-consuming and resource intensive studies. At the moment, descriptive statistics are therefore more easily available.

461. Some of results we do see, are that patenting takes place in small enterprises and in large enterprises, with the frequencies being lower in medium sized firms. Design protection is mostly taking place in smaller enterprises.

462. The second question asked "what IPR-specific regulatory measures, policies and practices do Members consider to be conducive to, or even necessary for, creating new businesses, e.g. how easy is it to create a new business for young entrepreneurs and, in light of that, what is the role of IP in that process? Furthermore, what impact does international cooperation have in promoting a positive new business IP environment".

463. Awareness of intellectual property values, when to use formal protection and some insight into patent law; it translates into stronger IPR inclusion in higher education, business studies, engineering and such areas.

464. Awareness translates into the two sides of IPR: my rights and how I exercise them, and others' rights and whether I infringe on them. In our case, raising awareness was an aim of a recent White Paper on IPR (2014).

465. The third question invited Members to share "any specific examples of new businesses, their IP-protected innovations and other IP-related assets, or successful governmental IP-related policies that help new businesses integrate into the global economy".

466. In 2012, a group of PH.D.-students and their professor at a polytechnical University in Norway (NTNU) co-founded the start-up company CrayoNano AS. With production in Asia and customers all over the world, this start-up was born global.

467. The company has developed nanowire/graphene based deep-UV LEDs for sterilization and disinfection. CrayoNano has patented the use of graphene as a semiconductor substrate. The technology platform is protected through nine priority patents. Some of the underlying results have been published in journals like Nano Letters and Nature Communications.

12.8 Brazil

468. I would like to thank the co-sponsors for presenting this agenda item on IP and Innovation. Our delegation welcomes the debate for its contribution to deepening the understanding of the intellectual property system related to the achievement of the objective of Article 7 of the TRIPS Agreement. In fact, we identify complementarity between this agenda item and the one on IP and Public Interest. They both highlight the complex relation of the IP system with the concrete reality routinely faced by policymakers and stakeholders. This is one of the reasons why Brazil is a cosponsor of both documents IP/C/W/648 and IP/C/W/649.

469. There is a range of regulatory measures that can be used by Members to support new business. For instance, our patent office provides fee reductions for micro and small enterprises as well as to individual inventors. Since 2016, the patent office offers accelerated examination of patent applications from SMEs. One of the reasons for these initiatives is that start-ups begin relatively small and rely on the patents to attract investments. A fast and affordable patent application process will undoubtedly improve their competitive conditions.

470. Furthermore, we are active in promoting awareness-raising activities on the importance of IP protection for innovation, disseminating a better understanding for the strategic use of IP by companies and allowing the culture of IP to flourish. In order to bridge the gaps between start-ups

and funding, Brazil has a start-up programme implemented by FINEP, a governmental agency. FINEP grants investments of up to USD 1 million to start-up companies.

471. Brazil is also interested in developing studies that allow us to evaluate existing mechanisms for supporting innovation. Last month, in partnership with the OECD we initiated a review of SMEs and entrepreneurship in Brazil. The goal is to assess the structure and performance of Brazilian SMEs, map policies and programmes that support their entrepreneurship and strengthen policy design and implementation. We hope to present the results of that work in future sessions of the Council.

472. I would like to present two cases of success of Brazilian start-ups. The first one is a company called Integra, a University spinoff originated from the University of Brasília. Integra developed a genetically-modified yeast that can be used to convert residues of the biodiesel industry into bioplastic. Protected by four patents, the company received investments of more than BRL 1 million that allowed it to do further research on technologies to convert agroindustrial residues into products of high added value. Integra's goal now is to achieve a turnover of BRL 40 million by 2020, underlying its success.

473. TNS Nanotechnology is a company that won a start-up prize promoted by the Brazil-Germany Chamber of Commerce for an antibacterial that can be used to clean air conditioners and washing machines. The company also developed a biological sensor for diagnosing salmonella in food products. The sensor allows the detection of salmonella in up to five hours, in comparison with the seven days required by the previous technology. Those inventions are protected by patents and allowed the company to receive investments from Germany and Italy. The company currently exports its products to ten countries in South America, Europe, Africa and Asia.

474. Our discussion should also take into account other barriers to the dissemination of the use of the IP system by innovative companies. For instance, those companies may have limited resources for spending with lawyers. Patent search is another costly area for smaller companies. Lastly, enforcement measures and the need for surveillance of possible infringements of their IP assets often require much resources. A broad discussion on the subject cannot overlook those obstacles. Members would greatly benefit from exchanging experiences on the solutions found.

475. As also stated by other delegations, it is important to highlight that patents are not the single element driving innovation, but rather one element among different tools. Having the right infrastructure for innovation, collaboration and research are fundamental ingredients of innovation. Earlier this week the WTO organized a seminar on IP and knowledge flows, in which a recurrent idea mentioned by speakers was the need for providing an ecosystem that fosters innovation. This includes not only appropriate and effective IP protection, but also other mechanisms such as adequate funding for start-ups, tax measures and free trade agreements that enhance integration to global value chains. The absorptive capacity of countries is another important aspect mentioned by speakers.

476. I would like to conclude by stressing the efforts that Brazil has been undertaking to improve our internal innovation environment. The process of accession of Brazil to the Madrid Protocol is ongoing in Congress and we hope that it will provide an additional opportunity for companies interested in internationalizing their businesses. In the meantime, INPI initiated preparatory procedures, such as hiring additional trademark examiners and adapting IT infrastructure. Those initiatives allowed us to substantially reduce the trademark backlog and pendency time: we expect that by the middle of next year the examination of trademark applications can be concluded in eight months counted from the date of filing.

477. There are also ongoing efforts by INPI in patents. We have hired 210 new patent examiners in the last two years, almost duplicating the office's capacity to process patent applications and allowing us to slash the patent backlog by 10% in the last eighteen months. We hope we can continue the trend of reducing the patent backlog and pendency time, benefiting applicants and competitors alike through faster examination and enhanced legal certainty.

478. Brazil is deeply committed to continue encouraging and rewarding innovation and its widespread dissemination in the economy and society.

12.9 Singapore

479. Thanks to Switzerland and the proponents for preparing this very useful discussion paper.

480. In today's knowledge-driven economy, Singapore sees innovation as a key driver for our development and IP as the new currency for economic growth.

481. With 67,000 companies registering in Singapore annually, the Singapore Government has put in place several efforts to help these businesses innovate and grow. For example:

- To help create synergies amongst technology start-ups, a shared physical space (Block 71) has been set up to pull together a community of entrepreneurs, innovators and investors. To date, this physical space/hub is home to more than 250 start-ups, 30 incubators, accelerators and venture capitalists;
- Efforts have also been made to provide a conducive environment for the financial technology (fintech) sector to flourish;
- Singapore's National Intellectual Property Office has as one of its objectives, enabling companies with IP resource potential to move to the next development stage, such as to develop new products or to expand to new markets; and
- We have undertaken efforts to encourage voluntary mediation, so as to make it easier to enforce contracts, including on IP matters. This is part of our ongoing effort to improve the ease of doing business in Singapore.

482. Singapore's IP regime also aims at striking a balance so as to encourage the development of innovative enterprises in ways that do not stifle competition. In this way, we hope to promote a positive new business IP environment that enables businesses to integrate better into the global economy. For example:

- We are strengthening our linkages with other IP regimes for better market access. Since 2010, patent applications by Singapore firms via the Patent Cooperation Treaty (PCT) system have grown almost 60%, while applications via the Madrid system have grown more than four-fold; and
- Singapore also participates in patent acceleration programmes, such as Global Patent Prosecution Highways and the ASEAN Patent Examination Cooperation. There are also many other ASEAN initiatives that facilitate the protection of IP of international investors in the region, as well as encourage greater domestic innovation in the region.

483. Through our work, we have also observed challenges that new businesses face in relation to IP. For example, we note that start-ups tend to have a preference for debt funding in order to preserve their ownership stake in the business. However, innovation-driven start-ups are usually light on tangible assets. As such, this poses a challenge for raising debt as the current banking model is not designed to collateralise intangible assets such as IP rights. Singapore believes there is a need to overcome this debt financing constraint faced by IP heavy enterprises, and is working on policies to address this.

484. We also look forward to hearing from other Members on their best practices and experiences in fostering new businesses in relation to IP.

12.10 India

485. India thank those Members for the new submission.

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

487. Innovation is a sine qua non for growth. It is in this context that India has taken many steps to improve the innovation ecosystem - whether it is through the quality of the human resource or the research and development activities or strengthening of academia industry linkages and availability of capital.

488. The result of such actions is visible. India has moved up on the Global Innovation Index from a rank of 76 in 2014 to 57 in 2018. At the indicator level, India ranks well in a number of important indicators including, graduates in science and engineering, productivity growth, ICT service exports. This year India was second in both the quality of its universities and the quality of its scientific publication among the middle-income economies. This has been possible due to a number of initiatives taken by the Government to support and promote innovation. Start-up India is one such programme of the Government.

489. Another development is India's ranking in the World Bank's Ease of Doing Business 2019 Survey. It climbed up 23 places to 77th among 190 countries surveyed, making it the only country to rank among the top ten improvers for the second consecutive year. Since 2014, India's ranking improved 65 places from 142nd in 2014 to 77th in 2018.

490. While we strongly believe in promoting and nurturing innovation, we are also of the view that IPRs are neither a necessary nor a sufficient condition for innovation. If it had been so software development would not have thrived on open source development.

491. On the contrary, unbridled power to IPR holders can adversely affect innovation. We are all well aware of how patent thickets, exclusive grantbacks and coercive licenses can deter innovation. Non-Practicing Entities (NPEs) also have been identified by many policymakers as a costly impediment to innovation and economic growth.

12.11 Chinese Taipei

492. As the co-sponsor of this proposal, we are very happy to share our thoughts on this subject.

493. In the era of knowledge economy, innovation and use of knowledge are the main driving forces of a member's competitive edge and economic growth. There is no doubt that patents are crucial to the success of a start-up or new business.

494. However, it can be a huge burden for a new company with limited capital to pour in manpower and expenditure on developing a new product that may or may not be successful.

495. Considering this, we are proactively creating an environment that is friendly to entrepreneurs with creativity or innovation wishing to expand their businesses. I would like to share two points regarding our policies and measures on establishing new businesses and bridging financial resources.

496. First, there is no minimum capital requirements for setting up new companies according to our Company Act. A new company may be registered so long as there is enough capital to this end. The Act also allows for capital contribution by shareholders in the form of technologies. In other words, technology owners (or intangible assets) may use their technologies as contribution for stock and invest it in the company through transferring or licensing of their technologies. This will not only ease the pressure of capital flows for technologies owners in the process of commodification but also help companies obtain the results of technologies developed by domestic and foreign businesses. Over the years, this approach has successfully facilitated many Start-ups or new businesses overcome financing constrains by demonstrating the value of their patents.

497. Second, many small and medium-sized enterprises and academic institutions have invested in research and development, possessing patents and technologies, but have not been able to obtain bank financing. Many good ideas and inventions cannot be commercialized because of lack of financial assistance. In this context, we launched the "Start-up angel project" to pour in more than USD 3 million, targeting 300 start-ups in five years period. Its policy goal is to assist companies with ideas or patents to successfully convert intellectual property rights into business opportunities. Also, this influx of business operation capital will effectively help innovators cross the start-up threshold.

498. A very good case benefited from this "Start-up angel project" is a company named "Deepblu". Deepblu is a start-up concentrating on developing a diving watch, which is able to record and instantly share diving data using the connection between built-in apps and cloud services. Following its receipt of the angel fund in 2015, the company has successfully conducted sales of its product in countries/regions with a thriving diving industry, such as Indonesia, Malaysia, Thailand in Southeast Asia, as well as the European Union and the United States. The amount of the company's capital has grown from USD 130,000 since its founding in 2013 to USD 1.65 million in 2018, registering an increase of 12 times.

499. To sum up, intellectual property and innovation are indispensable driving forces of economic development, especially for start-ups or any new business. In other word, start-ups need patents. Patents help facilitate venture capital investment, defend attack by rivals, ensure a freedom to operate, increase the chance for partnership, and most importantly, secure a long-term competitiveness. Therefore, how the government helps innovators start new businesses through well-planned patent strategies remains an important lesson. We welcome and look forward to hearing other Members share their experiences and views on relevant measures.

12.12 Canada

500. Canada is pleased to participate in the discussion on "IP and New Business", as part of the three-part theme "The Societal Value of IP in the New Economy". We would like to thank Switzerland for the discussion paper that serves as the basis of this agenda item (IP/C/W/648), as well as those Members that have shared their experiences and insights so far on the role of IP in the development of new businesses.

501. In order to get at the issue of how IP-specific measures can assist new businesses, it is perhaps useful to first provide an overview of the start-up landscape in Canada. According to a recent study by Canada's Department of Innovation, Science and Economic Development (or ISED) entitled "Canadian Start-Ups – A perspective based upon the 2014 Survey on Financing and Growth of Small and Medium Enterprises", almost 8% of small and medium-sized enterprises (SMEs) in Canada in 2014 were start-ups. In Canada, these are defined as firms that are two years or younger. Notably, the study also found that firms appeared to be more innovative when they were young and in the growth stage. For instance, in 2014, 43% of start-ups and 44% of firms three to ten years old introduced at least one type of innovation (defined as a product, process, organizational or market innovation), compared with 40% of firms 11 to 20 years old and 41% of firms more than 20 years old. The study also found that sales growth expectations were higher among start-ups than non-start-ups, with younger firms more growth-oriented than older firms.

502. However, despite being relatively more innovative, the study also found that start-ups were less likely to own IP than non-start-ups. In 2014, for instance, roughly 19% of Canadian start-ups owned some type of IP compared with 22% of non-start-ups. Notably, this dynamic is also evident when firms grow, as well as age. For instance, according to ISED's 2014 "Survey on financing and growth of SMEs", among SMEs with between one and four employees, just over 21% held IP, whereas among businesses between 100 and 499 employees, 51% of these firms held at least one type of IP. ISED's study on start-ups also found that Canadian start-ups were less likely to export than older forms, and also were more likely to seek external financing, than non-start-ups.

503. In addition, Canadian start-ups have been found to have relatively higher demands for external financing than non-start-ups, with 58% of start-ups requesting some form of external financing compared with 51% of non-start-ups. As well, requests for debt financing were also higher among start-ups. In 2014, 37% of start-ups requested debt financing compared with 31% of firms in operation for three to ten years. The inverse was also apparent in respect of debt financing approval rates, which were marginally lower than for non-start-ups (75% and 78%, respectively).

504. In view of these dynamics, and returning to the topic of IP and new business, it is important then, to consider the role that IP-specific measures, and other related policies, can play in assisting start-ups to both grow and seek export opportunities in other markets. For instance, with respect to financing, in January 2016, the Government of Canada announced the launch of CanExport, a five-year programme which will provide CAD 50 million (or approximately USD 40 million) in direct financial assistance to SMEs that are registered in Canada and seeking to develop new export opportunities. Delivered by Global Affairs Canada's Trade Commissioner Service in partnership with

the National Research Council Industrial Research Assistance Programme, CanExport provides financial support for a wide range of export marketing activities, including in respect of IP protection and certification expenses in foreign markets. As well, the Business Development Bank of Canada (or BDC), which is a federal Crown corporation owned by the Government of Canada, provides financing and advisory services with a focus on SMEs, such as start-up financing and small business loans. For instance, BDC's Xpansion Loan is designed to help business develop products that are key to growth and expanding their market, as well as to seek IP protection and purchase IP licenses.

505. Turning to IP policy more specifically, the Canadian Intellectual Property Office (CIPO) also provides a number of measures to encourage small businesses to use the IP system. For instance, with a view to encouraging small businesses to seek patent protection, certain CIPO fees for obtaining and maintaining a patent are reduced by 50% for "small entities". Canada's Patent Rules define a small entity as one that employs 50 or fewer employees or is a university. In order to take advantage of the reduced fees for small entities, applicants must submit a small entity declaration before or at the time of their fee payment, if there is not already one on file.

506. CIPO has also launched an IP Awareness and Education Programme to deliver products, services, and training to SMEs. For instance, CIPO's IP Awareness and Education Programme offerings include guides, one-pagers, and process maps, in addition seminars and training sessions that provide businesses with tools and information to better acquire, manage, and leverage their IP assets (IP for Business); seminars and training services for businesses, partners and intermediaries (IP Academy); and a suite of networked services, including referral, consultation, and support to advisory services (IP Hub).

507. Finally, IP for new and growing businesses serves as a key focus of Canada's recently-launched national IP Strategy. With research showing that start-ups are relatively more innovative than older firms, but less likely to own IP, initiatives to assist new and growing businesses in obtaining and utilizing IP can serve as an avenue to leverage their innovations into commercial success. Canada's IP Strategy focuses on addressing a number of IP issues facing growing businesses, as well as to provide clarity for IP stakeholders. These include forthcoming legislative amendments, such as minimum requirements for patent demand letters, as well as measures to reinforce the importance to use in the trademark regime (e.g. to prevent the misuse of the trademark registration system, or what is sometimes referred to as "trademark squatting"). The IP Strategy also includes measures on IP awareness, education and advice, which will build on CIPO's current learning tools and resources, and will also include IP legal clinics, as well as IP advisors through existing federal programmes. Finally, in recognition of the importance of business growth and success in the global marketplace, the IP Strategy will include measures on strategic IP tools for growth, such as expedited IP dispute resolution; a centralized IP marketplace for businesses, entrepreneurs and innovators; and the establishment of a patent collective to support SMEs in coming together to facilitate better IP outcomes for collective Members.

508. Canada will be pleased to present on these and other elements of our national IP Strategy as they further develop over in the coming months. In the meantime, we would like to again thank those Members that have shared their insights and experiences so far, and look forward to hearing further views on this important topic.

12.13 China

509. We recognize that innovation plays a positive role in cultivating new industries. Many emerging industries, including e-commerce, are driven by innovations and an effective intellectual property protection system. To these emerging industries, innovation ability of SMEs is particularly important.

510. In order to promote the development of SMEs and to enhance the generation, usage and management of IPR in SMEs, China has adopted a series of measures. Particularly, at the end of 2016, China National Intellectual Property Administration and Ministry of Industries and Information Technologies jointly released a document "Guiding Opinions on the Comprehensive Implementation of the SME Intellectual Property Strategy Promotion Project", providing seven possible methods to enhance the abilities related to IPR in SMEs.

511. The first is "patent information navigation" system, that is regularly sending high-quality, low-cost intellectual property information to SMEs. The second is to establish incentive mechanisms to

stimulate the vitality of SMEs, including promotion on industry-university cooperation mechanism. The third is to enhance the ability of IPR management in SMEs. This includes providing new financial services, such as patent insurance. The fourth is to strengthen the protection of IPRs for SMEs, including providing specific IPR protection enforcement actions. The fifth is to provide scientific guidance for SMEs, including guiding SMEs to build suitable and scientific IPR management systems. The sixth is to deepen international IPR cooperation in SMEs, including actively conducting international IPR activities for SMEs. The seventh is to provide more public services for SMEs, including encouraging industry associations to recruit more SMEs. We believe those measures will have a positive effect on promoting the protection and utilization of IPRs of SMEs.

512. However, we also hope to draw Members' attention to the following facts. First, it is agreed that for the generation and development of emerging business, besides innovation and IPR protection, we also need capital, human resources and other essential elements. To developing Members, capital and human resources play an even more important role. Second, innovation cannot be achieved in one day. It needs huge amount of investment and primitive accumulation. Compared to developed Members, developing Members suffer deficiency in many areas. Currently, there still exists a wide gap between developed country Members and developing Members on the level and ability of innovation. We hope that Members can pay attention to these facts and explore effective solutions.

12.14 South Africa

513. South Africa would like to thank the co-sponsors for putting this important item on the agenda.

514. Like many developing countries, South Africa faces a great development problem relating to the high failure rate that is present among Small and Medium Enterprises (SMEs). This is due to the fact that entrepreneurs are not able to turn their businesses into sustainable ventures. SMEs play a significant role in a number of economic development issues that South Africa is facing as a nation. The SME sector has contributed immensely to job creation, poverty alleviation and assisting in the prosperity of the nation.

515. South Africa has progressively shifted away from dependence on primary resource production and commodity-based industries to open up to international trade and to building capacity in some knowledge-intensive industries. However, the country's economic growth has remained weak by emerging-market standards, with GDP rising at 3.1% per year from 2000 to 2014.

516. The National Development Plan (NDP) - A Vision for 2030 (2011-30) provides a general roadmap for South Africa's transition towards a diversified economy, with innovation underpinning almost every aspect and a strong focus given to strengthening human capital. The National R&D Strategy (2002 onwards) has planned for increasing public and private investment in the science base and improving the system of S&T governance. In parallel, the Ten-Year Innovation Plan (2008-2018) identified five areas of competitiveness to be developed, i.e. bio-economy (formerly pharmaceuticals), space, energy security, global change including climate change, and social and human dynamics. In that respect, the National Industrial Policy Framework (NIPF) articulates South Africa's overarching approach to industrial development and innovation.

517. Innovation is widely viewed as a driver of company competitiveness and, indeed, the economic growth of countries. The South African Government has approved Phase I of the National Intellectual Property Policy. It earmarks the IP Policy as one of the core elements needed to thrust South Africa toward a knowledge economy. This objective is the cornerstone of the Government's broader National Development Plan which includes a greater emphasis on innovation, improved productivity and better exploitation of comparative and competitive advantages. South Africa is also focusing on creating an enabling environment for businesses to operate. The 2018 World Bank Ease of Doing Business Report (EDB) notes two areas of improvement in 2018. These include South Africa making starting a business easier by reducing the time for online business registration and the country improving the monitoring of electricity outages through recording data.

518. There are various Government schemes that assist small businesses and start-ups. The IDC (Industrial Development Corporation), founded in 1940, is a state-owned finance institution. It functions as a means to generate balanced and sustainable growth in Africa. The IDC funds start-ups and existing businesses up to a maximum of ZAR 1 billion. The Small Enterprise Finance Agency was

established in 2012 and has the mandate to foster establishment, survival and growth of SMMEs. They also aim to contribute to poverty alleviation and job creation. SEFA provides loans from ZAR 50 000 to ZAR 5 million to SMMEs and co-operatives. The Isivande Women's Fund specialises in start-up funding, business expansion, rehabilitation as well as financing.

519. The IP Policy is aimed at promoting local manufacture, utilising and preserving the country's resources, encouraging innovation and empowering the domestic stakeholders to take advantage of the IP system. The IP Policy acknowledges that there is no automatic correlation between an increase in protection of IP and an increase in innovation. However, the South Africa Government believes a stronger framework is required to ensure that other objectives are met, including access to public health. South Africa regards the IP system as an important policy instrument to promote innovation, technology transfer, research and development and economic growth. However, the public understanding of benefits remains incomplete. In this regard, South Africa recently co-hosted the High-Level Conference on Respect for Intellectual Property with the World Intellectual Property Organization (WIPO), the International Criminal Police Organization (INTERPOL), the World Customs Organization (WCO) and the World Trade Organization (WTO). More than 400 participants from a broad range of countries and sectors came together to discuss various IP issues ranging from the economic value of IP and its public value, to the practical challenges that face authorities when enforcing IP frameworks.

520. As to some examples of start-ups, there are a good number of companies and start-ups in South Africa that would not just be classified as big but also innovative. South Africa has made a huge impact in science and technology. Several important scientific and technological developments originated from South Africa. An early internet security company started by Mark Shuttleworth was bought by VeriSign, while another South African born and educated entrepreneur, Elon Musk went on to found companies like Tesla Motors, PayPal and SpaceX.

12.15 Colombia

521. Colombia is extremely interested in the promotion and development of the creative industry, which is why it issued Law No. 1834 of 2017 promoting the creative economy (Ley Naranja – Orange Law), presented under agenda item 1. Our interest is justified, because "the creative and cultural industries reportedly generate revenues of USD 2.250 billion and 29.5 million jobs worldwide, employing approximately 1% of the active population". In Latin America and the Caribbean, estimates suggest that the creative industries generate USD 124 billion worth of revenue, or 2.2% of the regional GDP (Ernst & Young, 2015).

522. The "orange" sectors of Colombia include activities that are different from those of the great creative economies of the world capitals. Opting to "squeeze the orange" may help to solve the country's production and employment challenges. Colombia has an enormous potential for developing the orange economy, linked with the need to take advantage of the demographic dividend (Buitrago & Duque, 2013). The development and consolidation of the creative sectors is essential to generate employment and value added, transform production, increase competitiveness and boost exports, and attract foreign direct investment (FDI) (Duque, 2018; Benavente & Grazi, 2017).

523. The development of the creative economies will bring benefits to the rest of the economy, including tourism. Creativity and design, being closely linked to innovation, contribute to the proliferation of new ideas and increase the probability of their reaching the business and marketing stages (Hollanders & Cruysen, 2009).

524. Colombia's policy to harness the potential of the orange economy will be conducted on three fronts:

- Establishment of an institutional environment conducive to the development and consolidation of the orange economy and the consolidation of information on the different sectors of the orange economy;
- Development of the necessary conditions and public goods for the different sectors of the orange economy and the so-called Orange Development Areas (ADN). This includes human capital development for the orange economy, protection and promotion of intellectual

property, financing mechanisms, and stimulation of domestic consumption and exports of orange economy goods and services; and

- The development of tools to help generate "orange value added" transversally throughout the Colombian production system.

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

13.1 South Africa

525. The communication circulated in document IP/C/W/649 continues the *ad hoc* item on "Intellectual Property and the Public Interest: Promoting Public Health Through Competition Law and Policy" that was introduced by the co-sponsors in documents IP/C/643 and Add.1 of 24 May and 29 May 2018 respectively.

526. IP protection *per se* cannot be presumed to confer market power or to indicate anti-competitive behaviour. IPR holders are, for this reason, as a general rule, not prevented from exercising their exclusive rights. Different approaches are taken by various jurisdictions regarding the interface of competition law and policy and IP. A recent WTO staff working paper found that despite different levels of development, constitutional systems and/or economic structures and industrial profiles in jurisdictions surveyed displayed a pervasive interest in the interface between competition law and policy and IP. All the jurisdictions surveyed in this study have rudimentary rules that have a bearing on potential anti-competitive abuses of IPRs. It is also apparent that clearer competition policy treatment of IPRs has evolved over time through either iterative processes or evolving practice of competition authorities. This evolution is informed by jurisdictional cross-fertilization and peer learning as evidenced by greater interest in and concerns with ensuring an appropriate balance between IP and competition law and policy in these jurisdictions. This development underscores the need for further debate and analysis since competition law and policy is no longer the preoccupation of only a few jurisdictions.

527. During the June 2018 TRIPS Council session, the cosponsors demonstrated that there are various pro-competitive provisions in the TRIPS Agreement, including 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. As a consequence of accommodating the variety of potential competition approaches, remedies available to address anti-competitive behaviour may permit a broader range of remedial action than some other public health-related flexibilities associated solely with patents. Competition policy has an important role to play in ensuring access to medical technology and fostering innovation in the pharmaceutical sector. WTO Members have absolute policy space under international law to design their national competition laws in accordance with their domestic interests and needs and the level of their development.

528. The use of competition law is not without difficulties, since many developing countries may not have the capacity to administer or enforce such a system. Since a substantial body of precedent exists, the sponsor of this document wishes to demonstrate that many WTO Members already use competition law to address various anti-competitive practices that affect access to medicines and medical technologies. Practices that have been identified as detrimental include, but are not limited to the following instances: (i) abuses of IPRs due to a refusal to deal with or imposition of overly restrictive conditions in medical technology licensing; (ii) preventing generic competition through anti-competitive patent settlement agreements; (iii) mergers between pharmaceutical companies that lead to undesirable concentration of research and development and IPRs; (iv) cartel agreements between pharmaceutical companies, including between manufacturers of generics; (v) anti-competitive behaviour in the medical retail and other related sectors; and (vi) bid rigging in public procurement. In this respect, not all jurisdictions follow the same approach, for instance, refusal to license may amount to an abuse of dominance in some jurisdictions while others consider this within the rights of IPR holders.

529. The "objectives" and "principles" enshrined in Articles 7 and 8 of the TRIPS Agreement form central elements of the interpretation of the TRIPS Agreement, especially with regard to the relevant provisions that recognize flexibilities to legislate at the national level. In the WTO case of *Canada* –

Patent Protection for Pharmaceutical Products, the panel noted that "the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions." To this end, the goals enumerated in Articles 7 and 8.1 are relevant when doing so.

530. The Panel in *Australia – Tobacco Plain Packaging* referred to the report in *Canada-Patent Protection for Pharmaceutical Products* regarding the interpretation of the terms of Article 30 of the TRIPS Agreement in light of its object and purposes. It noted that paragraph 5 of the Doha Declaration is formulated in general terms, thereby inviting the interpreter of the TRIPS Agreement to read "each provision of the TRIPS Agreement" in light of the object and purpose of the Agreement, as expressed in particular in its objectives and principles. Fundamentally, the panel concludes that paragraph 5 of the Doha Declaration constitutes a subsequent agreement of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties. This finding may have important consequences for how flexibilities in the TRIPS Agreement are interpreted.

531. Competition law and policy remains an important topic and is subject to much multilateral focus and discussion. The United Nations Conference on Trade and Development (UNCTAD) produces seminal work on this subject-matter and provides technical assistance in order to improve worldwide cooperation on competition policy matters. Each year, an Intergovernmental Group of Experts (IGE) on Competition Law and Policy meets to discuss ways of and enhancing convergence through dialogue. UNCTAD produces a list of competition laws and annotated commentary contained in the Handbook on Competition Laws (Volume II) (UNCTAD/DITC/CLP/2009/2). It also has a Model Law on Competition which is available in all the UN languages.

532. The World Intellectual Property Organisation (WIPO) has actively discussed the issue of IP and competition. At its thirteenth session (3–5 September 2018), the WIPO Advisory Committee on Enforcement discussed, *inter alia*, the interface between IP enforcement and competition law. Brazil and Peru presented case studies of competition on administrative approaches to address the interplay of IP enforcement and competition law. Through concrete examples, the contributors discussed the limitations of unfair competition laws in relation to the exercise of IP rights as well as interventions of competition rules in cases where the IP system was abused to prevent competitors from entering or remaining in a market.

533. The sponsor urges Members to once again share their national experiences and examples of how competition law is used to achieve public health and related national objectives. Debate and information exchange could serve to enhance the understanding of Members of 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 agreement that unreasonably restrict access to new technology, and the use of measures that prevent the entry of generic companies and result in higher prices for medicines. Capacity building and technical assistance remain the most important means to enable WTO Members to increase their capacity to administer and implement competition law regimes.

Guiding Questions

534. The questions are designed to build on previous questions circulated in document IP/C/W/643. Some delegations indicated that they may revert to some of the questions that were posed during the last TRIPS Council session. Bearing this in mind, delegations are invited to share their experiences of using competition law regimes to address anti-competitive practices that affect access to medicines and medical technologies or to share challenges that they face in the enforcement of competition law issues that affect access to medicines or medical technologies.

(1) What types of behaviours do WTO Members consider abuses of intellectual property rights in the pharmaceutical and medical sectors? Has there been any evolution in the approaches that WTO Members take to assess such types of behaviours?

(2) What examples of best practice can Members identify on the subject of the control and remedies for excessive pricing? Are there context-specific methodologies employed by Members for determining if prices are excessive, and the mechanisms to remedy and control pricing abuse?

(3) What examples of best practice can be identified through national competition laws and practices? Are there certain common trends that can be identified across various jurisdictions?

(4) To what extent can technical assistance and capacity building contribute to the delivery of more effective policies by WTO Members in the field of competition law to address the abuse of intellectual property rights?

13.2 Brazil

535. I would like to thank South Africa for circulating document IP/C/W/649. The communication builds on documents IP/C/W/630 and IP/C/W/643, with the goal of expanding the discussions on the complex interplay between intellectual property and public interest. The debate on the relation between intellectual property and competition lies at the heart of the IP system and is certainly of interest to this Council. This is an issue that has been attracting increased attention in international forums, as evidenced by the discussions held in September at the WIPO Advisory Committee on Enforcement.

536. Intellectual property and antitrust law have common objectives: to stimulate economic development, promote innovation and foster competition. However, these two disciplines deploy different methods to achieve these same objectives, which, at first, may seem contradictory. Antitrust law stimulates economic development by promoting competition and preventing abuse of dominance and exclusionary practices, whereas intellectual property stimulates innovation by creating exclusive rights, which prevent competition and use of immaterial goods by unauthorized third parties.

537. For a long time, the two fields were considered incompatible. However, the debate has evolved to consider that antitrust and intellectual property are complementary, even though there may be a tension between them. A dynamic analysis of the competition process shows that intellectual property is not by itself harmful to competition. Rather, exclusive rights granted under IP laws promotes competition between companies, which are compelled to invest in research and development in order to innovate and keep up with the market.

538. Therefore, antitrust and intellectual property should work together towards their common goals. This is particularly true in the context of the new economy, in which innovation, knowledge and intellectual property rights are a central part of the competition dynamics. It does not mean, however, that the two fields will remain without conflicts. In the concrete economic reality, there is growing attention from competition authorities to the relationship between the two areas, because there is also an increasing possibility of abuse of IP rights in innovative and digital markets.

539. At the Council's last meetings, we presented a case of sham litigation involving a drug used against breast cancer. Our competition authority, whose acronym in Portuguese is CADE, imposed a fine of BRL 36.6 million or USD 10 million on the defendants.

540. I would like now to mention two other cases decided by CADE, the first one regarding the use of auto parts industrial design rights in the aftermarket and the second involving a merger filing.

541. The "ANFAPE Case", as it came to be known, was filed by the National Association of Independent Manufacturers of Automobile Parts against original equipment manufacturers. The plaintiff alleged that the defendants had abused their dominant position and their IP rights over automobile spare parts by exercising their industrial design rights in the aftermarket, thus effectively monopolizing the aftermarket. Certain original manufacturers filed legal claims in the judiciary to safeguard their intellectual property and preclude the independent manufacturers from commercializing auto parts without properly licensing the industrial design. ANFAPE argued that those injunctions intended to prevent independent manufacturers from effectively competing in the aftermarket and argued that the industrial design was restricted to the primary market. The decision by CADE held that the Brazilian Industrial Property Law did not restrict the enforcement of the industrial design protection in the aftermarket. The registrations were obtained lawfully and the means used to enforce the IP rights were reasonable, so there was no trace of sham litigation. For this reason, no abuse in the exercise of the IP rights was identified and the case was closed. This understanding reveals CADE's balanced position when confronting intellectual property matters, achieved after careful consideration of the issues.

542. In the merger filing between Bayer and Monsanto, CADE had the opportunity to address intellectual property rights issues as they pertain to the sale of goods and tangible assets. The

merger involved the seeds and agricultural defensives markets. The analysis undertaken by CADE highlighted the importance of IP rights for the companies involved, who heavily rely on patents and plant varieties protection. Bayer and Monsanto are active in all those areas, which gave rise to competitive concerns related to increased entry barriers and market concentration deriving from IP rights. CADE conditioned approval of the merger on remedies that addressed the competitive concerns caused by the concentration of IP rights. For the merger to go through, the companies were required to license certain patented seed traits and protected plant varieties. This merger analysis shows that competition authorities can effectively and timely intervene to prevent the concentration of economic power generated by IP rights, as well as potential abuses of dominant position by IP rights holders.

543. Policy coherence between the IP system and competition must be strengthened in order to promote to the full extent innovation and access to technologies. Article 8.2 of the TRIPS Agreement provides flexibilities for governments to adopt competition law measures to prevent abuse of intellectual property rights, including IP rights related to the life sciences.

544. Abuses of intellectual property rights, such as reverse payment agreements and anticompetitive licensing practices, may favour undue extension of the market power granted by a patent. These practices impact both traditional and innovative companies, stifling competition and harming consumers. One way to deal with these practices is through the improvement of the patent system, for example by carefully designing patentability requirements. While some changes may indeed decrease or eliminate abuses, they should be implemented cautiously to avoid unforeseen outcomes.

545. Competition law, on the other hand, may be useful in situations where changes to IP policies are ineffective in dealing with these types of practices. In the pharmaceutical industry, competition policy benefits consumers in the form of increased access to affordable medicines by detecting, halting and correcting anti-competitive practices, without harming the dynamic competition effect granted by IP rights. Furthermore, countries should be able to retain freedom to utilize to the full flexibilities available in the TRIPS Agreement to ensure access to medicines. It is also important that technical assistance and capacity building contribute to the delivery of more effective policies on potentially abusive practices in the pharmaceutical sector in support of access to medicines.

546. The relationship between antitrust and intellectual property is complex and there are still many issues to be addressed by authorities. As new competitive strategies related to new businesses arise, there will be a growing number of antitrust cases involving IP rights. The core issue is to determine the optimal level of competition law intervention in the field of intellectual property rights. We must fine tune enforcement work to ensure competition and intellectual property laws each play their complementary role in encouraging innovation and enhancing consumer welfare.

13.3 India

547. My delegation would like to support the statements made by South Africa and Brazil.

548. In India, both specific IP legislations and the Competition Act deal with anticompetitive activities, abuse of dominance and other market unfriendly activities when it comes to abuse of intellectual property rights. Therefore, complaining parties often move to either the Competition Commission of India (CCI) the adjudicating authority under the Competition Act, or High Courts (under different IP legislations) for redressal. In 2015, questions were raised regarding the self-sufficiency of IP legislation where complaining parties alleged that the IP legislation is sufficient to deal with anticompetitive concerns and does not need any interventions from the Competition Act. This dispute is settled for now as the Hon'ble High Court of Delhi has meticulously analysed both IP provisions and the Competition Act and has come to the conclusion that the objectives, procedure and nature of remedies of both the legislations differ to good extent. Therefore, both the laws can determine the manner in which the anticompetitive issues are to be resolved.

549. In recent years there have been several instances, where courts have engaged on the issue of anticompetitive practices in the context of Standard Essential Patents and in some other industries. We have, however, not had any authoritative decisions on an issue that interacts directly with competition law and public health. We expect that the jurisprudence on competition law issues in the public health will also evolve overtime to address the concern more comprehensively.

13.4 China

550. We would like to thank South Africa, Brazil and India for submitting this proposal. We share the same concern and would like to co-sponsor this proposal.

551. During the second meeting of the TRIPS Council in June this year, Members have been actively involved in this issue. Although divergences still exist, we believe a full discussion will help Members to get a better understanding and promote deepening of this issue.

552. First, we believe that intellectual property protection should not exclude the application of competition law. In the TRIPS Agreement, Articles 6, 8.1, 31(k) and 40 are closely related to competition. As part of the TRIPS Agreement, most of these provisions have been transformed into Members' domestic laws or regulations that must be abided by. In addition, judicial cases related to intellectual property and competition have been found worldwide. These all clearly indicate that intellectual property protection is not boundless, it should be constrained by the application of competition laws.

553. Second, we believe that intellectual property protection and competition are not in conflict. They share the goal of improving economic efficiency, safeguarding consumer interests and protecting public interests while promoting competition and innovation. According to Article 7 of the TRIPS Agreement "[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations." It clearly indicates that the purpose of intellectual property protection is to achieve a balance between the creators and users of IPR, rather than to form a monopoly. The legislative purposes of each member's competition law are basically the same, that is, to protect fair competition, to stimulate innovation, and to safeguard the legitimate rights of operators and consumers. It is clear that there is a common goal between intellectual property protection and competition. In fact, China's Anti-Monopoly Law and the regulation on the Prohibition of Conducting, Eliminating or Restricting Competition by Abusing Intellectual Property Rights have also followed the above principles.

554. Third, we believe that the TRIPS Council is the appropriate forum to discuss intellectual property and competition issue. Currently intellectual property and competition issue have become an important subject in WIPO and FTAs. With clear competition provisions in the TRIPS Agreement, as an important forum for intellectual property, the TRIPS Council could not avoid this issue.

555. China believes the discussion on intellectual property and public interest should be open and inclusive. Members are encouraged to exchange views and experiences on how to make better use of flexibility provisions of TRIPS Agreement, including the competition law and policy.

13.5 Indonesia

556. Indonesia would like to thank South Africa for the proposal outline in document IP/C/W/649.

557. As the world's fourth most populous country, Indonesia places public health as an important part of its national development strategy and policies, that include access to medicines and medical technologies as well as the development of its pharmaceutical industry.

558. We understand that in the fields of medicines and medical technologies development, IP plays an important role to stimulate Research and Development. However, we need to always remind ourselves, that competition, fair working market-competition process, also stimulates R&D and the development of pharmaceutical industry. Competition policy and competition authorities are therefore important in making sure that markets are working well, and that no industry has to leave a market do to abuses of market rights, such as monopoly rights.

559. In Indonesia, in addition to IP rules and regulations, we believe that regulating antimonopoly and unfair practices in the pharmaceutical sector is paramount in achieving our national development objectives, especially in the field of public health.

560. Indonesia enacted the Law No. 5 of 1999 concerning the Prohibition of Monopolistic Practices and Unfair Business Competition which contains specific and comprehensive rules governing competition between business actors. Article 3 of the Law states that its basic objective is to safeguard the public interest and improve the efficiency of the national economy to improve the welfare of the public.

561. To that effect, Indonesia has established an independent agency to enforce the Law called Commission for the Supervision of Business as Komisi Pengawas Persaingan Usaha (KPPU).

562. In this regard, we would like to share a case handled by KPPU regarding high price of medicine caused by monopoly practices.

563. In Indonesia, the structure of pharmaceutical market is competitive. It can be seen from the healthy amount of national players or companies in the market, such as Kalbe Farma, Sanbe, Soho, Deka Medica, Tempo Scan Pacific and Pharos Indonesia. However, market practices are distorted by pharmaceutical agents and doctors that undermine competition mechanism. A doctor has a dominant role in determining the choice of drugs, both to be obtained by patients and those available at hospitals. It is suspected that there is a transactional deal between doctors and pharmaceutical companies that gives incentives to doctors in prescribing particular medicines.

564. Acting upon that, KPPU issued recommendations to the Ministry of Health for:

- Improvement of pharmacist's role, "Pharmacists must inform about patent and generic drugs that have the same active substance to every patient";
- The obligation to write prescription of the generic name and drug availability at Pharmaceutical Installations of Private Hospitals; and
- Enforcement of Doctor's Code of Ethics.

565. Improving pharmacist's role helps strengthening their role to minimise doctor's role in prescribing certain brand names and in eliminating transactional deals between doctors and pharmaceutical companies.

566. KPPU's Policy recommendations related to the strengthening of pharmacist's role were well accepted and actualised by the Ministry of Health of the Republic of Indonesia with the stipulation and issuance of Regulation of the Ministry of Health of the Republic of Indonesia No. 98 of 2015 on Providing Information of the Highest Retail Price for Drugs, set out in Articles 8 and 9.

567. Article 8 reads as follows:

- Pharmacists at the pharmacy or hospital/clinic's pharmaceutical installation must inform the Highest Retail Price for Drugs to patients or patients' family when giving services related to doctor's prescriptions; and
- In addition to providing information on the Highest Retail Price for Drugs as stipulated in paragraph (1) Pharmacists must inform patients or patients' family of other drugs, particularly generic drugs that contain the same active substance as those prescribed that are available at the pharmacy or hospital/clinic pharmaceutical installation.

568. Article 9 reads as follows:

- Patients or patients' family have the right to make choices of drugs based on the information conveyed by the Pharmacists as referred to in Article 8.

569. The policy recommendation provided by KPPU is effective because it is recognized by the Ministry of Health of the Republic of Indonesia through its regulation. It has shown what competition law and policies could do to protect competitive process, by honouring consumers' preferences with respect to the quality, price, and other attributes of goods and services, in this case, of medicines.

570. In concluding, we would like to once again highlight that stimulating the development of the pharmaceutical industry should take into account the relationship between IP protection and competition law.

571. Finally, we look forward to hearing other Members' comments and experiences on this subject matter. Indonesia would also like to take the opportunity to once again thank South Africa as the proponent of this agenda. Therefore, we support that this agenda item be maintained for the next meeting of the TRIPS Council, especially with regard to discussions on IP issues and Public Interest including the sharing of experiences regarding the utilization of TRIPS flexibilities by Members.

13.6 South Africa

572. South Africa has a proud history of robustly engaging with issues that concern the intersection between intellectual property rights 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.

573. The South African Competition Act, for example, is intended to "advance the social and economic welfare of South Africans", "correct structural imbalances and past economic injustices" and "reduce the uneven development, inequality and absolute poverty" which is so prevalent in South Africa. The South African Competition Commission has not issued specific guidelines on application of the Competition Act to IP. However, it has explained its general approach by indicating that firms are not automatically exempt from the rules of the Competition Act as a result of the rights granted in terms of laws like the intellectual property laws. It further reiterated that firms cannot be automatically allowed to continue with a particular prohibited practice as outlined in the Competition Act because that practice is allowed by another Act.

574. The Competition Act covers both horizontal and vertical modes of competition. Horizontal anti-competitive activity refers to conduct among independent enterprises that are suppliers of competitive (or potentially competitive) goods or services. Vertical anti-competitive activity refers to the supply chain controlled by a producer, beginning with inputs to production, into production, intermediate distribution and, ultimately, the retail sale of goods or services. Instances of horizontal anti-competitive behaviour that are *per se* illegal in most jurisdictions include price-fixing among competitors, output restraints and allocation of geographic territories. Examples of vertical restraints that are *per se* illegal in many, but not all, jurisdictions are resale price maintenance (or fixing the minimum price at which retailers may sell) and 'exclusive grant-back' requirements in patent licences.

575. There are some significant risks of anti-competitive conduct in pharmaceuticals markets that are fairly widespread and deserve close attention from competition authorities. These include bid manipulation in procurement of health technologies, whereby a group of potential competitors may agree not to submit bids below a set price and to allocate the 'lowest set price' bid to a particular firm. Such activity may also involve inappropriate payments to government officials who might otherwise report the anti-competitive practice. Anti-competitive conduct by patent-owning enterprises may include requiring a distributor or retailer of health technologies to purchase a complete line of products as a condition of purchasing a particular product or products (i.e. a tying arrangement). Perhaps the most widely discussed form of anti-competitive conduct involving patent owners involves 'buying out' generic challenges to patents that might otherwise result in generic products entering the market at an early date.

576. Since 2001 many generic manufacturers secured voluntary licenses to produce medicines in South Africa, including over 20 licenses for medicines in the antiretroviral category. The increase in voluntary licensing agreements for ARV drugs was often a result of civil society pressure, and the use of competition law. For example, in 2002 activist initiatives of the Anti-Retroviral Therapy (ART) treatment campaign, resulted in some multinational companies found guilty of excessive pricing by the South African Competition Commission.

577. South Africa's Competition Commission investigated several cases involving the interface of IP and competition concerns, particularly in cases where complaints of excessive pricing and refusals

to license competitors were alleged. The landmark case in South Africa arose out of a September 2002 complaint by Hazel Tau and the South Africa Treatment Action Campaign (TAC) and others against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI), suppliers of the first-line antiretroviral medicines zidovudine and lamivudine. In the Hazel Tau case, the prices for antiretroviral medicines from the patent holders were, at the time, from three to ten times higher than the least expensive generic version of the same medicines.

578. There had been requests for licenses by generic pharmaceutical producer Cipla and from the medical services humanitarian organisation, Médecins Sans Frontières (MSF, or Doctors without Borders). Respondents admitted in documents filed with the South African Competition Commission a general policy to refuse licences for the generic supply of their products. It also admitted that their prices were unaffordable by at least 80% of all South Africans. The case resulted in an order of the Commission finding that high prices and a refusal to license Indian generic manufacturers constituted three abuses of dominance under Section 8 of the Competition Act: (a) excessive pricing; (b) refusing to give a competitor access to an essential facility, when it is economically feasible to do so; and (c) engaging in exclusionary conduct if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gains. In reference to remedy, the Commission stated that it would "request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of the respondents' patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty".

579. Before the referral and prosecution of the case, GSK and BI negotiated a settlement agreement in terms of which they admitted no liability. GSK and BI agreed to:

- Grant licences to generic manufacturers;
- Permit the licensees to export the relevant ARV medicines to sub-Saharan African countries;
- Where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;
- Permit licensees to combine the relevant ARV's with other ARV medicines; and
- Not require royalties in excess of 5% of the net sales of the relevant ARV's.

580. In 2007, the Commission received another complaint relating to an HIV/AIDS medicine from the TAC alleging that Merck (and its South African subsidiary, MSD) had abused their dominant positions in the markets for the ARV medicine efavirenz (EFV) by refusing to license other firms to import and/or manufacture generic versions of this medicine on reasonable and non-discriminatory terms. MSD held a twenty-year patent on efavirenz that expired in 2013. The TAC case resulted directly in MSD and Merck reaching agreement with multiple licensees on reasonable terms to bring a wide range of generic products containing EFV (an essential drug used as part of first-line ARV treatment in South Africa) to market. While the Hazel Tau case was settled only after the Commission had taken a decision to refer the matter to the Tribunal for adjudication, the TAC case was resolved before the Commission completed its investigation on the matter.

581. In February 2009, Aspen notified the Commission of its intention to acquire the Lanoxin brand from GSK South Africa. In its investigation, the Commission noted that GSK had voluntarily licensed three patented antiretroviral medicines, including Zidovudine, where the parties (GSK and Aspen) held a combined market share of 95.7%. The Commission focused predominantly on the horizontal aspects of the merger since GSK, to some degree also competed with its generic licensees. To avoid the reversal of gains obtained by licensing of patented products in the Hazel Tau case (above), the Commission sought conditions for extension of the license of antiretroviral medicines to include the Abacavir product. Abacavir was a GSK patented product which was used primarily for the treatment of children suffering from HIV. At the time of the merger, GSK was the only supplier of this product in South Africa. The Commission sought and obtained as a condition for the approval of the merger an undertaking by GSK to not only license the production and/or importation of this product by Aspen but to also extend the license to other generic companies.

582. The Commission announced in April 2018 its intention to investigate local pharmaceutical company Aspen Pharmacare for alleged "abuse of dominance". Reports in April this year indicated that the Spanish Markets and Competition Commission initiated anti-trust proceedings against Aspen. In October 2016, Aspen was fined over EUR 5 million by the Italian Competition Authority for having abused its dominant position by increasing prices of four of its anti-cancer medicines by up to 1,500%. The Commission also announced in June 2018 that it would initiate an investigation against pharmaceutical company Pfizer Inc. for "suspected excessive pricing of lung cancer medication". Furthermore, the Competition Commission announced in July 2018 that it would investigate the price of cancer medicines of three pharmaceutical companies. One of these companies is Roche Holdings AG, which will be investigated for the excessive pricing of Trastuzumab. The investigation specifically relates to "excessive pricing", "exclusionary conduct", and "price discrimination".

583. The Competition Commission has also finalized its Health Market Inquiry which looked at how pharmaceuticals and related activities may be a cost driver in the private sector.

13.7 United States of America

584. The United States notes the desire of some Members to introduce discussion of competition law and policy before the TRIPS Council, and recalls the June 2018 intervention of the United States on this subject matter.

585. The United States believes that the intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare, but also that intellectual property and competition are distinct disciplines implemented and overseen by different administrative authorities. Given that relatively few TRIPS Council delegates can be expected to have deep expertise both in intellectual property and competition law and policy, the TRIPS Council is not the ideal venue to hold the discussions proposed under this agenda item.

586. Work by non-experts could easily lead to a misapplication of competition law in the context of intellectual property rights.

587. In the words of a leading United States competition law enforcement official, "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."

588. I would also like to remind the Council that the UN Secretary General's High-Level Panel on Access to Medicines Report includes the following statement from one panellist: "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."

589. The United States references but will not otherwise repeat its June 2018 intervention on this agenda item. We continue to express our reservations regarding discussion of this subject matter in this forum.

13.8 Japan

590. 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.

591. 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. From this perspective, this delegation has concerns about document IP/C/W/649. In addition, it is important to note that any measures taken under these provisions

should be fully consistent with the TRIPS Agreement, as is stipulated in Article 8 of the TRIPS Agreement.

13.9 European Union

592. As already stated at the last TRIPS Council, in general, we do not consider the TRIPS Council the appropriate forum to discuss competition policy. There are other international fora, such as the International Competition Network, where such international exchanges and cooperation are taking place.

593. While the submission from South Africa seems to consider the use of competition policy a TRIPS flexibility, the European Union would be cautious and would emphasise the following: while the TRIPS Agreement is obviously compatible with the application of competition policy measures, it clearly does not allow for "absolute policy space". As provided for in Article 8.1 and 8.2, 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.

594. Generally, competition policy plays an important role in controlling and sanctioning anti-competitive market behaviour in any sector, including the pharmaceutical sector.

595. Concerning excessive pricing as a competition law infringement in the pharmaceutical sector, there have been only very few decisions in the European Union, specifically, by Denmark, Italy, and the United Kingdom.

596. At the European Union level, the European Commission is currently conducting one investigation into unfair pricing of medicines. That case concerns pricing practices by Aspen, 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. Aspen acquired these medicines many years after their patent protection had expired and hence the investigation concerns generic pharmaceutical products. The European Commission's investigation of Aspen's pricing in the European Union markets with the exception of Italy is ongoing and therefore we cannot comment it any further.

597. In a related case concerning the Italian market, the Italian competition authority found that Aspen's pricing amounted to an abuse of dominance, and ordered the company to set new fair prices for the medicines concerned. The Italian authority applied a two-step test (referred to as the United Brands test). First, it examined whether the difference between cost and price indicated excessive profit margins and, second, whether that the price was unfair in relation to a number of factors.

598. Apart from the investigation into unfair, or excessive pricing, the European Commission has sanctioned also other measures. In 2005, the Commission found that AstraZeneca misled patent offices to enjoy a patent extension (in the form of a Supplementary Protection Certificate) to which it was legally not entitled. This finding was confirmed in a final judgment by the Court of Justice in 2012. In 2013 and 2014, the Commission issued three pay-for-delay decisions (Lundbeck, Johnson&Johnson, Servier) against agreements which sought to extend exclusivity of originator products by paying out would-be generic entrants, including for discontinuing litigation to remove patent barriers.

599. The European Union Commission has not pursued any 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.

600. At the European Union level, the application of competition policy has so far not been needed as a remedy against excessive pricing as a result of IPR protection (i.e. a licence to generics to bring down the price) or to otherwise remedy patent barriers to generic entry.

601. The above examples show that competition law enforcement in the European Union is done on a case-by-case basis. Where the Commission intervenes in cases involving IPRs, it gives particular attention to preserving the balance between static competition (short term price effects) and dynamic competition (long term innovation effects).

602. On the international level, the European Union cooperates with other national authorities, including from WTO Members, on competition policy and enforcement issues of mutual interest. Our main objective has been to promote convergence of competition policy instruments and practices across jurisdictions and to facilitate cooperation with competition authorities in other jurisdictions in enforcement activities.

603. Cooperation with other competition authorities takes place at two levels. First, the Commission discusses competition-related matters in various international fora, such as the International Competition Network (ICN), where excessive pricing was discussed during its annual conference in Portugal in 2017. ICN brings together competition authorities from more than 100 jurisdictions which exchange experiences and best practices in several meetings every year. Second, the Commission is also regularly engaged in bilateral cooperation, including related to the pharmaceutical sector. The nature of the cooperation activity varies between countries and can cover cooperation on specific investigations, dialogue on competition policy issues as well as capacity building support.

604. Therefore, we remain to be convinced about the need to discuss competition policy at the TRIPS Council.

13.10 World Health Organization

605. The World Health Organization (WHO) works under the premise that "Health is a human right. No one should get sick or die just because they are poor, or because they cannot access the services they need" (Director-General, Dr Tedros Adhanom Ghebreyesus). The Nations of the world agreed on SDGs, in particular SDG 3 to "Ensure healthy lives and promote wellbeing for all at all ages". WHO needs to work with all Members and other international organizations to achieve this specific health goal, but health is also relevant for all the other SDGs and it lays the foundation for long-term economic development.

606. Competition Law is one important tool to promote innovation and access to health technologies. Anti-competitive behaviour in relation to intellectual property could appear, for example, with life-cycle management practices and defensive patenting. For example, the European Commission welcomed the Court of Justice judgment in a case on abuse of dominant position to prevent or delay market entry of generic competitors through misuse of the patent system and regulatory procedures. There are also other cases in relation to overly restrictive conditions in medical technology licensing or mergers between pharmaceutical companies that can lead to undesirable market concentration and pay-for-delay agreements between originator and generic companies. More examples of abuse of dominant position for driving out competitors are in China where NDRC fined two pharmaceutical companies for abusive conducts, found the UK Competition Authority imposed a fine on two pharmaceutical companies (originator and distributor) for abuse of a dominant position and charging excessive and unfair prices for a medicine. Other cases in Indonesia, Thailand or cases involving more than one country are reported by UNCTAD Commission on Investment, Technology and Financial Issues and also a further case analysis was made by UNDP in several publications on that topic.

607. Anti-competitive practices may lead to barriers to innovation and access in the medical sector. It is essential therefore to utilize all policy tools available to increase access to medicines, vaccines and other health technologies. IP protection is not exempted from the application of competition law. Effective use of competition policy could be in the best interests of patients and health systems.

608. WHO with its transparency policy in terms of pricing of medicines is seeking to contribute to the assessment of such anti-competitive practices. We are open to work in this field with Members and other international organizations, including the WTO.

13.11 Brazil

609. I would like to comment on two interventions that were made before by Members.

610. The first one, was a comment made that IP and competition are distinctive disciplines and are implemented by different agencies, thus they should not be discussed at the TRIPS Council. We disagree with that point. We observe for instance that enforcement measures are implemented by very different agencies than those responsible for trademarks and patent applications. Enforcement

measures for instance are implemented by customs which have very different disciplines and very different stakeholders involved in comparison with patent offices. The same could be said for copyright and patent, which are dealt by different agencies. The TRIPS Council is mandated to discuss issues which are disciplined by the TRIPS Agreement. This involves copyrights, transfer of technology, patent, enforcement and competition policy.

611. The second point was a comment made that the International Competition Network already discusses competition. We certainly recognize the very high-level work that is done by the International Competition Network but it is an informal venue, as mentioned on their website, and we do not think that this should preclude discussion at the TRIPS Council. There is an established relation between IP and competition in academic literature and by national agencies. So, we think this is an appropriate forum. We look forward to continuing this discussion perhaps in another session of the Council.

14 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

14.1 Dispute Settlement

14.1.1 Honduras

612. Honduras wishes to support the statement to be made by the Dominican Republic.

613. Honduras believes that the Panel made a number of serious errors in its report, both of legal interpretation and in its appreciation of the facts.

614. The implications of these errors are not limited to tobacco products, and set a dangerous precedent for all Members, undermining the protection of trademarks.

615. Given that the appeals of Honduras and the Dominican Republic are pending before the Appellate Body, Honduras prefers not to make any statement regarding detailed aspects of the panel report. We hope to be able to discuss these details once the Appellate Body issues its report.

14.1.2 Dominican Republic

616. The Dominican Republic wishes to note that the Panel Report under discussion under the first point of agenda item 14 refers to the panels established by Cuba and Indonesia in relation to Australia's tobacco plain packaging measures. There were separate panels established in the four complainants' complaints against Australia's measures for plain packaging of tobacco products under Article 9.3 of the DSU. The other two complainants, the Dominican Republic and Honduras, appealed the Panel Report, on 23 August 2018, and 19 July 2018, respectively. The fact that Cuba (DS458) and Indonesia (DS467) have not appealed their panel reports has no impact on the rights of the Dominican Republic (DS441) or the rights of Honduras (DS435) to appeal their panel reports.

617. As the appeals of the Dominican Republic and Honduras are ongoing, the Dominican Republic considers that it would not be appropriate to make any statement on the Panel's findings in the cases brought by Cuba and Indonesia. The Dominican Republic notes only that it is of the view that the Panel committed several legal errors as set forth in its Notification of an Appeal (WT/DS441/23). We look forward to the Appellate Body's review of the merits of the Dominican Republic's appeal in due course.

14.1.3 Norway

618. Norway has followed the development in these panel cases with particular interest while participating as a third party. Public health and tobacco control are topics of particular interest to Norway, something that we have repeatedly stressed in various fora.

619. Norway was therefore very pleased to note the Panel's acknowledgement of Australia's right to introduce the plain packaging measures, in consistency with its WTO obligations, to fulfil its obligations under the Framework Convention on Tobacco Control to protect public health.

620. In our view, it is within the rights of each WTO Member to adopt measures which are necessary to protect public health, as long as the measures chosen are consistent with the WTO agreements.

14.1.4 Australia

621. Australia reiterates its strong support for the decision by other WTO Members to legislate for the mandatory plain packaging of tobacco products.

622. The important steps made by these Members in tobacco control demonstrate that efforts to delay the adoption of tobacco plain packaging measures in these countries have not been successful. They reinforce that tobacco plain packaging is a legitimate public health measure to combat the tobacco epidemic.

623. Contrary to claims previously made in this forum, tobacco plain packaging is not about the destruction of intellectual property rights. The measure prevents the use of tobacco product packaging to advertise and promote a unique product that causes significant damage to public health.

624. As other Members are aware, in its report circulated in June of this year, the Panel found that Australia's tobacco plain packaging measure is a legitimate public health measure that is capable of making a meaningful contribution to reducing the use of, and exposure to, tobacco products; and rejected all claims that the measure is inconsistent with Australia's WTO obligations.

14.1.5 Indonesia

625. We thank Australia for bringing this issue to this Council.

626. Indonesia associates itself with the position taken by the Dominican Republic and Honduras. It reiterates its position as stated during the DSB Meeting on 27 August 2018.

627. Indonesia did not appeal the panel report in DS467. However, we believe that the decision of the Panel is not just about the regulation of tobacco products and packaging. Indonesia believes that the Panel report in DS467 will harm trade in other perfectly legal and legitimate products such as certain foods and drinks. As everyone presumably knows, there have been calls to introduce measures similar to tobacco plain packaging to high-fat and high-sugar products in order to combat obesity and diabetes. As a result of the Panel's decision, plain packaging requirements may now be applied to alcoholic beverages for religious or moral reasons. In short, Indonesia fears that the report in DS467 and its companion disputes signal the beginning of a slippery slope to fundamental disruption of global consumer markets.

14.2 IPR-Related Issues in Trade Policy Reviews

14.2.1 WTO Secretariat

628. Since the last TRIPS Council Meeting in June, the Trade Policy Reviews of Colombia, Norway, Uruguay, China, Israel, Chinese Taipei and Vanuatu have taken place. We will not attempt to summarize the full range of IP issues covered in each of these reviews. Updates are limited to those matters on which Members, including both developed and developing countries, actively registered an interest by posing questions during the review process. The issues that were of particular interest in this concrete sense included:

- copyright and neighbouring rights management;
- geographical indications;
- protection of well-known and unregistered trademarks in use;
- legislative amendments and updates regarding copyrights, trademarks and patents;
- patent linkage;

- intellectual property protection of medical and pharmaceutical inventions;
- protection of undisclosed information and trade secrets;
- protection of domain names;
- identification of owners of traditional knowledge or cultural expressions;
- relationship of IP with e-commerce and competition policy;
- national strategies to foster innovation and economic growth;
- enforcement of IPRs, civil remedies, criminal penalties online and at the border;
- customs intelligence and cooperation with neighbouring countries;
- commercialization and trade of IPRs; and
- Accession to WIPO Conventions.

629. Additionally, we have contributed to the TRIPS-related section for the forthcoming G20 and WTO-wide Director-General's Monitoring Reports. The contribution highlights certain trade-related IP policy initiatives undertaken by Canada, the Kingdom of Saudi Arabia, Republic of Moldova, and South Africa.

15 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

15.1 Cooperation Council for the Arab States of the Gulf

630. I am taking the floor to reiterate the request of my Organisation, the GCC, for the granting of a permanent observer status to the Council for TRIPS.

631. Our six years' experience as an *ad hoc* observer have been very rich in substance and have helped us to actively follow, since 2012, the valuable work of the TRIPS Council. The GCC Secretariat General, which gathers among its operational bodies the GCC Patent Office and the IP Training Centre, was able, thanks to this status, to present to the TRIPS Council its yearly report on technical cooperation activities with the aim of sharing its experience and those of the GCC Members States in the field of IP.

632. The GCC achieved different level of cooperation among its Members in intellectual property such as patents, trademarks, copyright, trade secrets, in addition to effective collaboration with many international organization and patent offices around the world; such as WIPO.

633. In the field of patents and trademark the GCC achieved the following;

- a. Adopting the statute of the GCC Patent Office in 1992;
- b. Adopting the patent office (GCC Patent Law) in 1992;
- c. Establishing the GCC Patent Office in 1992;
- d. Establishing Intellectual Property Training Centre in 2011; and
- e. Adopting the Trademark Law of the GCC in 2012.

634. The GCC Secretariat General is an executive and coordinating institution in charge of managing the day-to-day business of economic and trade-related issues, including in the area of enforcement of intellectual property rights.

635. The GCC intends to develop its activities on all IP aspects mainly on technical cooperation and capacity building in cooperation with the WTO and WIPO, as well as with the relevant institutions in the WTO Members.

636. That is why we are convinced that granting the GCC permanent observer status to the TRIPS Council will help us to better follow the work of the TRIPS Council on a predictable basis and develop our IP-related activities to support the GCC Members in enforcing national IP laws and GCC IP laws.

15.2 Jordan

637. Jordan supports the request to grant the GCC a permanent observer status as its works cover the economic and trade-related issues, including in the area of enforcement of intellectual property rights.

15.3 Kuwait, the State of

638. We would like to fully associate ourselves with the statement made by the GCC representative.

639. The State of Kuwait supports granting of permanent observer status to the GCC SG, to allow it to follow the work of the Council for TRIPS on a regular basis.

640. The GCC Secretariat General has always attached a great importance to all aspects of the work of the TRIPS Council, including its work related to the implementation of the TRIPS Agreement and IP systems.

15.4 Morocco

641. We believe that the request made by the Cooperation Council for the Arab States of the Gulf (GCC) reflects a keen willingness to follow more closely, and in a constant and institutionalized manner, TRIPS-related developments within the WTO.

642. The delegation of Morocco supports this request and believes that granting permanent observer status to the GCC will ensure the involvement of this organization and encourage its Members to make further progress in this area.

15.5 Oman

643. The Sultanate of Oman echoes the statement delivered by the GCC Secretariat General. The GCC Secretariat General has always attached a great importance to all aspects of the work of the TRIPS Council, even prior to having been granted an *ad hoc* observer status since November 2012. The GCC Secretariat is actively following under its current observer status the discussion in the TRIPS Council on all its agenda items especially those related to capacity building and technical cooperation. Taking into account the role that the GCC Secretariat would play in different aspects of the work of the TRIPS Council, the Sultanate of Oman supports granting the GCC Secretariat permanent observer status.

15.6 Qatar

644. We would like to associate ourselves with the statement made by the GCC Secretariat and the statement of the State of Kuwait as coordinator of the GCC. We believe that there will be a lot of benefits of granting the GCC Secretariat permanent observer status at the TRIPS Council. As they are in charge of the day-to-day operation and host the GCC regional Patent Office they have been granted an *ad hoc* observer status since November 2012. We would like to seek the support of the WTO membership in granting them permanent observer status.

15.7 Bahrain, Kingdom of

645. Like others before us, we would also like to support the proposal to grant the Gulf Cooperation Council permanent observer status at the TRIPS Council.

646. While holding *ad hoc* observer status, the GCC via the GCC Patent Office has been actively following the TRIPS Council, assisting GCC Members to comply with their IP-related obligations and has provided several technical assistance and capacity building activities.

647. This is why we support its permanent observer status and hope for a favourable consideration by the Council.

15.8 Egypt

648. Six years ago, the GCC Secretariat General and its Patent Office have been granted a status of an *ad hoc* observer in the TRIPS Council, since then they attended all the sessions of the Council, presented reports on technical cooperation activities annually, and made statements on this issue under the relevant agenda item.

649. The GCC is an intergovernmental regional organization which places the economic issues at the heart of its activities. Its Secretariat General is the executive body in charge of coordinating the daily business of the GCC including the area of intellectual property enforcement. It is responsible for developing common regulations and institutions to ensure protection of intellectual property rights, as well as assisting GCC Members in implementing the TRIPS Agreement.

650. We believe that granting the GCC Secretariat General permanent observer status will be of merit, and will help in enhancing their engagement in the Council's work on a closer and more regular basis.

15.9 Brazil

651. Brazil would like to express its support in granting permanent observer status to the GCC. We recognize the merits of the request and also their very active participation in the TRIPS Council. We think that giving them permanent observer status will be beneficial for the whole community.

652. We also think that permanent observer status should be granted to the South Center and CBD Secretariat as soon as possible.

15.10 China

653. Over years, as an *ad hoc* observer of the TRIPS Council, the GCC has actively participated in the TRIPS Council and fulfilled observer's obligations. China supports GCC to be granted permanent observer status. We believe that granting a permanent observer status to GCC would help deepening Members' knowledge on the GCC and its Members' IP system.

16 ANNUAL REPORT

654. No statements were made under this agenda item.

17 OTHER BUSINESS

655. No statements were made under this agenda item.

17.1 Dates for the Council's Meetings in 2019

656. No statements were made under this agenda item.

17.2 Work Programme on Electronic Commerce

657. No statements were made under this agenda item.
