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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 17-18 OCTOBER 2019

Chair: H.E. Ambassador Lundeg Purevsuren (Mongolia)

Addendum

The present document contains the statements made during the Council for TRIPS meeting held on 17 and 18 October 2019.

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AT THE MEETING OF COUNCIL FOR TRIPS 17-18 OCTOBER 2019*

* 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 Mexico

1. This delegation is pleased to inform the TRIPS Council that Mexico has issued a General Declaration on Protection of the "Raicilla" appellation of origin.

2. The Declaration has been notified to the Secretariat and published on the WTO website under document symbol IP/N/1/MEX/G/8. We would therefore like to comment on the main points of this notification.

3. The General Declaration grants protection of the "Raicilla" appellation of origin in accordance with the Law on Industrial Property for the protection of distilled alcoholic beverages made from various types of agave, which is produced in 16 municipalities in the State of Jalisco and one municipality in the State of Nayarit.

1.2 Canada

4. Canada is pleased to take this opportunity to present notifications IP/N/1/CAN/20 and IP/N/1/CAN/21, on recent amendments to Canada's Trademarks Act, as well as Canada's new Industrial Design Regulations, respectively.

5. Canada's first notification for this meeting (IP/N/1/CAN/20) provides an overview of recent amendments to Canada's Trademarks Act under Bill C-79 (An Act to implement the Comprehensive and Progressive Agreement for Trans-Pacific Partnership between Canada, Australia, Brunei, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Viet Nam). Bill C-79 amends the Trademarks Act to expand the application of subsections 53(1) and 53.1(1) to apply to goods that have a mark applied to them that is confusing with a registered trademark. The amendments to Canada's Trademarks Act received Royal Assent and entered into force on 25 October 2018.

6. Canada's second notification (IP/N/1/CAN/20) introduces Canada's new Industrial Design Regulations. The new Industrial Design Regulations carry out amendments made to the Industrial Design Act by Bill C-43, A second Act to implement certain provisions of the budget tabled in Parliament on 11 February 2014 and other measures (as previously notified under IP/N/1/CAN/D/3), which facilitate Canada's accession to the Hague Agreement, and modernize Canada's industrial design regime. The amendments to the Industrial Design Act and the new Industrial Design Regulations entered into force on 5 November 2018. By joining the Hague Agreement, Canadian businesses and innovators will have access to an efficient and effective means of protecting their industrial designs around the world. The modernization measures will also update, codify and improve aspects of Canada's industrial design regime, aligning it with our key trading partners, reducing red tape for business and improving e-services for Canadian clients.

7. Canada would also like to take the opportunity to briefly notify four notifications on recent amendments to Canada's Patent Act, Trademarks Act, and Copyright Act, as well as the enactment of the College of Patent and Trademark Agents, under Bill C-86 (A second Act to implement certain provisions of the budget tabled in Parliament on 27 February 2018 and other measures).

8. Bill C-86 includes amendments to Canada's Patent Act to establish a regime for written demand letters relating to patents, and also codifies the research exemption in Canadian law. Bill C-86 also amends the Act to specify that licensing commitments that bind the owner of a standard essential patent bind any subsequent owners. Bill C-86 also amends the Act to expand the rights of a person in respect of a claim in a patent who meets the requirements to be considered a prior use.

9. With respect to Canada's Trademarks Act, Bill C-86 amends the Act to add bad faith as a ground of opposition to the registration of a trademark and for the invalidation of a trademark registration. It also amends the act to prevent the owner of a registered trademark from obtaining relief for certain acts during the first three years after the trademark is registered, unless the trademark was in use in Canada during that period (or special circumstances exist that excuse the absence of use). Bill C-86 also includes amendments to clarify that certain prohibitions of the Trademarks Act do not apply with respect to a badge, crest, emblem, or mark that was the subject of a public notice of

adoption and use as an official mark if the entity that made the request for the public notice is not a public authority or no longer exists. As well, Bill C-86 modernizes the conduct of various proceedings before the Register of Trademarks, and also makes certain housekeeping amendments to provisions of the Act.

10. Bill C-86 also amends the Copyright Act in order to specify that certain information is not permitted to be included within a notice under Canada's "notice-and-notice" regime for Internet service provider liability, and to provide for a regulation-making power to prohibit further types of information from being included within such a notice. Bill C-86 also amends the Act to modernize the legislative framework relating to the Canadian Copyright Board so as to improve the timeliness and clarity of its proceedings and decision-making processes.

11. Finally, Bill C-86 enacts the College of Patent Agents and Trademark Agents Act, which establishes Canada's College of Patent Agents and Trademark Agents. The College is to be responsible for the regulation of patent agents and trademark agents in the public interest.

12. We would like to thank the Secretariat for accommodating our submission of these notifications prior to this meeting, and note that they will be circulated to TRIPS Council in due course.

1.3 Chinese Taipei

13. In compliance with Article 63.2 of the TRIPS Agreement, we notified the TRIPS Council of our recent amendments to the Copyright Act and the Patent Act in documents IP/N/1/TPKM/23 and IP/N/1/TPKM/24. In brief, the changes are as follows.

14. First, to curb malicious online infringement, Articles 87 and 93 of the Copyright Act were amended on 1 May 2019. Under the amendment, persons knowingly broadcasting or publicly transmitting works that infringe economic rights, or that manufacture, import or sell equipment or devices preloaded with the computer programmes which have aggregated the Internet Protocol Addresses of such works and receive benefit therefrom, will face a sentence of up to two years imprisonment or detention, or in addition thereto, a fine of not more than TWD 500,000.

15. The Patent Act was amended on 1 May 2019 and will take effect on 1 November 2019. The main amendments include: extending the term of design patent from 12 years to 15 years and loosening restrictions for the division of invention and utility model patent applications after approval.

16. We will continuously fulfil our obligation to ensure accessibility and the transparency of our intellectual property system and encourage other Members to do so.

1.4 Japan

17. This delegation is pleased to inform the Council that Japan recently amended its Unfair Competition Prevention Act, Patent Act Design Act, and Trademark Act. The amendments have been notified to this Council in accordance with Article 63.2. The reference numbers are IP/N/1/JPN/U/3, IP/N/1/JPN/P/17, IP/N/1/JPN/D/9, and IP/N/1/JPN/T/11. Taking this opportunity, we would like to briefly explain some major points about the amendment.

18. Firstly, the Unfair Competition Prevention Act was revised so as to encourage utilization of valuable data defined as "Protected Data", which is technical or business information accumulated by electronic or magnetic means and provided to limited users.

19. Specifically, the revised Act positions wrongful acquisition, usage and disclosure of Protected Data, including unauthorized access and fraud, as acts of unfair competition and provides civil remedies, such as claim for injunctions and damages, to plaintiff.

20. Secondly, the Patent Act was revised in order to promptly and appropriately resolve litigations relating to IP infringement.

21. Concretely, an in-camera procedure has been established that enables a court to determine whether documentary evidence possessed by plaintiff or defendant will prove an act of infringement

or calculate damages. When such documents are found to be evidence for the proof or calculation, the court can issue an order to submit the documents for the examination of documentary evidence. Technical experts can also involve in this in-camera inspections.

22. In addition, in cases where trade secrets are contained in the supporting documents for the advisory opinion system, viewing restrictions are set on these documents in order to protect them.

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

1.5 Mauritius

24. I would like to briefly introduce the Notification of the Mauritius Copyright Act 2017.

25. The objective of the Copyright (Amendment) Act 2017 is to amend the Copyright Act 2014 in order to, *inter alia*:

- First, to make provisions regarding phonograms;
- Second, to increase the length of the duration of copyright;
- Third, to make better provisions in relation to the payment of equitable remuneration, from 50 to 70 years after the death of the author;
- Fourth, to replace the Mauritius Rights Management Society by the Mauritius Society of Authors and provide for the composition of its Board and its functions; and
- Fifth, to provide for the procedure regarding Membership of the Mauritius Society of Authors.

1.6 Brazil

26. Brazil would like to inform that it has recently notified to the TRIPS Council the legislation that will be the basis to eliminate Brazil's backlog on patents, in a similar way we have done with our backlog on trademarks. These are Resolutions 240 and 241 of our national patent office, which are available in English.

27. These and other efforts are part of Brazil's vision of the fundamental role of intellectual property for economic development. We are carefully reflecting on initiatives to stimulate innovation as a top priority. Important steps are being made to improve our legal framework and increase the production and dissemination of creativity and knowledge.

28. The Patent Backlog Elimination Plan aims to reduce 80% of pending requests by 2021, when there will be a new assessment on the matter. Our aim is also to reduce the average concession time to about two years from the examination request.

29. We will give more information to Members on these legislations in the next meeting of the TRIPS Council, when they are going to be circulated.

1.7 WTO Secretariat

30. The Secretariat takes this opportunity to provide a further regular update to the TRIPS Council on the e-TRIPS project. Delegates will recall that e-TRIPS aims at streamlining and updating the information services the Secretariat provides for Members, within the framework established by the TRIPS Agreement itself and the decisions of this Council. It comprises two separated but integrated online tools – first, the e-TRIPS Submission System, which is a means for submitting TRIPS notification, reports and review material; and second, the e-TRIPS Gateway, which provides a wide range of opportunities for delegates to access and make use of TRIPS information.

31. Now, let me provide a quick update on the state of play of these two online tools.

E-TRIPS Submission System

32. Let me start with the e-TRIPS Submission System, which is an online tool for submitting:

- TRIPS notifications, such as newly passed laws and regulations relevant to TRIPS;
- TRIPS review materials, such as responses to the questionnaires established by the TRIPS Council; and
- TRIPS-related reports, such as regular reports on technical assistance and on incentives for technology transfer filed by some Members and some international intergovernmental organizations.

33. The e-TRIPS Submission System, initially launched on 8 March 2019, is now ready for use in each of the three WTO working languages: English, French and Spanish. To date, around 60 WTO Members have requested their log-in credentials to access the System. The great majority of the documents submitted to the TRIPS Council since then have been provided through the e-TRIPS Submission System.

34. We are grateful to the delegations for sharing their suggestions on how to adjust and refine the e-TRIPS Submission System in order to meet the practical needs of delegations. We thank those Members for their helpful comments, and we will be making improvements to the System in due course.

35. We would also like to extend our gratitude to those Members who used the e-TRIPS Submission System to provide their 2019 reports on the implementation of Article 66.2 of the TRIPS Agreement and their 2019 reports on technical cooperation activities. We appreciate the extent of time and resources Members may devote to the task of preparing these reports, and our aim is to help you optimize the way in which information for these reports is compiled and made available. In that light, feedback on how the System can better accommodate specific scenarios are more than welcome.

36. The most significant benefit of using the e-TRIPS Submission System to submit these reports is that it enables the possibility in the e-TRIPS Gateway to search by, for example, the programme or project name, the beneficiary Member targeted, time periods, etc. Reports submitted outside of the System are only searchable through a full text search (similar to WTO Documents Online now). This means that individual programmes and projects will not appear in searches for specific beneficiary countries on the e-TRIPS Gateway, if they have been submitted without using the e-TRIPS system. It is against this background that we encourage delegations to use the e-TRIPS Submission System to submit these reports.

37. To maximise the use of the e-TRIPS Submission System in this specific context, we also encourage delegations to bear in mind, as early as possible in the process, the relevant fields and the overall structure of the System. -This will have the effect of facilitating the process of compiling information from different agencies for these reports. The Submission System is especially designed to permit distributed online inputs. For example, different government agencies can provide inputs into the same e-TRIPS draft report, which can then be finalized by the submitting agencies. This means Members would no longer have to compile a document off-line (e.g. in Word) that is then adapted and entered into the system. Rather, the individual contributions can be made directly into the draft report by the different contributing agencies.

38. As ever, we remain at the service of all Members to provide informal demonstrations and training sessions. From the e-TRIPS Submission System homepage, you can access a Guidebook on how to use the system. In addition, we will produce further training materials in due course, that will illustrate any new features. If your delegation would like to use the e-TRIPS Submission System and has not already requested log-in credentials, please contact us at e-TRIPS@wto.org.

E-TRIPS Gateway

39. Let me now turn to the broader e-TRIPS Gateway – in other words, the online information portal that allows you to search and extract the full range of TRIPS information managed by the Secretariat.

40. A beta version of the e-TRIPS Gateway was launched in June this year. The Chair of the TRIPS Council also invited Heads of Delegations for an informal demonstration of the Gateway on 23 September 2019.

41. TRIPS delegates have been invited to offer any comments, suggestions or general impressions of this early trial version – and we warmly thank those of you who have taken the time to let us know what you think and what we can do to improve the user experience. As always, we continue to welcome your comments.

42. As an update, we are pleased to inform you that the interface of the e-TRIPS Gateway is now available in all three official WTO languages (French, Spanish, English). The underlying data contained in the e-TRIPS Gateway will be made available in all three official WTO languages in the course of next year.

Next steps

43. Regarding next steps, we will begin making incremental improvements to both the e-TRIPS Submission System and the e-TRIPS Gateway on the basis of your feedback.

44. We will also turn our focus to the redesign of the TRIPS-related public WTO webpages and their integration with the e-TRIPS Gateway. The Secretariat will provide further updates to the TRIPS Council in the course of next year. As ever, we are very grateful for your invaluable input and look forward to your continued guidance.

45. In concluding, we invite you to an informal demonstration of the e-TRIPS Gateway in this room, CR, at 2pm. During this informal demonstration of approximately 30 minutes, we will highlight a few e-TRIPS Gateway features you might find most useful. Flyers with additional information on the e-TRIPS Gateway are available at the back of the room.

2 REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

46. 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 Ukraine

47. In July, Ukraine has submitted its responses to the Checklist of questions related to the review of the provisions of Article 27.3(b) of the TRIPS Agreement using the recently developed e-TRIPS online system, which we found user friendly.

48. We would like to make a brief presentation on the substance of those answers. In particular, the protection of intellectual property rights to plant varieties in Ukraine is provided under the Law "On Protection of Plant Variety Rights". This Law stipulates criteria of variety suitability for the acquisition of intellectual property rights, the procedure for acquiring protection, the duration of protection and enforcement of the rights.

49. Thus, Ukraine provides for the protection of plant varieties by a *sui generis* system set out in national legislation.

50. Patent protection is granted for products such as micro-organism strains, plant or animal cells culture etc., as well as for non-biological and microbiological processes for the production of plants and animals according to the Law of Ukraine "On Protection of Rights to Inventions and Utility Models", if they meet requirements for patentability.

51. We believe that this review exercise has the potential to enhance the transparency of domestic systems for the protection of plant varieties and we invite WTO Members to have a look at Ukraine's answers as contained in document IP/C/W/125/Add.26 for further detail.

52. We also would like to encourage other WTO Members to provide or update their answers to the relevant questionnaires related to the Review of the Provisions of Article 27.3(b) of the TRIPS Agreement.

5.2 South Africa

53. The issues addressed under items 3, 4 and 5 are commonly known as the triplets. These issues relate to TRIPS implementation issues and were part of the original built-in agenda under the TRIPS Agreement. Despite the call by ministers in the Doha Work Programme that these implementation issues be addressed as a matter of urgency, very little or scant attention has been given to these issues. I will address these items in turn.

Review of the Provisions of Article 27.3(B)

54. The three criteria for patentability (novelty, inventive step and industrial application) are not defined under TRIPS. Each WTO Member is free to interpret their meanings, which can determine what is patentable under local law. In addition, governments can refuse to grant patents for various reasons that may relate to public health, including inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2); diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a); and certain plant and animal inventions (Article 27.3b).

55. South Africa has a depository system for the registration for patents, meaning that patent applications are examined only as to formalities and are not examined substantively. Accordingly, South Africa has not benefited from the above-mentioned exemption and limitation; and will only be able to do so once the substantive examination of patent applications has been implemented. The adoption of Phase 1 of the South Africa National IP Policy corrects this shortcoming by setting a framework for the operationalisation of substantive examination of patent applications. The IP policy also recommends statutorily codifying various approaches to assessing the patentability criteria, and this work is currently underway.

56. Under current South African law, exceptions to patent rights are provided in Sections 25 and 36 of the Patents Act which provide:

> Section 25(4): A patent shall not be granted - (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process."

57. The key impact of this flexibility is that countries can ensure that only true inventions are patented. Accordingly, in order to give full effect to the provisions of Article 27 of TRIPS, South Africa will in the near future embark on the substantive examination of patent applications and give further statutory guidance to courts regarding the interpretation Section 25(4) of the Patents Act.

Relationship between the TRIPS Agreement and the Convention on Biological Diversity

58. South Africa recalls its previous statements on this agenda item. The 2001 Doha Declaration, in paragraph 19, mandates the TRIPS Council to work on the issue of the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity, as well as the protection of traditional knowledge and folklore.

59. A large group of WTO Members have sought to introduce a mandatory disclosure requirement in patent applications. The best way to ensure the proper use of genetic resources and associated traditional knowledge is through an amendment of the TRIPS Agreement as set out in document TN/C/W/59.

60. On the procedural side, we renew our call for Members to endorse a briefing by the CBD Secretariat on developments within the implementation of the Convention on Biological Diversity as well as for the TRIPS Secretariat to update the three technical notes contained in documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1.

Protection of Traditional Knowledge and Folklore

61. The demand for an international regime to protect traditional knowledge, genetic material or indigenous biological resource and folklore stems, for instance, from biopiracy. Historically genetic resources were accessed for free based on the world view that these were common heritage of humankind. However, with an increasing emphasis on protection of intellectual property rights and the impact of the private ownership of knowledge or products of genetic resources, this view changed - particularly through the introduction of the Convention on Biological Diversity and the Nagoya Protocol.

62. Many Members have passed national laws and implemented the Nagoya Protocol, but biopiracy still continues to thrive, since national laws have limited territorial application. When challenging such violations, including the illegal and erroneous granting of patents in foreign jurisdictions, where patentability criteria may differ from one jurisdiction to another, enforcement and opposition costs may be prohibitive.

63. There is no paucity of ideas in how we can deal with this matter, noting proposal TN/C/W/59. In our experience, even in light of an amendment of our Patents Act (57 of 1978, read together with the Patents Amendment Act 2005 (Act No. 20 of 2005)): Section 25(3A) requires every patent application for inventions for which protection is claimed, and that are based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use, to disclose such information upon submission of the application with proof of prior informed consent (PIC) and ABS. Despite this requirement, biopiracy continues to occur. Amending the TRIPS Agreement to incorporate disclosure norms remains the most viable and effective way to address the issue of traditional knowledge and folklore as envisaged under Article 12 of the Doha Ministerial Declaration, noting that WIPO IGC process has not been able to make any headway in dealing with this matter.

5.3 Bangladesh

64. On agenda items 3, 4, and 5, the position of Bangladesh has not changed. We reiterate our position for the sake of record.

65. On agenda item 3, on the issue of the review of the provisions of TRIPS Article 27.3(b), Bangladesh does not support the patenting of life forms comprising plants and animals. We call for a review of this Article in order to protect the interests of 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 should be prohibited.

66. On the relationship between the TRIPS Agreement and the CBD, Bangladesh holds that Members 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.

67. 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 reduce the number of erroneous patents and biopiracy.

68. Bangladesh believes that traditional knowledge should receive legal recognition as its protection could as well contribute significantly to the achievement of the sustainable development goals.

5.4 India

69. The issues under agenda items 3, 4 and 5 have been on the Council's agenda for a long time. In our previous statements, we have underlined in detail, the need for an international enforceable regime to end the misappropriation of genetic resources and traditional knowledge, happening especially in biodiversity-rich countries. India is a country rich in traditional knowledge associated with biological resources. India is also amongst top 20 identified mega diverse countries in the World. The TRIPS-CBD linkage is important for all countries as it seeks to address biopiracy. We need to move forward on the long-standing issues of the TRIPS-CBD linkage, GI Register and GI Extension on the basis of the modalities contained in document TN/C/W/52.

70. Some Members, in the previous Council meetings, have stated that WIPO IGC is the appropriate forum for discussions on genetic resources. In our view, WIPO is trying to develop a sui generis system of protection and is examining much more complex issues with a view to address the issue in a more comprehensive manner. The discussions in WIPO and those in the TRIPS Council are two complementary processes and do not conflict in any way. However, given the enforceability of the TRIPS Agreement and the fact that much of the misappropriation is a consequence of trade, there is a need to build the linkage between the TRIPS Agreement and the CBD under the aegis of this Council. The Doha Ministerial Declaration had tasked the TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. It also mandated that while doing so, the Council should be guided by the objectives and principles set out in the TRIPS Agreement and should fully take into account the development dimension.

71. India is also of the view that a briefing by the CBD Secretariat on the latest developments in the implementation of the Nagoya Protocol would be very useful for the large majority of the Membership of this Council and we support updating the three factual briefs by the Secretariat on these issues.

5.5 Ecuador

72. Ecuador reaffirms its commitment to encouraging the strategic regulation of intellectual property as a useful tool for promoting research and innovation balanced with the full exercise of other rights, such as the protection of all life forms.

73. Regarding such protection, Ecuador reiterates its appeal to the Council to reflect on the importance of prohibiting patents on all life forms or parts thereof in order to avoid endangering or negatively affecting them, since they should not be considered tradeable goods subject to inventions and, therefore, patents.

74. We believe that a balanced and fair system will only be possible if we include specific issues in our discussions, in accordance with sovereign regulation to ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions.

75. In this regard, the TRIPS Agreement and the Convention on Biological Diversity are related and complement each other. We believe it is important that the two are mutually supportive in their objectives.

76. Accordingly, disclosure of origin and source, prior informed consent and the equitable sharing of benefits should, as unattachable, imprescriptible and inalienable collective rights, be taken into account.

77. Lastly, we reiterate our request that the Secretariat update the factual notes on previous topics, given that the last compilation of the ideas discussed was produced in 2006.

78. We highlight the fact that this update will provide greater clarity on the issues discussed without prejudice to each Member's position, and, in this way, advance the work of this Council.

5.6 Indonesia

79. Our delegation attaches great importance to the negotiation of the relationship between the TRIPS Agreement and the Convention on Biological Diversity, as well as the protection of traditional knowledge and folklore. We reiterate our position that Article 27.3(b) and Article 29 of the TRIPS Agreement do not provide any legal obligation for Members to take all necessary measures for fair and equitable sharing of benefits as required by the CBD and the Nagoya Protocol. This legal lacuna provides room for misappropriation and misuse of genetic resources and traditional knowledge that, in the end, defeats the purpose and objective of the CBD and the Nagoya Protocol.

80. Substantive discussions of this issue should not be delayed simply because it is being negotiated in other fora, such as WIPO. The discussions in this Council should reinforce what has already been agreed at the multilateral level, such as the CBD, and should complement negotiations/discussions in other fora. We believe that parallel discussions will enhance effort and understanding in achieving a fair and balanced trading system with regard to intellectual property.

81. Indonesia hence believes that it is timely for the Council to give simultaneous and adequate attention to address the issue towards a common goal to ensure that GRTKF are protected in an appropriate manner.

5.7 Bolivia, Plurinational State of

82. The delegation of Bolivia would like to state that our position on these agenda items remains unchanged. We nevertheless consider it fitting to highlight some key points regarding this position. Bolivia contends that natural processes and environmental functions cannot be commercialized, as this would, inter alia, raise concerns for many peoples and cultures of the world who, as in our case, attach importance to practices and principles that enable them to live well and in harmony and balance with Mother Earth. We therefore reiterate our position against the patenting of all life forms, including plants and animals and parts thereof, gene sequences, micro-organisms, as well as all processes including biological, microbiological and non-biological processes for the production of life forms and parts thereof.

83. Patenting of life forms promotes an imbalance in the current intellectual property system. The TRIPS Agreement, while establishing monopoly rights for private parties, does not explicitly recognize the collective rights of indigenous peoples and local communities over their biological resources and traditional knowledge, farmers' rights, or the rights of sovereign States. Nor does it call for conformity with the provisions of the Convention on Biological Diversity (CBD), including those relating to prior informed consent and benefit sharing.

84. In that same vein, Bolivia believes that the non-patentability of traditional knowledge and traditional cultural expressions that belong to the indigenous peoples is crucial to achieving full recognition of their rights.

85. We therefore once again wish to point out that Bolivia is the centre of origin of genetic diversity for many species that must be protected. We believe that such protection must be based on a non-market approach that emphasizes the conservation and sustainable use of biodiversity.

86. In our view, protection of biodiversity must progress in a holistic, and not isolated, manner. Bolivia therefore supports any and all initiatives and efforts aimed at finding a balance between the CBD and the TRIPS in developing an effective international framework.

87. Bolivia cautions that the absence of a balanced and effective framework that protects genetic resources, traditional knowledge and traditional cultural expressions has enabled the proliferation of illicit practices such as misappropriation and biopiracy, leaving developing countries in particular without appropriate mechanisms to provide adequate protection. It is therefore vital to continue discussions on this topic in order to achieve effective outcomes.

5.8 Zimbabwe

88. The Government of Zimbabwe as a signatory to the Convention on Biological Diversity attaches great importance to its international obligations under the CBD. We join other delegations in calling for the harmonisation of the TRIPS Agreement and the CBD, as we are of the view that TRIPS does not prevent a person from claiming patent rights on an invention based on a genetic resource or traditional knowledge.

89. Recalling paragraph 19 of the Doha Ministerial Declaration of 2001, we reiterate that section 33 of the constitution of Zimbabwe inculcates a right to culture for our people, and states, "The State must take measures to preserve, protect and promote indigenous knowledge systems, including knowledge of the medicinal and other properties of animal and plant life possessed by local communities and people."

90. The TRIPS Agreement is indifferent to acts of biopiracy and obligations under the CBD in respect of prior informed consent and benefit sharing for accessing biological resources. Furthermore, TRIPS does not require patent applicants to disclose the origin of GR and TK used in a claimed invention.

91. It is therefore our considered proposal that the TRIPS Agreement be amended to introduce a requirement of mandatory disclosure of the country or source of origin of GR or associated TK. The argument that this issue should be dealt with in another organisation, being the World Intellectual Property Organisation, is redundant as none of the WIPO treaties and discussions deal with trade related aspects of intellectual property.

5.9 Brazil

92. As we have stressed in our previous statements, Brazil favours the inclusion of a requirement in TRIPS for the disclosure of origin of genetic resources in patent applications.

93. Brazil, as well as other countries, believes that this subject is within the scope of patent rights and obligations. There are currently around thirty disclosure regimes worldwide, and other countries are studying to follow this trend. The creation of different national legislations on the subject could lead to legal uncertainty in the detriment of users, providers and knowledge holders.

94. We thus believe that a multilateral provision on disclosure is paramount, besides being the most effective means to protect genetic resources as determined by the Convention on Biological Diversity.

95. The ideal scope of disclosure in our view 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.

96. While it is true that WIPO is conducting negotiations on genetic resources, whose mandate was renewed by the WIPO Assemblies in October 2019, we still do not have consensus for calling a diplomatic conference.

97. We therefore urge delegations to engage in order to allow for advances in the negotiations. This will enable the multilateral IP system to provide a concrete answer to the rights of countries hosting a rich biodiversity.

5.10 Nigeria

98. We wish to thank the Chair and the Secretariat for organizing this meeting.

99. The need for the mutual supportiveness of the TRIPS Agreement and the Convention on Biological Diversity cannot be overemphasized. Enhancing cooperation with other relevant international organizations and international instruments remains a basic principle of the TRIPS Agreement.

100. Traditional communities are greatly impacted as a result of the illegal use of biological resources or associated traditional knowledge, and over 80% of earth's biodiversity comes from developing countries, but yet they do not own many patents. Biodiversity has evolved to be a trade issue. Therefore, in order to develop a sound and viable technological base in developing countries and LDCs, any utilization of genetic resources from these regions must involve their sustainable use in other to conserve biological diversity, as well as show evidence of a fair and equitable sharing of benefits as are the principles of the CBD.

101. My delegation has mentioned in previous TRIPS Council's meetings that Article 29 of the TRIPS Agreement is not sufficient in fulfilling adequately the requirement for disclosure prior to a patent grant. Therefore, we support proposals requiring traceability and a prior informed consent from the source in respect of any product made from the utilization of genetic components or traditional knowledge and folklore, in other words, full disclosure of the origin and source of any genetic resource or associated traditional knowledge.

102. A full disclosure requirement will not only be beneficial to Nigeria, but it will also improve the quality of our substantive patent examination, which will in turn ensure the validity of patent grants in our country.

5.11 Australia

103. Australia believes that the WIPO IGC is best placed, with appropriate technical expertise, to consider the complex issues relating to intellectual property and genetic resources and associated traditional knowledge and cultural expressions.

104. We hope Members will adopt a spirit of compromise when the issue of genetic resources is next considered.

105. 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.

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

107. 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.

108. Australia regards the current flexibilities under TRIPS Article 27.3(b) as sufficient to allow Members to take decisions on the patentability of life forms in accordance with national policies. These flexibilities should be retained.

5.12 Thailand

109. Thailand would like to reiterate our position that we do support to have a Multilateral Legal Framework which incorporates the key provisions of the CBD related to the disclosure requirement, fair and equitable benefit-sharing, and prior informed consent principles. These principles ensure and enhance transparency and legal certainty in the patent application system.

110. We believe that the promotion of a balanced patent system that benefits both patent applicants and the public interest should be recognized and implemented.

111. We also believe that the TRIPS Council is an appropriate forum to discuss this important issue and the work under this Council could pursue in parallel and in a mutually supportive manner with the work in the WIPO IGC.

112. In addition, Thailand would like to reiterate our support for the Secretariat to update the three factual notes, and also for inviting the CBD Secretariat to brief the Council on the Nagoya Protocol.

5.13 Chile

113. Our country's position regarding agenda items 3, 4 and 5 is well known, and we would simply like to reiterate the importance of the flexibilities contained in the TRIPS Agreement. In this respect, we understand that the flexibilities provided for in Article 27 of the Agreement enable each Member to take into account its own ethical and public health standards, among other criteria, when developing its intellectual property system.

114. For Chile, it is important that such flexibility be preserved insofar as it allows each Member to rethink and modify its intellectual property model in the light of its own social, cultural and economic changes.

115. In Chile's view, intellectual property systems are not an end in themselves, but are tools for promoting innovation and development while also facilitating access to information and health. This vision is reflected in Law No. 19.039 on industrial property, which excludes the patentability of plants and animals.

116. Chile, like other delegations, considers that the TRIPS Agreement and the CBD are complementary instruments. We therefore believe that there is no need to make any amendments to the Agreement to ensure consistency.

117. 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 promote dialogue.

5.14 China

118. This is a very important issue in this Council. We believe that Members should be involved in this discussion more constructively.

119. Regarding the substantive issues, China supports amending the TRIPS Agreement so as to ensure the mutual support of the TRIPS Agreement, the CBD and its Nagoya Protocol.

120. As to the issue of disclosure, China, with a majority of Members, has provided detailed suggestions on negotiation modes, improving transparency on genetic resources utilization, preventing the misappropriation of genetic resources and traditional knowledge, and preventing the grant of erroneous patents in two documents TN/C/W/52 and TN/C/W/59. We believe that setting up a reasonable system for prior informed consent and benefit sharing could ensure better protection for genetic resources.

121. As regards the procedure, China hopes that the WTO Secretariat could renew the three factual notes and supports inviting the CBD Secretariat to brief on the Nagoya Protocol. And we believe that the discussion and negotiation in WIPO could not hinder Members to find a solution in WTO.

5.15 Canada

122. With respect to the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), Canada continues to believe that TRIPS and the CBD are complementary, and that there is therefore no need to amend the TRIPS Agreement in this regard.

123. On the protection of traditional knowledge and folklore, Canada welcomes the ongoing work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). In particular, the IGC has served, and continues to serve, as an important venue that brings together the necessary technical expertise and views, to identify evidence-based, balanced, and mutually-beneficial approaches to these issues. Canada has been, and continues to be, an active and committed participant in the work of the IGC, and welcomes the concrete discussions and exchanges of national experiences in that venue, which remain key to considering the issues at hand.

124. With respect to procedural matters at TRIPS Council, as Canada has previously noted, and without prejudice to our position on substantive matters, Canada can continue to support a procedural briefing from the CBD Secretariat to the TRIPS Council, should there be sufficient interest from other Members on the matter. Similarly, without prejudice to Canada's national positions on these issues, Canada could also support the compilation of the three factual notes on the TRIPS Agreement and the CBD (documents IP/C/W/368, IP/C/W/369, and IP/C/W/370) by the WTO Secretariat. As it has been previously noted in this committee, Canada remains of the understanding that this would remain an information-collating exercise.

5.16 Japan

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

126. 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 utilization 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.

127. This delegation is firmly convinced that to include the disclosure requirement in the IP system 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. Japan believes that the disclosure requirement is not an adequate means for dealing with the utilization of genetic resources.

128. In line with the above-mentioned position, we firmly believe that the protection of GRs, TK and folklore should be designed in a manner that both supports creativity and innovation.

129. In addition, this delegation believes the WIPO IGC is the most appropriate forum for holding technical discussions on genetic resources, traditional knowledge and folklore from IP aspects, and the IGC meetings will be held in 2020. 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.

5.17 Switzerland

130. Switzerland supports the introduction of a non-burdensome requirement into the TRIPS Agreement to disclose the source of genetic resources in patent applications for inventions directly based on a genetic resource. Introducing such a requirement makes in our view sense, when we also accept the principle of patentability of biotechnological inventions.

131. In cooperation with the W/52 coalition (TN/C/W/52), a group of 109 WTO Members, Switzerland has submitted modalities proposals for three outstanding implementation issues at TNC level, next to the GI register and GI extension, these proposals including on a disclosure requirement for genetic resources and traditional knowledge in patent applications.

132. These outstanding TRIPS implementation issues should be included in any future work programme of the WTO in view of finding appropriate solutions for them.

133. The Council's discussion under agenda items 3, 4 and 5 can helpfully contribute to this objective. Sharing fact-based experience among Members enhance our understanding of what is at stake and of how the WTO should address best the interests and concerns of Members.

134. Finally, my delegation can agree with the two proposals made - to request the Secretariat to update its three factual briefs under the triplet agenda items, and to invite the Secretariat of the CBD to give a briefing on the Nagoya Protocol to the TRIPS Council.

5.18 United States of America

135. The United States position is well-known and has not changed. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues.

136. 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.

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

138. With respect to the various request 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 this Council's meetings.

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 India

139. 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 few countries that notified its acceptance of the Protocol in March 2007.

140. 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 problems 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 GC 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.

141. The United Nations Secretary-General’s 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.

142. 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.

6.2 Brazil

143. Brazil thanks the WTO Secretariat for preparing the draft report. Legislation to implement the Amendment to the TRIPS Agreement contained in Article 31*bis* has been in force in Brazil since 21 February 2018.

144. We mostly welcome capacity building activities and assistance material aiming at the promotion of access to medical technologies and innovation for the implementation and use of the System, in order to enable interested Members effectively to assess it.

145. A basic tenet of the patent system is that legislation should provide incentives that lead to new discoveries and inventions, while ensuring that those incentives are not overly restrictive and do not create barriers to innovation and dissemination of knowledge.

146. Brazil believes that all Member have the obligation to pursue a balance between the interests of the IP right holders and those of society as a whole. Preserving such balance is the best way to safeguard the legitimate interests of all stakeholders of the patent system. For instance, the regulatory review exception, also known as the Bolar exception, plays an important role in providing the realization of that balance, especially by ensuring that the market power granted by a patent does not create anti-competitive externalities beyond the term of protection of 20 years.

147. This is also true regarding compulsory licensing for patents. Brazil is of the view that this is a very important exception to restore the balance in the special cases when its use is required, such as, but not limited to, emergency health situations or the anticompetitive use of patents.

148. We find that this particular exception should be used within the rules provided in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health in the context of finding a balance between the incentives to innovation and the enhancement of access to the technology embodied in the patent.

149. Brazil thus thanks the Secretariat and supports the proposal to the General Council for a decision to extend the period for acceptances of the Protocol.

6.3 South Africa

150. We would like to thank the Secretariat for this update. The Protocol Amending the TRIPS Agreement entered into force on 23 January 2017, since at that time two thirds of WTO Members had accepted it. Given the importance of the amendments effected by the Protocol we call on Members who have not yet accepted the Protocol to do so as soon as possible.

151. The Protocol is currently open for acceptance by these Members until 31 December 2019. In order allow Members who have not yet deposited their instruments of acceptance, South Africa would be in favour of a further extension of the 2017 Extension Decision until 31 December 2021 or a date that may be stipulated by the next Ministerial Conference as suggested in the proposed draft decision contained in Annex 2 of document JOB/IP/34. South Africa would be in favour of supporting such a draft decision.

6.4 Canada

152. Canada notes the importance of access to medicines in promoting global health and prosperity. For instance, Canada has supported international financing organizations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; Gavi, the Vaccine Alliance; and the Global Financing Facility, which strengthen health systems and undertake targeted programming to increase access to medicines and vaccines.

153. Canada's Access to Medicines Regime (or CAMR), which implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, is another measure used in Canada to promote access to medicines. 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.

154. Canada also takes note of the 2017 entry into force of the Protocol amending the TRIPS Agreement, and as the only country to have exported medicine pursuant to the temporary waiver, as was noted by the delegation of India, Canada would be pleased to share its experiences and lessons learned in implementing our own system with any Members who wish to learn more.

6.5 United States of America

155. The United States welcomes the entry into force of the Protocol Amending the TRIPS Agreement.

156. We welcome the Secretariat's draft Report and its work throughout the year to facilitate and encourage all Members to notify their acceptance of the Protocol.

157. We also congratulate the Members that have accepted the Protocol since the entry into force of the amended TRIPS Agreement.

158. While the entry into force of the amended TRIPS Agreement represented an important step in promoting our shared goal of facilitating access to medicines, it is only one piece of the puzzle.

159. We encourage Members to continue to focus efforts to address other salient barriers to access while also recognizing the important role that intellectual property and international trade liberalization play in incentivizing drug development and expanding access to medicines around the world.

160. For example, the World Health Organization has identified numerous considerations, including pricing and procurement policies, taxes, mark-ups and tariffs, and other national policies that ultimately result in higher costs for consumers and for health systems.

161. While we remain disappointed that such a large number of Members have yet to notify their acceptance of the Protocol, we support the proposal to extend the period of acceptance for two-years.

6.6 Japan

162. This delegation would like to express our gratitude to the Secretariat for preparing a draft report as the basis for the review of the Special Compulsory Licensing System. We welcome this work, hoping that it will encourage all remaining Members to notify their acceptance of the Protocol.

163. 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. Therefore, the System should not be considered as the only solution, but rather as just an option we could consider.

164. Regarding the extension of the period for acceptance of the Protocol, this delegation supports the proposed two-year extension.

6.7 Zimbabwe

165. The delegation of Zimbabwe reiterates previous submissions on this subject matter. In reference to the goals of the Protocol amending the TRIPS Agreement, we would like to lend our unconditional support to the extension of the period for Members that have not yet joined the Protocol to accept it.

6.8 Barbados

166. Barbados would like to indicate that the domestic acceptance process is in an advanced stage. We will fully support the extension of the period for acceptance until 2021.

6.9 India

167. India fully supports the two-year extension of the period for acceptance.

7 NON-VIOLATION AND SITUATION COMPLAINTS

7.1 Chile

168. Our delegation's position is well-known among Members. During the current week's session of the General Council, our delegation and others proposed that we should begin discussions on the renewal of the moratorium on this topic, taking into account the timeline provided within the mandate of the Buenos Aires Ministerial Conference.

169. Formal and informal talks on this subject in the Council, have pointed, in our view, to the need to take more time to try to forge common understandings and consensus on the various aspects contained in the mandate of Article 64 of the TRIPS Agreement.

170. To that end and considering the historical positions of the countries regarding this topic, our delegation proposes that the Council for TRIPS recommend to the next General Council that it extend the moratorium until the Twelfth Ministerial Conference and continue to study the scope and modalities for this type of complaint.

171. As far as our delegation is concerned, with our long history of participation in Ministerial Conferences, this is one of the significant topics, and this is why we believe it is important to maintain a constructive dialogue between delegations and to give ourselves time to pursue our quest for common understanding.

7.2 Bangladesh

172. The position of Bangladesh on the proposed lifting of the moratorium on non-violation and situation complaints is well-known. We are in favour of establishing a permanent moratorium.

173. Bangladesh invites the views and ideas of our friends who were proponents of the application of 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.

174. In the General Council meeting on 16 October 2019, a proposal for temporary extension of the Moratorium has been tabled. However, the TRIPS Council is the right forum where the issue should be discussed with deeper engagement of all concerned. The concept of NVSCs 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, defined and thoroughly examined first.

175. Bangladesh reiterates its readiness to constructively engage with Members on this issue further.

7.3 Colombia

176. Colombia expresses its support and fully endorses the statements made by the previous speakers from Chile, New Zealand and Panama.

177. We wish to express our interest in continuing the practice of not initiating non-violation and situation complaints under the TRIPS Agreement. Colombia is convinced that TRIPS sets the foundation for the development of intellectual property systems, so we must maintain complete clarity on the scope and limitations of its applicability. Pursuing this type of complaints undermines that certainty, jeopardizing governance itself when the national authorities implement legitimate measures in pursuit of public policy objectives.

178. As we said during the General Council, we reiterate our support for the extension of the two moratoriums until MC12, and it should be there, during the Ministerial Conference in Nur Sultan, that we hold constructive discussions pertaining to the Work Plan on Electronic Commerce and the two moratoriums which were extended at the Ministerial Conference held in Buenos Aires.

179. Lastly, as is clear from the documents that we co-sponsored, it is vital to draw the entire Membership's attention to the fact that the Ministerial Conference is the highest deliberative body of this Organization and it must be of the utmost interest to preserve this body as the appropriate and legitimate forum for discussions of greatest relevance to the WTO.

7.4 Thailand

180. Thailand would like to thank Chile, Colombia, New Zealand, and Panama for introducing the document WT/GC/W/783 in the General Council Meeting this week.

181. There is a short period of time left before the current Moratorium expires in December 2019, we are therefore of the view that the best way forward for the Members at this stage is to maintain the current practice of the WTO while also taking steps to delve into deeper discussions in this area.

182. In this regard, Thailand supports the continuation of the Moratorium until the next WTO Ministerial Conference in June 2020.

183. It is also important to take into account the reality in the discussion especially the divergence perspectives among the well-known positions of the Members, and to bear in mind that the further discussion should focus on the concrete recommendation of the Council for the next General Council Meeting in December.

7.5 Mexico

184. Mexico supports the proposal for the extension of the moratorium on non-violation complaints under TRIPS until the 12th Ministerial Conference. At the same time, we will actively participate in the discussions of the scope and modalities during this period.

7.6 Nigeria

185. To go straight to the point, the scope of application of non-violation complaints under GATT Article XXIII:1 (b) and (c) is still being examined by the TRIPS Council. Therefore, no decisions have been made in that regard. My delegation is of the view that non-violation and situation complaints should not be allowed to apply under the TRIPS Agreement. Nevertheless, while we are still in the process of examining its scope of application, we welcome the proposal by Chile, Colombia, New Zealand and Panama seeking the extension of the moratorium of the TRIPS non-violation and situation complaints and we support this proposal. We believe that the moratorium should be extended until we are able to agree on the scope, and this extension should not be linked to any other issue before us. It is now time for all Members to suggest concrete direction on this issue in line with MC12. We continue to thank the Chair in facilitating these discussions.

7.7 Panama

186. As mentioned during the General Council, my delegation strongly supports the extension of the moratorium until the upcoming Twelfth Ministerial Conference. For this reason, we would like to ask for consultations and discussions to be intensified in the formats and levels deemed appropriate in order for us to adopt the Decision in question at the General Council in December.

187. We therefore ask for further in-depth discussions on scope and modalities to be held, at which time the concerns expressed by some Members may be explored and recommendations that will allow Members to adopt a decision for a permanent solution to this issue may be formulated.

7.8 Indonesia

188. Indonesia reaffirms its position that applying NVSC to intellectual property could result in an imbalance between the rights of IP-holders, IP users, as well as public interest. The absent of scope and modalities for NVSC would introduce new obligations and raise the standards for protection beyond what has been agreed upon.

189. This would affect Members' policy space, especially with regard to implementing public health measures. It would then induce an increase of disputes against existing and future IP-related public interest measures undertaken by developing countries and LDCs.

190. Moving forward from MC12, Indonesia supports a permanent moratorium on NVSCs under the TRIPS Agreement.

7.9 Ecuador

191. Ecuador is co-sponsoring document IP/C/W/385/Rev.1 in the belief that non-violation and situation complaints raise fundamental concerns by establishing minimum standards on the scope of intellectual property rights.

192. The TRIPS Agreement does not seek to protect market access, as there is no exchange of tariff concessions, but rather it is a sui generis agreement that establishes minimum standards on the acquisition, exploitation, scope and exercise of intellectual property rights.

193. In this regard, and as expressed in document IP/C/W/385/Rev.1, introducing these complaints would undermine the security and predictability provided by the multilateral trading system, which would be inconsistent with the long-term best interests of the multilateral trading system and its Members.

194. We therefore reiterate our view that complaints of the types provided for under Article XXIII:1(b) and (c) of the GATT 1994 are not applicable in the area of TRIPS.

7.10 New Zealand

195. New Zealand maintains its position that non-violation and situation complaints should not apply to the TRIPS Agreement for the same reasons expressed in previous Council meetings and at the General Council the present week. New Zealand agrees with the statements of others made that more time is needed and that the moratorium should be extended until MC12.

7.11 India

196. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged. Serious concerns remain on the debilitating impact that non-violation complaints in TRIPS can have on the regulatory policy space of Members and on TRIPS flexibilities, thereby increasing the complexity in interpreting the TRIPS provisions. It can not only have a chilling effect on Member's exercise of their IP regimes but also severely restrain ability of Members to achieve other public policy objectives.

197. 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. Introducing non-violation and situation complaints into the TRIPS Agreement is unnecessary and inconsistent with the interests of the WTO Members. As such, 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, without any need for introducing the legally uncertain notion of non-violation and situation complaints.

198. India looks forward to working with like-minded Members in making non-violation complaints inapplicable to TRIPS.

7.12 Russian Federation

199. The Russian Federation is of the opinion that the issue of "TRIPS Non-violation and situation complaints" needs a permanent solution rather than a temporary one. However, we would support an interim decision explicitly extending the moratorium till MC12 to avoid any grey area, i.e. whether the moratorium still stands after 1 January or not. Having said so, we are also of the view that a technical extension of the moratorium shall go hand in hand with intensified examination of the scope and modalities for non-violation and situation complaints under the TRIPS Agreement as per the Ministerial decision made at the eleventh session of the Ministerial Conference.

7.13 Canada

200. Canada's longstanding position on this issue is well-known and remains unchanged. Canada notes our recognition that the current moratorium exists thanks to consensus, and trusts that Members can continue to discuss these issues in a collegial manner, especially in view of the high concentration of Members with concerns in this area. Canada also wishes to express its continued interest in participating in any consultations that take place on this issue amongst other interested Members.

201. With respect to the proposal to extend the moratorium regarding TRIPS non-violation and situation complaints, as discussed during the current week's General Council meeting under document WT/GC/W/783, Canada would like to the thank the co-sponsors of this item for bringing forward the important and timely issue of the status of the moratorium regarding TRIPS non-violation and situation complaints, which was renewed most recently at the 11th Ministerial Conference in Buenos Aires in December 2017. Canada, like other Members, is aware that the expiry of this moratorium is approaching rapidly in December and preparations for the Twelfth Ministerial Conference are now upon us.

202. While Canada was not in a position to co-sponsor this communication during this current week's meeting of the General Council, our longstanding position on this issue is well-known, and we intend to confirm our official position by the next meeting of the General Council.

203. In the meantime, Canada will continue to participate in informal consultations with any interested Member on this issue, including during this current week's TRIPS Council meeting.

7.14 Brazil

204. Brazil makes reference to its previous statements on this issue. We continue to hold the view that the best way forward is to maintain the moratorium of NVSC.

205. The dispute settlement mechanism as currently applied to the TRIPS Agreement is sufficient to guarantee effective and adequate protection of intellectual property rights.

206. Moreover, according to Article 1.1 TRIPS, Members are free to determine the appropriate method of implementing the provisions of the agreement within their own legal system and practice. The flexibilities indicated in the Agreement shall also be preserved. To allow for NVSC would include an unnecessary element of uncertainty in Member's balance of rights and obligations.

207. Furthermore, the current impasse in the Appellate Body would not recommend another set of possible complaints, since we are currently close to not having a system of double judicial review in the WTO.

208. In conclusion, and considering that the General Council is expected to discuss this matter in December, we still believe that time is not ripe for the end of the moratorium on NVSC. In this sense, we thank the proponents of the General Council proposal.

7.15 Singapore

209. I would like to thank Chile, Colombia, New Zealand and Panama for their timely proposal, and to you also, Chair, for facilitating discussions on this important issue. Singapore supports the

continuation of the moratorium on NVSCs until the next Ministerial Conference in June 2020 and will continue to engage actively on this issue.

7.16 Guatemala

210. My delegation would like to reiterate what was stated during the recent General Council, with respect to supporting the proposal presented by the delegation of Chile and other proponents contained in document WT/GC/W/783, consisting in extending the renewal of the moratorium for the 12th Ministerial Conference, in order to continue constructively discussing the scope and modalities in this area.

7.17 Norway

211. Norway's position is that NVSCs should not be used for TRIPS related issues. We support a prolongation of the current moratorium on non-violation and situation complaints.

7.18 Argentina

212. Argentina's position on this issue is well-known and, to date, 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.

213. Non violation and situation complaints in the TRIPS context are unnecessary. They raise serious systemic concerns, run counter to the long-term interests of the multilateral trading system and upset the delicate balance of rights and obligations in the Agreement.

214. We believe it is necessary to continue to explore this matter, and Argentina is ready to pursue constructive discussions on this issue with a view to finding an acceptable and permanent solution.

7.19 European Union

215. The European Union supported extending the moratorium of 13 December 2017 on not using TRIPS non-violation and situation complaints.

216. However, the EU remains open to hear and discuss any possible solutions for the future.

7.20 Hong Kong, China

217. Hong Kong, China considers that the uncertainties surrounding non-violation and situation complaints have made it harder for Members to rely on the agreed text of the TRIPs Agreement to define their obligations. As a staunch supporter of the multilateral trading system, Hong Kong, China shares the concern that introducing non-violation situation complaints in the TRIPs context may undermine the security and predictability provided by the system. This in the long term would weaken the public support of the system and the WTO.

218. As WTO Members have yet to identify a solution to resolve the issue, we support extending the current moratorium until MC12, so as to provide more time for Members to work out solutions to the issue and avoid bringing unnecessary uncertainties and confusions to the system in the meantime.

7.21 Chinese Taipei

219. We understand 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 over the scope and type of the said non-violation and situation complaints applicable under the Agreement.

7.22 Bolivia, Plurinational State of

220. Bolivia's position on this agenda item has not changed and has already been stated before this Council and at the General Council. We believe that non-violation complaints do not apply in the context of the TRIPS Agreement. The scope of this concept does not need to be broadened in order to protect the balance of rights and obligations inherent to the TRIPS Agreement, especially given that it has not yet been clearly established how and when remedies may be applied, or how Members would benefit. This is also the case for situation complaints.

221. Benefits under the TRIPS Agreement could be adequately protected by applying the text of the Agreement, in accordance with the principles of international law, and without introducing this legally uncertain notion. In no way does its absence jeopardize the enforceability of the rights and obligations under the Agreement. On the contrary, its application in this context would create contradictions between the rights of intellectual property owners and the ability of governments to legitimately implement their regulatory policies.

222. Given the lack of consensus on the matter, it is our delegation's opinion that the moratorium should be extended until the following Ministerial Conference, and we reiterate our willingness to continue these discussions in a constructive manner.

7.23 Switzerland

223. Switzerland is of the view that, in accordance with Art. 64 of the TRIPS Agreement, non-violation complaints are applicable in the TRIPS context after the expiry of the moratorium. In the Uruguay round, negotiators had initially agreed on a five-year moratorium for such complaints under the TRIPS Agreement to give Members the opportunity to examine the scope and modalities of such complaints in the TRIPS context. Since 1999, Ministers have extended this moratorium a number of times to give WTO Members more time to do so. However, in all these years, no such modalities have been proposed by Members who may consider additional modalities necessary to those contained in the DSU. My delegation thus fails to see the benefit of recommending more time to discuss modalities.

7.24 China

224. China remains of the same position on this issue. We believe that non-violation and situation complaints should not be applicable under the TRIPS Agreement. But we can support the proposal by Chile, Colombia, New Zealand and Panama' to extend the moratorium until the 12th Ministerial Conference.

7.25 South Africa

225. We would like to thank you for your consultations in this matter. Members remain divided on the question of whether non-violation and situation complaints should apply to the TRIPS Agreement at all, or whether the application of these types of complaints should be subject to certain modalities.

226. South Africa is not a proponent for the application of non-violation and situation complaints to the TRIPS Agreement. It may also be useful for the proponents of the NVC remedy to clarify what situations they wish to avoid by having a non-violation remedy available under the TRIPS Agreement. We would be concerned with any NVC remedy that would have the effect of expanding existing TRIPS obligations or reduce flexibilities that Members currently have. In this regard, South Africa has been proactive in reaching out to various delegation to assess Members readiness to engage substantively on the various options available to address NVCs. There seems to still be a divergence in the approach and positions that delegations hold. My delegation would like to point out that in recent times Members have agreed to the non-application of NVCs to Article 31bis of the TRIPS Agreement.

227. Article 31bis paragraph 4 of the TRIPS Agreement states the following: "Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraph 1(b) and 1(c) of Article XXIII of GATT 1994."

228. We heard certain Members raise a link between the NVC and e-commerce moratorium. My delegation would like to put on record that we do not see any linkage between the two moratoria. Each moratorium should be judged on its own merit and as a result we would disagree that the two moratoria should be automatically linked. Furthermore, we note the proposal put forward in the General Council (13 and 14 October 2019), as referenced in document WT/GC/W/783. As pointed out by the Chair of the General Council, the TRIPS Council is competent to deal with this matter and is called to make recommendations regarding the scope and modalities to the General Council/Ministerial conference. Also, noting that, between ministerial meetings, the General Council is competent to take decisions. We hope that proponents will follow the prescribed protocol in dealing with this matter as contained in Article 64.3 of the TRIPS Agreement and subsequent ministerial practice.

7.26 United States of America

229. The United States' position on this issue remains unchanged. We reiterate our support for allowing the moratorium to expire so that Members may bring non-violation nullification or impairment (NVNI) complaints in the future, as appropriate.

230. In the previous meetings of the TRIPS Council, some Members raised concerns over the application of NVNI complaints to the TRIPS Agreement. We believe that while valid questions have arisen, they are fully and adequately answered by the text of the TRIPS Agreement itself and further clarified through GATT and WTO adjudication, as we have enumerated in our communication to the TRIPS Council, which was circulated to Members as document IP/C/W/599, as well as in our recent interventions.

231. The United States has provided detailed and extensive analysis in each of our statements under this item over the past several years. We have explained the legal basis for such claims in the GATT and TRIPS Agreement texts, the panel and Appellate Body jurisprudence involving NVNI disputes, the extensive safeguards that exist to protect Members rights and obligations under the TRIPS Agreement, and concrete descriptions regarding how such disputes would work in practice.

232. As we have detailed in past interventions, NVNI claims have a long lineage in the WTO and in international trade law generally. The applicability of such claims to the WTO Agreements is the rule; their non-application is the exception. The TRIPS Agreement moratorium is the exception.

233. 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 moratorium so that complaints of this type may be applicable to the TRIPS Agreement.

234. 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 proposals from Members wishing to further examine the scope and modalities for complaints of these types.

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

235. 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

236. No statements were made under this agenda item.

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

10.1 Canada

237. As part of its ongoing commitments under TRIPS Article 66.2 , 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.

238. Canada's 2019 report on the implementation of TRIPS Article 66.2 (document IP/C/W/656/Add.4) updates on the range of projects and initiatives undertaken by Canada in recent years. Before discussing some of the more noteworthy projects included in 2019 report, it is noted that Canada's report on TRIPS Article 66.2 focuses primarily on non-market projects, as financed by Canadian departments, agencies, and institutions, through official development assistance, 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 a range of 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).

239. In addition to updates on existing projects, the 2019 report includes information on more recent projects, such as EQWIP HUBS, a partnership with Canada World Youth and Youth Challenge International. The project, which focuses on multiple countries including Tanzania and Senegal, aims to increase the capacity of local partner organizations to deliver innovative, sustainable, gender responsive livelihood programming for young women and men through volunteer placements and the co-implementation of youth-focused innovation hubs. These hubs serve as adaptive, accessible, youth-friendly spaces that bring together the training, support services, access to capital, networks and technology young people need to access sustainable livelihoods.

240. Another new project included in the 2019 update, Capacity Building for Sustainable Irrigation and Agriculture in Ethiopia, sets out to improve the capacity of Ethiopian public and private institutions, including colleges, to design, build and manage small-scale irrigation and micro-irrigation systems. A related project, Scale-up of Conservation Agriculture in East Africa, aims to scale up the results and innovations developed by the Canadian Food grains Bank in conservation agriculture among farmers in multiple countries in East Africa, including Ethiopia and Tanzania. As well, 2019 report includes information on USC Canada Seeds of Survival 2015-2020, which aims to increase seed, food and economic security in multiple countries including Ethiopia, Burkina Faso, and Mali, such as through participatory research to develop new crop seed varieties adapted to different agro-ecological zones.

241. Canada would be pleased to provide further information on these and other technology transfer projects and programmes contained in Canada's 2019 report on the implementation of Article 66.2, 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.

242. Finally, Canada would also like to take the opportunity to again thank the Secretariat for organizing the February 2019 Workshop on TRIPS Article 66.2, and to thank those Members that shared their experiences and valuable insights in this area. We look forward to the next workshop on the implementation of TRIPS Article 66.2 on the margins of the next session of the TRIPS Council, and to further discussions with other Members on these important issues.

10.2 United States of America

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

244. Our 2019 submission, document IP/C/W/656/Add.2, is an update to our 2018 report, detailing programmes aimed to support LDCs in fostering the necessary environment to encourage the effective, voluntary transfer of technology to LDC Members. The US submission details programmes ranging from intellectual property and trade capacity building to health, labour, and environment as well as entrepreneurship. Similar to the 2018 submission, this report includes comments from host countries regarding the value of several of the programmes listed in the report.

245. The United States continues to believe that the effective functioning of TRIPS Article 66.2 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.

246. Please allow me to mention some elements contained in our 2019 report, highlighting a few programme updates.

247. The Partnerships for Enhanced Engagement in Research (PEER) programme directly supports scientists in USAID-presence countries through institutional research awards ranging up to USD 300,000. Numerous US scientific agencies such as National Aeronautics and Space Administration, National Institutes of Health, National Science Foundation, National Oceanic and Atmospheric Administration, Smithsonian Institution, and US Department of Agriculture, as well as the private sector, and universities and research institutes around the world, have partnered with scientists in least developed country Members through PEER awards.

248. Several PEER projects use cutting edge digital technologies to facilitate climate-smart agriculture. For example, in Uganda, Makerere University is partnering with California State University - Monterey Bay, and the NASA Ames Research Centre for Earth Science and Technology to develop and deliver crop yield forecasts to farmers in Sub-Saharan Africa. These forecasts will integrate satellite data and advanced crop modelling. In 2019, the final platform, CropWIS, was designed and the smartphone mobile application can now be downloaded for Android phones.

249. Through a PEER grant, a researcher in Bamako, Mali is studying the best way to deliver Seasonal Malaria Chemoprevention (SMC), a World Health Organization-recommended method for malaria prevention in children under five. While the team is working closely with the Government of Mali during the scale-up of SMC during FY 2019-2020, the team continues to study the impact of SMC on antibody generation to see if SMC prevents the normal progression of innate immune protection generated by constant exposure to malaria.

250. Maputo Central Hospital in Mozambique, in collaboration with University of Texas MD Anderson Cancer Centre, Universidade Eduardo Mondlane, Rice University, and Population Services International, are promoting and testing affordable technologies for cervical cancer screening for low income countries to improve early detection of cervical cancer. The project aims to screen 2,000 women for cervical cancer, using a novel point-of-care HPV test developed by Rice University, through existing cervical cancer prevention and voluntary family planning programs.

251. We look forward to further discussing our report with LDC Members at the February workshop.

10.3 European Union

252. This year's technology transfer report shows that the European Union and its member States take their commitments and obligations under TRIPS Article 66.2 seriously and make efforts to put in place projects that incentivizes technology transfer to LDCs. The EU and its member States gave proof to promptly react to natural, social, health, climate and economic changes by putting in place projects specifically tailored to the current needs of least developed countries (LDCs). The report is an advanced working document, it has not been finalised yet.

253. 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, including know-how.

254. However, technology transfer is often one component of a more complex project, rather than a stand-alone activity. The acquisition by LDCs of a sound and viable technological base does not indeed 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.

255. 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 member States are accordingly aimed at providing such training and education.

256. Most projects that deal with sectors such as energy, water, agriculture, governance and infrastructure result in transfer of know-how and technology. Moreover, their prolonged duration reflects the goal of helping local forces to develop independent systems in the concerned sectors.

257. Let me give you some examples from the technology transfer programme of the EU:

258. First, the AfriAlliance project (Africa-EU Innovation Alliance for Water and Climate) continued also this year and aims to identify appropriate social innovation and technological solutions for key water and climate change challenges, leading to identification and boosting sustainable market and investment opportunities in Burkina Faso. The project supports effective means of knowledge sharing and technology transfer between Africa and the EU, all with the aim of increasing Africa's preparedness to address the vulnerability of water and climate change-related challenges as well as to improvement water and climate monitoring and forecasting processes and tools in Africa.

259. Second, the DAFNE project (Use of a Decision-Analytic Framework to explore the water-energy-food Nexus in complex and trans-boundary water resources systems of fast growing developing countries) applies an innovative integrated water management approach, tailored to local conditions, to water management in specific basins, operational water management across different countries, identification of vulnerabilities, improved local capacity and increased social and economic well-being within the study areas. The project activities range from monitoring, development of indicators and scenarios, modelling, development of decision support systems and interaction with stakeholders and policymakers to negotiation exercises and simulations. The beneficiaries are Mozambique and Zambia.

Accelerating Progress towards Maternal, Neonatal and Child Morbidity and Mortality Reduction in Zambia

260. The aim of this project is to improve maternal, neonatal and child health and the nutritional status of women and children; and in particular to increase utilisation of quality health and nutrition services by vulnerable women, adolescents and children in selected urban and rural districts (comprising 30% of the population in Zambia) within the provinces of Lusaka and Copperbelt.

Health Systems Strengthening – Support to the Ministry of Health and the Zambia Medicines Regulatory Authority

261. The aim of the project is to improve the health status of the people in Zambia in order to contribute to socio-economic development. The project also aims at improving the capacity of the Ministry of Health (MoH) and related institutions to deliver quality assured essential medicines, including their rational and correct use as well as developing and implementing evidence-based policies and strategies.

Projects by member States

Support of competitiveness and marketing of the constructed (artificial) wetlands technology in Cambodia – Czech Republic

262. The project aims to create the conditions for investment projects in the area of constructed wetlands in Cambodia. These wetlands represent an economically, technologically as well as aesthetically attractive alternative to standard mechanical and biological wastewater treatment plants. Certain innovative improvements of the well-proven constructed wetland technology have been developed by the companies implementing the project making the wastewater treatment more effective and manageable. The project seeks to improve sewage disposal in the rural areas of Cambodia and improve the quality of both surface- and groundwater. The technology is most suitable for the recreational facilities, smaller municipalities and industries and has a wide potential in the country and beyond. The pilot project in Siem Reap province has been completed in mid-2019 and handed over to the beneficiary.

Transfer of Environmental Multi-Stage Flash desalination technology to Mozambique – Czech Republic

263. The aim of this project is to transfer an unique Environmental Multi-Stage Flash (EMSF) technology to Mozambique in an area with extreme scarcity of freshwater supply for drinking as well as irrigation purposes. The technology has a potential for low-cost, energy-efficient and climate-friendly desalination in any region suffering from freshwater scarcity, but abundance of (solar) heat or other forms of energy. The initial phase of the project (feasibility study) intends to verify the suitability of EMSF technology in local conditions and prepare the ground for installation of 2 EMSF units during the implementation stage.

Sustainable Development of Mining in Rwanda (SDMR) – United Kingdom

264. Policy objective is to contribute to the economically and environmentally sustainable growth of Rwanda's mining sector through supporting an enabling environment that will increase private sector investment in mining in Rwanda, and by testing the effectiveness of targeted interventions for a new mining services aggregation model as a way of achieving a viable and sustainable mining sector. Budget or funds allocated is £750,000 provided by the United Kingdom. The intervention aims to build a digital collection of maps and reports on Rwanda's geology and mineral resources and up-to-date exploration information such as, for example, geochemical and geophysical data and mine production data. The expected impact of the project is to increase access to geological and cadastre information to support the private sector in securing finance, increase investment in mining and improve the transparency of mineral rights management.

10.4 Japan

265. Even though it is not necessary to mention again, this delegation recognizes the importance of TRIPS Article 66.2 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.

266. This delegation would like to briefly describe 2019 report on our implementation of TRIPS Article 66.2 (document IP/C/W/656/Add.1). 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.

267. 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.

268. 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.

269. 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.

270. 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.

10.5 Australia

271. Australia was pleased to submit its Article 66.2 report to the Secretariat on 19 September.

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

273. We would be happy to discuss our report further with Members at the next available opportunity.

10.6 Switzerland

274. Switzerland is also committed and dedicated to its obligations under Article 66.2 and is happy to respond to any questions Members may have on it. For the sake of time, we will not go in details to present it and we will happy to do so at the forthcoming workshop in February 2020.

10.7 Norway

275. Norway's report is contained in document IP/C/W/656/Add.6. The report provides information on incentives carried out by the same two agencies we have reported on in previous years, with funding for private sector development and technology transfer.

276. Norad, the Norwegian directorate for development cooperation, provides incentives for technology transfer to least developed countries (LDCs) through its facilities for pre-investment support, strategic partnerships, the Oil for Development programme and the Fish for Development programme. Many other Norad programmes also include elements of technology transfer.

277. Norfund, the Norwegian investment fund for developing countries, aims to build sustainable commercial businesses in developing countries by providing risk capital and expertise. Business sectors of priority are (i) clean energy; (ii) food and agribusiness; and (iii) the financial sector. By the end of 2018, 41% of Norfund's total investment portfolio was in LDCs, well above the target of 33%.

278. We look forward to presenting more details of these programmes at the seminar back-to-back with the next TRIPS Council meeting in February.

10.8 Bangladesh

279. The delegation of Bangladesh welcomes the annual reports on the implementation of the provisions of TRIPS Article 66.2 submitted by the developed country Members. However, these regular review reports do not clearly give information on incentives provided to enterprises and institutions in developed country Members. Instead, these notifications contain lists of mostly technical assistance programmes and projects aimed at enhancing capacities in the LDCs. No doubt, these programmes are very helpful for the LDCs and we are grateful to the developed country Members. However, these reports generally fulfil the requirements narrated under TRIPS Article 67 on technical cooperation and, consequently, do not satisfy the obligation of TRIPS Article 66.2.

280. The reports presented in the TRIPS Council are undoubtedly a mixture of the technical assistance programmes and a few technology transfer initiatives. Some of them have listed initiatives like building sea-wall for protection from land erosion, construction of weather forecasting system, research-grant for governance problem in the health sector, humanitarian assistance to refugees, communication training to forest rangers, skill development for young entrepreneurs and so on as technology transfer. Great amalgam indeed but not useful for the purpose!

281. Bangladesh acknowledges that, to create a sound technological base in the LDCs, we need support from the development partners. TRIPS Article 66.2 in the legal text point-blank directs us that, "developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base". The use of the modal verb "shall" denotes an obligatory requirement. TRIPS Article 66.2 states that the developed country Members are required to provide incentives to enterprises and institutions in their territories. The responsibility to provide incentives clearly falls on the developed country Members and not on the private sector entities and enterprises. On the scope of implementation of this Article, this is evident that primarily the LDCs are not in the scene in the first phase. LDCs will come in the

canvas in the next step when the enterprises and institutions in developed country Members will take further steps towards their contribution in transferring technology to the LDCs.

282. We request the Members in the Council to consider designating focal points from both the developed country and least-developed country Members to monitor the implementation status of TRIPS Article 66.2. Previously the proposal was tabled on behalf of the LDCs. And the Members candidly discussed the issue at a number of previous meetings of this Council. This has also been recommended in the WTO Workshop on Implementation of TRIPS Article 66.2 in February 2019. Now, we need to carry forward the monitoring issue to acknowledge the genuine contributions that the developed country Members have provided to the LDCs.

283. Bangladesh stands ready to engage in constructive discussion on the focal point and monitoring issue of TRIPS Article 66.2.

11 TECHNICAL COOPERATION AND CAPACITY-BUILDING

11.1 Canada

284. Pursuant to Article 67 of the TRIPS Agreement, Canada is pleased to submit its annual report on the implementation of Article 67, which provides an update on Canada's activities concerning IP-related technical and financial cooperation for developing and LDC Members, covering the 2018-2019 period (document IP/C/W/655/Add.5).

285. Canada undertakes a number of IP-related technical cooperation activities at the multilateral, plurilateral and bilateral levels. For instance, Canada closely collaborates with WIPO, as well as with the Asia-Pacific Economic Cooperation Intellectual Property Rights Experts' Group (APEC-IPEG), which Canada currently chairs, and where Canada participates in regular discussions aimed at sharing information and best practices on IP rights. Canada also provides technical cooperation activities through 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.

286. Notable projects in 2019 report on the implementation of TRIPS Article 67 include CIPO's participation in an October 2018 Patent Cooperation Treaty (PCT) regional seminar for Latin American countries, as well as CIPO's September 2018 to August 2019 participation in the WIPO Programme of International Cooperation in the Search and Examination if Inventions (or ICSEI). As well, in June and July 2019, CIPO hosted and delivered an annual CIPO-WIPO Executive Workshop on Management Techniques in the Delivery of IP Services for senior officials from developing countries. CIPO also continues to provide webinars on IP and patents through Trade Facilitation Office (or TFO) Canada, for embassies, consulates and businesses from developing and emerging countries.

287. Canada would be pleased to discuss these and other initiatives contained 2019 report on the implementation of TRIPS Article 67. We would like to thank those Members that have shared their views and experiences on this important topic so far, and look forward to furthering discussion on the topic of IP-related technical and financial cooperation for developing and LDC Members during the session.

11.2 Japan

288. This delegation would like to briefly describe 2019 report on Japan's technical cooperation, (document IP/C/W/655/Add.1). 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.

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

290. When it comes to industrial property, the Japan Patent Office organized 23 training courses for both government officials and the private sector in FY2018. More than 400 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.

291. Turning now to copyrights, in FY2018, the Japan Copyright Office, with the support of the WIPO, held seminars where around 100 people attended.

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

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

11.3 European Union

294. Details of European Union and EU member State technical assistance activities in LDCs and developing countries can be seen in the last updated submission made under TRIPS Article 67 and circulated on 14 October 2019 (it is an advanced working document). The following Member States have provided information on their technical cooperation and capacity building programmes under Article 67 of the TRIPS Agreement: Czech Republic, Finland, United Kingdom, Spain and Portugal.

295. The report confirms the EU's commitment to technical co-operation and capacity building and the EU fulfilling its TRIPS obligations.

296. The report confirms the EU's commitment to technical co-operation and capacity building and the EU fulfilling its TRIPS obligations.

11.4 United States of America

297. The United States is pleased to highlight its report under Article 67, contained in document IP/C/W/655/Add.2, on the technical assistance programmes provided by the US Government concerning the protection, utilization and enforcement of intellectual property rights, including patents, trademarks, and enforcement for developing and least developed country Members.

298. In 2018, our report accounts for more than 113 training, technical assistance, and capacity building programmes for 140 different countries, including developing countries and LDCs.

299. Of these 140 countries, 29 programmes were provided for 34 least developed country Members, including Afghanistan, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Chad, Democratic Republic of the Congo, Ethiopia, The Gambia, Guinea, Lao PDR, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Sao Tome and the Principe, Senegal, Sierra Leone, Sudan, Tanzania, Timor-Leste, Togo, Uganda, Vanuatu, and Zambia. (For more information about the Global Intellectual Property Academy, or GIPA, see www.uspto.gov/gipa).

300. Technical cooperation to improve IP legal, administrative and enforcement infrastructure is crucial to countries' economic development and directly contributes to foreign investment and voluntary, private-sector-led technology transfer in developing countries. It also allows developing country innovators to capitalize on their creativity.

301. US 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.

302. 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

303. Norway's report is contained in document IP/C/W/655/Add.3. The report provides information on relevant technical cooperation activities by two institutions: The Norwegian Industrial Property Office (NIPO) (Patentstyret) – and The Norwegian Copyright Development Association (Norcode). The report covers activities in both 2017 and 2018. We did not submit any report in 2018.

304. NIPO conducted a training course in the trademark area in September 2018 – in cooperation with WIPO. The target group was officers from developing countries who deal with IP at a practical level. The focus of the course was on practical work and administrative management of industrial property applications.

305. Norcode provides technical cooperation in the copyright field, in order to support the cultural sector in developing countries. From November 2017 to November 2018, Norcode carried out their training programme on exercise and management of copyright and related rights three times in different regions. The target group was leading persons in so-called collective management organisations in the cultural and creative industries, and/or officers in IP offices that work with such organisations. The programme follows a phased structure with preparations, onsite sessions, individual study projects, and evaluation. For the purpose of these programmes, Norcode also cooperates with several partner organisations, among them WIPO.

306. More details can be found in our report, which also contains contact info to NIPO and Norcode in case Members would like more information.

11.6 Australia

307. Australia takes an active role in promoting technical cooperation and capacity building in the intellectual property field as we have highlighted in our 2019 Article 67 Report, which we submitted to the Secretariat on 19 September.

308. 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 enhancement of their IP capabilities.

309. We are pleased to reiterate our commitment to technical cooperation and intellectual property capacity building activities.

310. We are also pleased to report that Australia will fund a third iteration of the FiT program, beginning in September this year, after Phase Two concluded in June.

11.7 Benin, on behalf of West African Economic and Monetary Union

311. On behalf of the group of West African Economy and Monetary Union (WAEMU) countries in Geneva, for which Benin serves as coordinator, I would like to express our sincere thanks to the WTO Secretariat for its technical and logistical support that enabled us to organize the Regional Workshop on Public Health, Intellectual Property and Public Procurement for capital based experts of WAEMU countries, which was held from 2 to 4 July 2019 in Dakar, Senegal.

312. Thank you, too, to WTO Members for their valuable contributions to the implementation of technical assistance and capacity building programmes.

313. I would also like to extend special thanks to the WTO's Institute for Training and Technical Cooperation and the other international institutions that played a role in this activity, namely the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) and the World Customs Organization (WCO), for their highly appreciated technical and logistical contributions.

314. The activities that took place over the course of these three days of work enabled us to bring our capital based experts up to date and to equip them to respond to existential concerns, such as

the protection of public health, access to existing medicines, and the ability of our local enterprises not only to produce good quality medicines at lower costs but to sell their products on other markets.

315. The discussions during the regional workshop and the results obtained showed the considerable interest of WAEMU countries in issues concerning intellectual property, government procurement and public health, as well as how to use the flexibility provided to our countries by various international agreements on these issues.

316. The knowledge acquired during this workshop will most definitely enable our capital-based experts, in synergy with the actions of the WAEMU Commission, to undertake reforms on government procurement and access to high quality medicines, the implementation of which will require more action with the close involvement of stakeholders.

317. To this end, capacity building and technical assistance initiatives in our countries should be multiplied in order to ensure our greater involvement in the multilateral trading system.

318. This is why we urge WTO Members and the Secretariat to continue technical assistance initiatives in our countries, particularly on issues relating to the TRIPS Agreement.

11.8 Bangladesh

319. The delegation of Bangladesh welcomes the report of the Secretariat and the reports under TRIPS Article 67 from the developed country Members and other international organizations on the technical cooperation and capacity building support to the developing countries and particularly in the LDCs. These reports provide us information on a wide range of programmes and activities customized for the beneficiary Members. These programmes are critically important for the LDCs.

320. Bangladesh sincerely thanks the developed country Members and the international organizations for their help and would like to encourage them to continue their valuable support for the developing countries and particularly the LDCs and the graduating LDCs.

11.9 WTO Secretariat

321. Document IP/C/W/658 contains a full report on technical cooperation activities in the area of TRIPS that we undertook between 1 October 2018 and 30 September 2019. The report provides an overall thematic introduction and list each activity in the Annex. In this brief report we also provide an overview of the activities.

322. The technical cooperation activities, undertaken by the 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 directly to the needs and priorities articulated by the Members concerned.

323. Activities are therefore driven by demand from developing country and least developed countries partners, as well as from governments in the process of acceding to the WTO. The activities touch on a range of areas such as innovation and industrial policy, health, regulatory aspects, competition policy and environmental protection, and how the trade and intellectual property regime can contribute to achieving concrete results 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.

324. A central focus remains on assisting Members and Observers to understand their rights and obligations under the TRIPS Agreement. They continue to receive tailored assistance, which includes their participation in the transparency work of this Council. It will be stepped up in line with the opportunities provided by the e-TRIPS Submission System, an online tool for WTO Members to submit notifications, review materials and reports related to the TRIPS Agreement, and the e-TRIPS Gateway, a database of the full range of TRIPS-related information managed by the Secretariat.

325. 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 in line with the addresses given in this Council.

326. In 2018, the Secretariat organized the first WTO activity dedicated to IP and knowledge flows in a digital era. The overall objectives were to provide participants with an understanding of how existing WTO rules, particularly the TRIPS Agreement, apply to the knowledge economy and to facilitate an understanding of how technological advancements have enhanced the means for cross-border knowledge flows.

327. The WTO also organized in 2018 the first joint regional workshop. An activity for Members and Observers from the Arab region. This regional workshop focused on the interlinkages between health, IP and trade.

328. Further, in early 2019, the Secretariat organized the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement in which capital-based officials from LDCs and from developed country reporting Members, as well as Geneva-based delegates, participated. LDC participants discussed priority areas for technological development in LDCs and projects relevant to those areas, and reporting country developed Members presented highlights from their 2018 reports on the implementation of Article 66.2 of the TRIPS Agreement.

329. We are pleased to announce that the 8th joint Technical Symposium, organized by the WTO, the WHO and the WIPO will take place on 31 October 2019. The Symposium this year will address the importance of innovation in, and access to, cutting-edge health technologies to ensure progress towards universal health coverage and the achievement of the health-related UN Sustainable Development Goals.

11.10 World Health Organization

330. We welcome the opportunity to present the technical cooperation activities of the World Health Organization (WHO) in the area of public health, innovation and intellectual property. We will just highlight a few of the activities that are contained in our annual report.

331. The overall objective of WHO's technical cooperation is to strengthen the capacity of developing countries in the areas of health innovation, access to medicines and management of intellectual property. 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 (GSPA-PHI) as well as other relevant resolutions of the World Health Assembly, including the recently approved resolution on "Improving the transparency of markets for medicines, vaccines, and other health products," WHA72.8.

332. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) was endorsed by consensus by all WHO Members. The strategy is designed to promote new thinking in innovation and access to medicines, which would encourage needs-driven research rather than purely market-driven research to target diseases which disproportionately affect people in developing countries. The eight elements of the global strategy are designed to promote innovation, build capacity, improve access and mobilize resources and includes "application and management of intellectual property to contribute to innovation and promote public health."

333. As requested by the World Health Assembly, the WHO Secretariat will present, in 2020, a report on progress as well as an implementation plan for the coming years relating to the prioritized recommendations of an expert review panel of the GSPA-PHI. WHO's work on access to medicines, vaccines and other health products, including activities in relation to appropriate application and management of intellectual property for the period 2019−2023 is contained in The Road Map on Access to Medicines, Vaccines and Other Health Products.

334. The WHO Model List of Essential Medicines (WHO EML) and the List of Essential Diagnostics (WHO EDL) are core guidance documents that help countries prioritize critical health products that

should be widely available and affordable throughout health systems. The EML has recently been reviewed and, based on current data from MedsPaL database, 11% of medicines in the revised EML are under patent protection, either primary and/or secondary patents.

335. The 2018 WHO "Technical Report on Pricing of Cancer Medicines and its Impacts" reviews pricing approaches applied throughout the "value chain" (i.e., activities required to bring medicines to patients, from R&D to service delivery). The report presents evidence relating to the impacts of pricing approaches on the price, availability and affordability of cancer medicines. WHO will continue its efforts to biennially convene the Fair Pricing Forum with Members and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products.

336. Finally, WHO will celebrate ten years of the collaboration with WTO and WIPO and will continue providing joint technical and policy support to countries 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 to ensure progress towards Universal Health Coverage and achievement of the health-related SDGs. The next Symposium on Cutting-Edge Health Technologies will be an opportunity to discuss major scientific progress as well as the persistent inequities within and between countries and challenges to conduct needs-driven research, as well as access to and affordability of new treatments for all.

337. You will find more information on our activities, including training workshops and technical assistance provided to countries in our report document IP/C/W/654/Add.1.

11.11 Cooperation Council for the Arab States of the Gulf

338. It is my pleasure to begin this statement by extending our gratitude to the WTO Members for the trust they have placed in the GCC by granting to it permanent observer status to the TRIPS Council. This will encourage the GCC and make it enthusiastic to redouble its efforts to make a more positive contribution to the work of the TRIPS Council.

339. The overall objective of the Gulf Cooperation Council (GCC) technical cooperation programmes is to strengthen the capacity of officials from the GCC Members to respond to needs in many areas, including intellectual property.

340. GCC's technical cooperation is based on its mandate derived from Article 20 of the GCC Economic Agreement which states that "Members shall develop programmes encouraging talented individuals and supporting innovation and invention; cooperate in the field of intellectual property and develop regulations and procedures ensuring protection of intellectual property rights; and coordinate their relevant policies towards other countries, regional blocs and international and regional organizations".

341. Technical assistance activities undertaken by the GCC Secretariat-General during recent months have been focused on various IP concrete aspects such as enforcement of IP laws, patent examination, patent applications drafting, arbitration in the field of IP, trade in counterfeit goods, cooperation in IT system, IP crime, etc. These activities were conducted in the form of workshops, on-the-job trainings, secondments or through supporting the participation in conferences or in international IP exhibitions, and a number of them were organized in cooperation of some IP national offices.

342. In the field of IT systems, on-the-job trainings were conducted in the Kingdom of Bahrain, Oman and the State of Kuwait in November 2018, December 2018, March 2019, and June 2019 respectively, with the aim of completing the development of electronic systems and infrastructure, raising awareness on GCC Patent Office E-Services and studying the system integration and payment gateway.

343. The GCC Patent Office continues to contribute in building capacity of GCC national Offices in examining and filling patent applications. On-the-job trainings devoted to this IP area continue to be organized for examiners from national patent offices. Two secondments, one year each, were organized during 2018 – 2019 in Oman IP Office aiming at examining number of patent applications,

including applications filed under PCT and sharing knowledge with the examiners of the Oman IP Office.

344. In the same vein, the GCC IP Training Centre, in cooperation with the Japan Foreign Trade Authority, has conducted for the benefit of Patent examiners and other specialists a training programme on Registration and Examination of Industrial Designs and Patents, in September 2019 in Kingdom of Bahrain.

345. Arbitration in the field of IP issues was also one of the areas of focus of the GCC technical cooperation activities. A conference took place, in November 2018 in the State of Kuwait, in cooperation with WIPO, Kuwait Arbitration Centre and GCC IP Training Centre (IPTC). The objective was to share opinions and making recommendations for appropriate solutions through arbitration aimed at settling disputes in all IP fields. Another activity was conducted for the benefit of GCC arbitrators and IP experts on "Industrial Property of Judicial Authority", held in France during September 2019, in cooperation with the French National Institute of Industrial Property.

346. As far as trade counterfeit goods, a workshop was held in Viet Nam on April 2019 for the benefit of Specialists from the GCC Members and in Cooperation with the United States Patent and Trademark Office (USPTO) to discuss several aspects of IP rights protection such as enforcement mechanisms and other tools to combat trade in counterfeit goods.

347. The GCC technical cooperation and capacity building programmes has included also other IP issues such as enforcement of IP laws and IP crimes. During September 2019, GCC IP officials participated in an important event organized in Indonesia in cooperation with the USPTO on the issue of IP rights enforcement at border. Also, an annual conference took place in the State of Kuwait on April 2019 in cooperation with IP Rights Centre and with the participation of Lawyers and patent attorneys. The conference was an opportunity to address various IP subjects in light of GCC IP Common laws, in addition to criminal protection of trademarks between national laws and international conventions.

348. Having in mind the WTO work programme on e-commerce and its relations with the TRIPS Agreement and the IP rights, the GCC has organized a workshop in Oman during September 2019 with the support of the WTO and the participation of GCC government officials, representatives from Telecom regulatory authorities as well as from Chambers of commerce and industry. The Workshop has given the opportunity for the participants to discuss many complex issues of e-commerce when it comes to intellectual property rights as well as the relation between e-commerce and the TRIPS Agreement. In this occasion, I would like to highlight the brilliant contribution of the WTO experts in this GCC workshop.

11.12 World Intellectual Property Organization

349. The World Intellectual Property Organization is a major provider of technical cooperation activities related to the implementation of the TRIPS Agreement. For the reporting period of September 2018 to August 2019, WIPO carried out approximately 600 technical cooperation activities. The cooperation covered a wide range of IP fields, including patents, trademarks, copyright, industrial designs, and IP enforcement.

350. Our needs-driven and tailor-made technical assistance activities focus on three main areas: policy and legislative advice, national IP strategies, and IP office business solutions.

351. Upon request from Members, WIPO provides legal advice relating to the drafting of new IP laws or regulations, the implementation of a new law, regulation or treaty, and national compliance with international treaty obligations, including advising countries on flexibilities.

352. WIPO also assists developing and least developed countries (LDCs) to produce national IP strategies to facilitate the effective creation, protection, management, and use of IP.

353. In the area of IP office business solutions, WIPO provides business systems for IP offices in developing countries and least developed countries (LDCs) to enable them to participate effectively in the global IP system.

354. Overall, WIPO technical assistance activities contribute to supporting the efforts of Members in fulfilling their TRIPS obligations.

355. Finally, WIPO reiterates its commitment to continue providing assistance to Members to facilitate the implementation of the TRIPS Agreement.

11.13 African Regional Intellectual Property Organization

356. Pursuant to its mandate, ARIPO organizes activities and programmes either solely or in collaboration with its cooperating partners. These programmes and activities are mainly aimed at assisting ARIPO's Members in intellectual property matters in order to capacitate them to better use the IP system for the benefit of their populations.

357. ARIPO circulated earlier a detailed report as per the Secretariat's request. I will hence not delve into details of the report, but I wish to single out some highlights in the awareness creation and capacity building.

358. For the awareness creation component on Intellectual Property, 2019 was mainly marked by activities organized in the framework of a Tripartite Agreement that was signed in 2018 between WIPO, ARIPO and OAPI. These activities include the IP Week programme in Ghana, Kenya and Rwanda; a high-level round table on geographical indications; the first Regional meeting for African Heads of Copyright Offices from 45 countries across Africa, and a conference that will be held in November in Harare, Zimbabwe, on IP, Innovation and Value Addition for Business Competitiveness in Africa.

359. On capacity building, one of the flagship programmes of ARIPO is the master's degree programme on intellectual property that was established 12 years ago. Through this programme 324 participants from 26 African countries were graduated. After launching a similar programme in Ghana in 2018, the Organization launched in 2019 a new programme in Tanzania in collaboration with the University of Dar es Salam.

360. Other activities that were undertaken in collaboration with our cooperating partners include: a workshop on patent drafting; a regional meeting on the development of Technology and Innovation Support Centres (TISCs) network; training on intellectual property enforcement for judicial instructors; publication of a Model Law on Copyright and Related Rights; and a Regional Seminar for ARIPO Members on the TRIPS flexibilities and access to medicines that will take place from 28 and 29 October 2019 in Harare, Zimbabwe.

361. Finally, this delegation wants to thank once again the Secretariat for having associated ARIPO and its Members in the Workshop on the Implementation of TRIPS Article 66.2 : Incentives for Technology Transfer, that was held earlier 2019 and express the wish that the Secretariat will continue organizing similar events as they are a good platform for expressing priorities in technology transfer especially for LDCs.

11.14 United Nations Conference on Trade and Development

362. The UNCTAD Secretariat, through its Intellectual Property (IP) Unit, located within the Division on Investment and Enterprise, implements a work programme on the development dimensions of IP rights. The work programme is designed to respond to the mandate received from Members at the Ministerial Conference in Nairobi of July 2016, as well as to intergovernmental requests under the WIPO Development Agenda and the World Health Assembly's Resolution 61.21 on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. It is partially funded by donor governments and institutions. Currently, the work programme targets:

- IP rights, policy coherence and local pharmaceutical production and supply. UNCTAD was requested by its Commission on Investment, Technology and Related Financial Issues of 2005 to assess ways in which developing countries can develop their domestic productive capability in the supply of essential drugs in cooperation with pharmaceutical companies.[1]

[1] See at http://www.unctad.org/en/docs/c2l22_en.pdf (paragraph 9 (c) of the Agreed Recommendations).

In the pursuit of this mandate, UNCTAD implements a work programme on local pharmaceutical production, with a view to assisting developing countries and least developed countries (LDCs) in particular, to utilise IP rights as tools that facilitate increased access to affordable medicines, and, where feasible, to promote domestic and foreign investment to create local or regional pharmaceutical production and supply capacities. Currently, the work programme focuses on the role of local production and supply management to address vaccines and antimicrobial resistance (AMR).

- IP rights, technology partnerships and regional economic integration. UNCTAD implements a programme on IP and technology partnerships, with the financial support from BMZ. The programme focuses on IP rights and regional economic integration. It also includes capacity building on technology transactions including voluntary IP licensing and research and development (R&D) cooperation for industrial development;
- IP rights for participation in the digital economy and e-commerce. In the context of a broader work programme on e-commerce, UNCTAD addresses the interface between IP rights and digital economy.

363. In implementing its work programme, UNCTAD conducts research and policy analysis, facilitates consensus-building and responds to requests for technical assistance for successfully integrating developing countries into the world economy. Our submission to the Council for TRIPS provides an overview of UNCTAD's IP and development-related activities from 1 November 2018 to 20 September 2019. For more information on UNCTAD's activities related to IP, please visit the website as indicated in our submission. In general terms, UNCTAD works in the following areas.

Research and policy analysis

364. UNCTAD undertakes research and analysis and provides advisory services for developing countries on trade and development aspects of IP rights. During the reporting period, UNCTAD:

- Worked together with United Nations Economic Commission for Africa (UNECA) and African Union Commission (AUC) for the preparation of the report on "Assessing Regional Integration in Africa (ARIA IX): Next Steps for the African Continental Free Trade Area (AfCFTA)". The report addresses investment, intellectual property, competition and e-commerce issues, among others. The report underscores the opportunity presented by the AfCFTA to a balanced IP rights system that responds to the aspirations contained in the continental programmes, including Agenda 2063 of the African Union. It recommends a step by step approach on cooperation in the field of IP rights, beginning with the issues critical for regional trade and value chain integration;
- UNCTAD also published an analysis of intellectual property rights policies in the digital economy, as part of UNCTAD's Digital Economy report, 2019.

Consensus-building

365. Consensus-building among stakeholders on IP, trade and development is an important element of the programme's work. UNCTAD's substantive contributions on the analysis of issues related to development and IP have enabled it to become an important forum, through its intergovernmental machinery, where governments, academia, civil society and the private sector can meet to exchange ideas. During the 2019 World Health Assembly, UNCTAD signed an "Interagency Statement on Promoting Local Production of Medicines and Other Health Technologies" together with the World Health Organization (WHO), the United Nations Industrial Development Organization (UNIDO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF), and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

Technical cooperation

366. On a request basis, UNCTAD conducts technical cooperation activities with developing countries in the integrated areas of investment, trade and IP rights. UNCTAD delivers its technical cooperation through:

- Capacity building programmes for beneficiary countries and regions under donor funded projects on IP rights and policy coherence for local pharmaceutical production and access to medicines, technology partnerships and regional economic integration, as well as IP rights for participation in the digital economy and e-commerce**;**

- Advisory reports on the development dimensions of intellectual property (DDIP). The objective of a published DDIP report is to provide advice on developing countries' and LDCs' policy, legal and institutional framework for IP rights, particularly as it relates to important development objectives such as innovation, technology, investment, competition, education and health. Developing countries specify the key development objectives they wish to examine. A DDIP report will take into consideration the socio-economic situation of the requesting country, the bilateral, regional and international commitments the target countries have entered into and the flexibilities available to them. Based on this analysis, the reports incorporate medium to long-term recommendations on how governments and other stakeholders could make these frameworks more coherent and transparent, with a view to making IP rights contribute to a country's sustainable economic and human development goals and respond to emerging global opportunities; and
- Finally, we also provide technical cooperation through ad hoc studies on IP and development issues as requested by developing countries.

Cooperation with other providers of IP-related technical assistance.

367. UNCTAD partners with major technical assistance providers on IP rights and development. During the reporting period, UNCTAD *inter alia* partnered with the United Nations Development Programme (UNDP), WHO, WIPO, and the WTO. Staff of UNCTAD's IP Unit frequently participate in capacity-building workshops on IP and development issues organized by other providers of IP-related technical assistance. For instance, UNCTAD was invited by WIPO and WTO to contribute to the 2019 WIPO-WTO Advanced Course on IP for government officials in March 2019.

11.15 World Customs Organization

368. The IPR, health and safety programme of the WCO maintains its decision to protect consumer health and safety, and continues to combat counterfeiting and piracy through a variety of activities.

369. The WCO's main activity is to raise awareness about customs work in other international organizations as well as promoting capacity building activities for our Member administrations. The capacity building consists of two factors; a training through workshops, education and a training through operational activities. I am going to introduce workshops, operations as the WCO activities for IPR border enforcement.

370. The WCO delivers various capacity building activities, mainly in the form of legislative training, documents for importation training to find suspected counterfeit goods and identification training to distinguish counterfeits with private sector cooperation.

371. The WCO also performs diagnostic missions. In the diagnostic missions, the WCO experts visit the Member country and assess the customs administrations capabilities in the domain of combatting counterfeits. The evaluation of diagnostic missions includes both the legal base and practical and procedural arrangements, and leads to a recommendation from the WCO. The detailed list of workshops the WCO implemented after the last report to the TRIPS Council is attached in the annex 1 of the document, IP/C/W/654/Add.2.

372. The WCO organizes simultaneous enforcement activities with multiple customs administrations. These operations are aimed at knowing the scale of global counterfeiting as well as providing participating customs officers with hands-on experience. Operations, which quantity and qualify the impact of counterfeit activities, can also serve as an excellent opportunity to strengthen customs' enforcement capacity.

373. Between October 2018 and September 2019, the WCO, in partnership with Interpol and Europol and health authorities, co-organized a large-scale operation, the global operation PANGEA which is against pharmaceutical products sold online. This resulted in 859 arrests worldwide and the seizure of USD 14 million worth of potentially dangerous pharmaceuticals. It involved customs, police and health authorities from a record 116 countries. The impact of such a substantial level of interventions around the world sends a strong message both to offenders and the general public.

374. Last, I would like to mention our annual counterfeit and piracy group meeting. The meeting provides a forum for customs, other international organisations and private sectors to exchange information, experience and best practices on combatting counterfeiting and piracy.

375. I would like to thank the WTO Secretariat for participating in the previous meeting.

376. At its 16th meeting from 30 September to 1 October 2019, Members explored the challenges posed by the internet and cyber investigations, e-commerce, small consignments, and food and plant varieties related IP rights were discussed. During the meeting, Members also shared their experiences and exchanged practices on fighting counterfeits.

12 AN INCLUSIVE APPROACH TO TRANSPARENCY AND NOTIFICATION REQUIREMENTS

12.1 South Africa

377. I have the honour of introducing this item on behalf of the co-sponsors of document JOB/IP/33/Rev.2 which include the African Group, Cuba, India and Oman.

378. Transparency remains an important issue within the operation and monitoring function of the WTO. The issue of compliance with notification obligations has been contentious. Developing countries often struggle to comply with onerous obligations, while in many instances, developed country Members also do not comply with their notification requirements or do so selectively.

379. In general, it can be said that the capacity of developing countries to comply with notification obligations is inextricably linked with their level of economic development and access to resources. The capacity and resource constraints that developing countries face cannot be underestimated. Notifications require a deep understanding of the entire range of WTO Agreements, mature institutional mechanisms and human resource capacities that are often lacking in developing countries. Any work in this area should be on supporting and incentivizing developing countries to address these difficulties, especially as it relates to transparency obligations.

380. The capacity and resource constraints that developing countries face are well documented. Under these circumstances, it is natural for Members to reserve economic resources for the most urgent and pressing matters. In so far as obligations undertaken under the Marrakesh Agreement and its annexes are concerned, there is no doubt that treaty obligations must be performed in good faith. Having said this, it is clear that the obligation to comply is not blind to the situation that a particular Member or groups of Members may find themselves in.

381. There was already discussion on this issue in 1996 in the Working Group on Notification Obligations and Procedures. In those discussions, "some developing country participants pointed out that in view of the ever-increasing workload, combined with limited resources in the small delegations, they had great difficulty in advising their governments on all aspects of the notifications required. Many developing countries had difficulty understanding the frequently complex and highly technical information demanded, and therefore faced a prohibitive task in providing complete responses to the notification requirements and formats. While they recognized that these notifications were part of their Membership obligations and they were prepared to respond to the maximum of their abilities, there were serious constraints to what they could achieve due to their limited resources."

382. This proposal deals not only with general issues of transparency but also focuses on specific TRIPS related issues.

383. TRIPS Article 66.2 requires developed country Members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable the creation of a sound and viable technology base.

384. Developed country Members have a positive legal obligation to provide incentives to enterprises and institutions in their territories to promote and encourage technology transfer to least developed countries (LDCs). For the longest time, LDCs have demanded that this requirement be

made more effective. Pursuant to the Doha Ministerial Conference, the TRIPS Council has put in place a monitoring mechanism, however this mechanism does not evaluate whether developed country Members are compliant with their obligations under Article 66.2.

385. The obligation articulated in TRIPS Article 66.2 is not only mandatory but also continuous since no time limit has been set for the termination of this obligation. The record of compliance by developed countries is abysmal since information submitted under TRIPS Article 66.2 is so wide-ranging that in most cases it is not possible to distinguish where the information applies to developing countries in general or only to LDCs.

386. Information provided in this context in no way targets LDCs. In order to enhance Members' understanding of Article 66.2 it may be necessary to agree on a definition of what constitutes 'technology transfer', whereas the lack of a common understanding of the type of incentive required for promoting and encouraging technology transfer to LDC Members may further clarify developed country Members' understanding of the TRIPS Article 66.2 obligation. More transparency in this area would be supportive of LDCs' efforts to build a viable technological base.

387. On disclosure of origin of biological resources and/or associated traditional knowledge in patent applications, paragraph 39 of the Ministerial Declaration of 18 December 2005 requires that WTO Members agree to amend the TRIPS Agreement to establish an obligation for Members to require patent applications to disclose the origin of biological resources and/or associated traditional knowledge, including prior informed consent (PIC) and access to benefit sharing (ABS).

388. Despite a long discussion in the TRIPS Council in Special Session, no outcome has been produced on an implementation issue. Non-disclosure of such resources severely effects developing countries' efforts at improving substantive examinations and in assuring the integrity of determinations under traditional intellectual property legal requirements, in providing greater certainty as to the validity of granted rights or privileges. Traditional communities are severely affected by unlawful appropriation of biological resources and/or associated traditional knowledge. It would be useful to require WTO Members to make annual notifications on the number of patent applications based on traditional knowledge.

12.2 India

389. We believe that transparency is an important pillar for the effective functioning of the WTO. As enumerated in the paper, LDCs and developing countries have genuine capacity constraints in terms of institutional requirements and human resources to fulfil the onerous notification obligations. Delays in notifying cannot be attributed to wilful non-compliance. Therefore, instead of punitive measures, we need to adopt an inclusive approach to incentivize the participation of LDCs and developing countries for complying with notification obligations. The other aspect which we need to consider is that transparency permeates all areas of our work in the WTO including processes of decision making in the organization and the ministerial conferences. It should, therefore, be applied to our work including priorities in negotiations and deliberations in the various regular bodies. We also need to ensure that the processes are transparent, inclusive and provide opportunity for participation of all Members.

390. Notification obligations cannot be seen in isolation only for certain areas related to goods. They should be applied holistically to all Agreements under the WTO. There are significant notification gaps which have been listed in the paper, in areas such as agriculture, services and TRIPS, where transparency needs to be strengthened. Our efforts should be to create a suitable ecosystem to strengthen the capacity of Members by providing technical assistance, simplification of notification requirements and reducing the administrative and technical burden for delegations who do not have the resources and capacity.

391. Lastly, we again wish to reiterate that any approach suggesting a resort to counter notifications, additional obligations and punitive measures will only deepen the divide amongst Members and we should rather focus on engaging in an inclusive and constructive approach to strengthen our work in this area.

12.3 European Union

392. The European Union appreciates this contribution, that was just presented by South Africa, to the important debate about how to improve transparency in general and compliance with our notification obligations in particular. Building on the extensive discussion at the last Council for Trade in Goods, let me share some observations.

393. The EU agrees with the African Group, Cuba and India that notifications are not the only aspect of transparency. We also recognise that notification task is resource-intensive and can be challenging, particularly for small developing countries.

394. Notifications are, however, the enabler of the WTO's monitoring function. Without Members providing the information about our trade policies to the WTO which we all committed to provide, we cannot expect the WTO to do its job properly. The notification task, in our own experience, is also capacity building in and of itself, as it strengthens inter-agency cooperation.

395. In any case, our suggestion was to move the debate from the meta-level into the respective committees and councils with the relevant expertise.

396. Furthermore, the EU is in no way opposed to deepening the discussions on notifications in the relevant other bodies – to the contrary, we look forward to engaging with all Members on these issues.

397. In order to reply to the document submitted by South Africa and the African Group, introduced by our excellent colleague from South Africa, I would like to add something. EU actions usually do not target groups of countries or regions. The reason is because the EU supports regional integration. That fosters better understanding and political and economic links between neighbouring countries. That is why many technology transfer programmes of the EU and its member States target regions including both LDCs and also other developing countries. So that is the reason why we do not subscribe to the point of view made by South Africa, saying that the record of compliance by developed country Members is "abysmal" since information submitted under Article 66.2 is so wide. Actually, there is a reason behind it.

398. We look forward to working with all Members on making tangible improvements to our collective notification compliance and enhancing transparency for the benefit of all.

12.4 China

399. China appreciates the efforts made by the African Group, Cuba, India and Oman for submitting this document.

400. As reflected in the document, the capacity constraints of developing Members, especially LDCs, should be fully considered. The concerns and proposals related to TRIPS given in the document are worth deep discussion. In this regard, we encourage direct dialogues among Members so that the difficulties of developing Members could be better understood and addressed.

401. For China, we share the concerns of other developing Members, and at the same time, as many other developing Members, we always try our best to fulfil the notification requirements.

402. For developed country Members, as the document shows, they are far from fully implementing their notification obligations. So, here, I would like to reiterate that, to enhance transparency and strengthen notifications, developed country Members should take the lead and developing ones should also endeavour to do so at their best.

12.5 Brazil

403. Brazil appreciates the contribution by the African Group, Cuba, India and Oman. We also thank the statement made by the EU.

404. Brazil is in favour of enhancing transparency and strengthening notifications in the WTO. We are ready to engage in discussions to explore alternative ways to address the issue and ensure a good combination of incentives for enhanced transparency, which should permeate all areas of the WTO.

405. As an example, this current week in the General Council, Brazil joined the United States in a statement for more transparency in the dispute settlement system. As noted in the statement, greater transparency can be promoted in different ways, all of them consistent with existing rules.

12.6 Japan

406. This delegation thanks the proponents for the useful communication that raised in particular developing and LDC Members' concerns. On the other hand, we re-emphasize that notification is an obligation which is embedded in the WTO Agreement. All Members made a commitment to comply with that obligation when they became Members.

407. In addition, the same subject has been discussed at the WTO General Council. This subject includes several issues which do not fall within the ambit of the TRIPS Agreement. This delegation believes the WTO General Council is the more appropriate forum for holding discussions on this subject.

408. As Japan stated in agenda item 10, 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 countries to transfer technologies to LDCs is the lack or insufficiency of the 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.

409. This delegation would like to point out that Ministerial Declaration paragraph 39 adopted on 18 December 2005 just confirmed to address the issue related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity. Therefore, we have recognized that there was nothing committed to impose a disclosure requirement on patent applicants in that conference.

12.7 South Africa

410. Having introduced this particular item, I would like to thank all delegations that took the floor. I think many constructive interventions have been made. This particular paper evidences the fact that all Members of the WTO have obligations to comply with the treaty undertaking which is clearly evidenced under the covered agreements. We recognize the international principle of *pacta sunt servanda* which means that when we enter into contracts or obligations that we should own them. This does not mean in the context of the WTO that we cannot differentiate between Members that are clearly in different situations. We believe that good faith implementation of obligations means that when Members require additional flexibility that this should be accorded. In 148 instances across the covered agreements, we have indicated that developing Members have access to these particular flexibilities.

411. This paper goes in the direction to recognize that there are common and shared obligations to ensure the proper functioning of this Organization. Nonetheless, there are issues that we need to address. For this purpose, as announced in Japan's intervention, we intend to introduce a draft decision at the level of the General Council at the next meeting calling for certain measures to be implemented under the heading of transparency. We would also like to thank India, China and the European Union for their interventions and we certainly think that this is a topic worth pursuing on something that is necessary for us to ensure the proper functioning of this Organization including this particular body.

13 INTELLECTUAL PROPERTY AND INNOVATION: PUBLIC-PRIVATE COLLABORATIONS IN INNOVATION - IP COMMERCIALIZATION

13.1 Switzerland

412. Switzerland is pleased to propose this agenda item on Intellectual Property and Innovation and co-sponsor submission document IP/C/W/657 in partnership with Australia; Canada; Chile; the European Union, Hong Kong, China; Japan; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; and the United States of America.

413. Protection of intellectual property is not an end in itself. It shall promote inventions and creativity. But inventions by and on their own are of not much use, either. Inventions, and innovation more broadly, must reach the potential beneficiaries, the users, the customers, the patients, and respond to their needs. Only then is innovation in the public interest and can contribute meaningfully to technological and economic development. The commercialization of intellectual property is thus key, but poses often also a considerable challenge to inventors and creators.

414. Public-private collaboration can be one way of addressing this challenge in a successful partnership. This is the topic of document IP/C/W/657 and of the discussion suggested under agenda item 13, for which the co-sponsors propose at the end of their submission a number of questions which may help to guide the Council's discussion.

415. Switzerland would like to contribute by sharing some of its own experience concerning public-private collaboration and IP-commercialization.

416. The Chair and me, and probably most delegates in the room, spend a good deal of their professional life in seated position. Unfortunately, nature had not intended us to do so and reminds us of this regularly - with backpain!

417. Almost one out of five patients going to hospital in Switzerland suffers from a musculoskeletal disorder (or in short: MSD)[2]. MSDs are among the leading causes of work disability and productivity loss. According to a study on the economic impact of MSDs, the total cost attributable to MSDs in Europe amounts to almost 2% of the gross domestic product (GDP)[3]. MSDs therefore have a significant socio-economic impact. In the following, we will explain how IP is an important piece in the puzzle of public-private partnerships for the development and commercialization of new therapeutic technologies to treat and heal MSDs.

418. Commercializing academic innovations in the medical and med-tech field is often a challenge. The reason why IP commercialization does not take off, lies sometimes with those doing research at universities. They often tend to focus on their academic career rather than investing the time and resources necessary for exploiting the commercial potential of their research. Not knowing how to go about this and lacking the necessary network of expert partners, are other reasons why they often shy away from the financial risk of a business venture. Lack of awareness of the IP system, and how to take advantage of it to promote their own research and development (R&D) is another reason. Careless disclosure of valuable information, for instance in publications or presentations, might make them miss out on later opportunities to commercialize their IP. Fortunately, a growing number of universities and medical technology teaching institutions establish technology transfer offices and incubators that support academics in developing and transferring their basic research to the stage of applied research, and support them in teaming up with knowledgeable partners from the private sector to reach the stage of commercializing their innovation.

419. In the following, we would like to present an example of such a successful cooperation in the health care sector, more specifically: in the treatment of MSDs. Innovation is vital to the health care industry. And governments face rising healthcare costs and increasing demand for new and more effective medicines. There are thus shared concerns and interests. For their partnership to function smoothly, IP plays an indispensable role.

[2] State Secretariat for Education, Research and Innovation SERI, *Swiss Roadmap for Research Infrastructures in view of the ERI Dispatch 2021-2024*, 2019.

[3] Bevan S., *Economic impact of musculoskeletal disorders (MSDs) on work in Europe,* 2015.

420. Public and private actors in innovation greatly value having access to collaborative research infrastructures. Medical trials, for instance, involve cooperation with hospitals. For innovation to happen in the complex field of medical technology, cross-disciplinary teams are often required. Innovative diagnostic instruments, for example, regularly feature elements from a number of fields of expertise like genetics, chemistry, software and engineering. The challenge is to find the right partners, including appropriate commercialization partners, within suitable research infrastructures. Careful planning is necessary if limited funds are to be used as efficiently as possible.

421. An example where such interdisciplinary partnerships work together, to research, produce and commercialize innovation in the medtech area, is the *Balgrist Campus*, which is closely associated and directly located next to the Balgrist University hospital in the city of Zurich. The Campus is an initiative of two foundations dedicated to creating an optimal infrastructure. It is not merely an infrastructure to optimize research for the purposes of the University hospital; the *Balgrist Campus* has also established a Swiss platform for nationwide research, development, and commercialization to resolve problems such as the high number of patients suffering from MSDs. The aim is to connect universities and academics with partners from the private sector. Many other hospitals have also dispatched expert staff to the Campus on a temporary basis. Collaborations exist with several private industry partners who seek to implement the knowledge gained into viable commercial solutions and marketable products. These partnerships enable companies to gain access to the latest research knowledge and open up new business relationships to the researchers. By establishing cross-licenses between each other, they develop and share their work and the IPRs attached to it. Once commercialized, IPRs enable involved parties to reap and share equitably the economic benefits from their collaboration. Without sound protection of the created IP, companies would not be willing to take the risk of commercializing an invention, nor would they probably receive the necessary financing. Strong IP portfolios make the *Balgrist Campus* an attractive partner to potential sponsors from industry and leading researchers, and academics from universities elsewhere in Switzerland or abroad.

422. The Campus additionally invests in promising start-ups. These start-ups benefit from the public-private funded infrastructure, the collaboration with public hospitals and private corporate entities. At the same time, they are considered as a fundamental link between the researchers and industries. From ideas to basic research, to applied research and to market ready solutions: they can all be carried out under the same roof. This strategy has so far been very fruitful.

423. One of the successful start-ups based on the campus is called "ZuriMED", which produces devices for ligament reconstruction. Such devices are applied, for instance, to swiftly restore the function of the knee after an injury, allowing MSD patients to recover faster.

424. "The *Balgrist Campus* is a perfect incubator for translational medicine", says CEO Elias Bachmann, referring here to the interdisciplinary branch of the biomedical research and development field. The goal of translational medicine is to combine disciplines, resources, expertise, and techniques from different domains to promote enhancements in prevention, diagnosis, and therapies. Bachmann emphasizes that without the infrastructure and the teamwork through public and private partners at the *Balgrist Campus*, commercial success would not have been possible. He underlines the importance of IPRs, not only as a prerequisite for commercial success, but also as a means to promote a good reputation and attract potential investors.

425. Steven Johnson, a science author and media theorist, once said: "If you look at history, innovation does not come just from giving people incentives; it comes from creating environments where their ideas can connect."

426. IPRs help public-private partnerships to commercialize great inventions. Such team work between public and private partners offers synergetic and competitive advantages such as access to technology and infrastructure, collaboration on scientific expertise, innovative development and, not least, the joint commercial exploitation of the resulting intellectual property.

13.2 United States of America

427. The United States is pleased to co-sponsor this agenda item and contribute to the discussion of "Public-Private Collaborations in Innovation - IP Commercialization."

428. I would like to thank Australia; Canada; Chile; Chinese Taipei; the European Union; Hong Kong, China; Japan; Republic of Korea; Singapore; and Switzerland for co-sponsoring this agenda item.

429. I would also like to take the opportunity to invite Members and the Secretariat to the annual IP and Innovation side event sponsored by Japan, Switzerland and the United States. The 2019 side event focuses on the year-long theme discussed in TRIPS Council concerning Public-Private Collaborations in Innovation. We have a diverse panel for the side event that will discuss experiences concerning R&D partnerships, brand promotion, support for the creative industries and IP commercialization. For further reference, there are flyers with the schedule of the event in the back of the room. I hope to see you there at 1:00 pm in Room E and an "innovative" lunch will be provided.

430. In general, the experience of the United States with public-private collaborations in innovation arises in the context of an economy in which private firms operate without substantial Government intervention. In the United States, innovation and development are the result of competition in the marketplace, without heavy state direction. One useful function of public-private collaborations is to help address the space that markets on their own cannot fill.

431. For the next few minutes, I would like to talk briefly about the importance the United States places on research and development to solve today's challenges and improve lives, as well as the funding mechanisms and legal framework that facilitate innovation and technology commercialization for the benefit of the public.

432. The United States Government spends about USD 150 billion annually for R&D activities.

433. The federal R&D budget covers both research conducted by federal agencies or their contractors in government-owned facilities, and research conducted by universities and other contractors under funding agreements.

434. The Government itself conducts over USD 50 billion of R&D. Eleven (11) federal agencies have substantial R&D facilities, or "federal laboratories". Each of the 310 or so federal laboratories has a specified mission, which addresses the needs of different users, and pursues the development of different technologies and products.

435. About 50% of academic research in the United States is funded by the federal government. That corresponds to over USD 30 billion of federal research funding awarded to the higher education sector.

436. The federal R&D investments are critical for US innovation, competitiveness and economic prosperity.

437. The American innovation framework involves partnering with the private sector to further develop early stage inventions arising from federal investment in science and technology and bringing them to the marketplace.

438. However, in the absence of strong intellectual property (IP) protection, investment in early-stage inventions would be too risky for businesses and most of these inventions would never see the light of day.

439. Thus, patenting of inventions is critically important for licensing, securing investment and forming partnerships that lead to the commercialization of inventions.

440. I would like to talk briefly about two very important pieces of legislation, both passed by Congress in 1980, that facilitated transfer and commercialization of technologies developed with federal funding.

441. The first major US technology transfer law, the Stevenson-Wydler Act of 1980, established technology transfer as a federal policy.

442. It required federal laboratories to set up formal technology transfer programmes and to actively seek opportunities to transfer technology to industry, universities, and state and local governments.

443. The Federal Technology Transfer Act of 1986, which amended the Stevenson-Wydler Act, created a collaborative mechanism to encourage federal agencies and laboratories to work with non-federal entities, such as universities, foundations and private companies, on joint research and development.

444. Under a Cooperative Research and Development Agreement, or CRADA, a federal laboratory may provide personnel, services, facilities, intellectual property, equipment and other resources, but no funds, to the joint R&D effort. A non-federal party may provide funds, in addition to personnel, services, facilities, equipment, IP and other resources.

445. A CRADA defines the tasks to be undertaken within an area of collaboration and the allocation of IP rights resulting from such cooperation. The laboratory may grant to a collaborating party patent licenses or assignments, or options thereto, in any invention made under the agreement. The federal government always retains a non-exclusive, royalty-free license to practice the invention or have the invention practiced throughout the world by or on behalf of the government (the so-called "government use" license).

446. Let me give you a few examples (and there are many more!) of technologies developed in federal laboratories that found their way to the market because of public-private partnerships.

447. The camera in every cell phone runs on a sensor originally developed at the National Aeronautics and Space Administration (NASA) Jet Propulsion Laboratory in the 1990s. These digital image sensors were significantly smaller and more efficient than the technology of the day and eventually enabled tiny, battery-friendly cell phone cameras, high-definition video cameras-such as GoPro-and social media as we know it today. It took nearly two decades for the technology to achieve its dominance in the field of digital imaging. By 2015, the market for these sensors reached nearly USD 10 billion.

448. Another example is an earpiece system (ACCES) developed by the Air Force Research Laboratory and Westone, a hearing protection technology company, through a CRADA. ACCES includes a silicone custom-moulded earpiece that joins with a speaker cable to deliver audio to the user at very high altitudes and detaches easily if the pilot needs to eject. It reduces risk of hearing loss due to extreme noise, increases pilots' ability to communicate with others during flight, and reduces risk of injury if they eject from the aircraft while wearing this earpiece. Although the Air Force remains the dominant purchaser of ACCES, Westone also markets the product to other branches of the military, law enforcement, and the commercial space industry.

449. Of course, there are many success stories of technologies invented in federal laboratories and commercialized by private industry partners. But let's turn now to federally-funded research performed at universities. As I mentioned earlier, universities perform over USD 30 billion of publicly-funded research annually.

450. In the United States, technology transfer from universities to the private sector is made possible in large part by legislation commonly known as the Bayh-Dole Act.

451. In fact, at the time the Bayh-Dole Act was enacted in 1980, the federal government held title to approximately 28,000 patents, fewer than 5% of which were licensed to industry for development of commercial products.

452. Companies were reluctant to invest in developing new products and markets, since competitors could later acquire the same licenses from the Government and then manufacture and sell the same products. This meant that American taxpayers were not getting the full benefit from the billions of dollars invested in cutting-edge research.

453. The Bayh-Dole Act created for the first time a uniform patent policy for government-funded research. It allowed universities and other recipients of federal funding to retain title to their government-funded inventions and grant exclusive licenses.

454. As a result of this policy, universities are encouraged to collaborate with industry to translate research results into products that benefit the public.

455. Robust university research, coupled with the enabling legal environment created by the Bayh-Dole Act, spawned entire new industries in the United States, such as biotechnology, where the United States continues to have a leadership role.

456. Since the enactment of the Bayh-Dole Act in 1980, over 200 drugs and vaccines have been developed through public-private partnerships, more than 11,000 start-ups have formed based on the results of university research, millions of jobs have been supported and hundreds of billions of dollars have been contributed to US gross domestic product.

457. Let me give you an example of successful collaborations between federal agencies, universities and private industry.

458. Melanoma, the most dangerous form of skin cancer, is caused by uncontrolled growth in pigment-producing skin cells. Highly curable in the early stages, it often spreads to other parts of the body, making treatment more difficult. In the late stages of metastatic melanoma, the average survival rate is just six months. In 1995, James Allison, a professor at the University of California, Berkeley, discovered ways to activate the immune system to unleash a robust antitumor response. Dr. Allison transformed the field of immunology and achieved clinical success by performing basic research on T-cells. This basic research was funded, at least partially, by federal dollars, through National Institutes of Health (NIH), and later, by private funding. It took many years and a number of private industry partners to translate Dr Allison's discovery into a life-saving medicine. In March 2011, the immunotherapy treatment for melanoma was approved by the U.S. Food and Drug Administration, and it is now being tested for the treatment of other cancers. Dr Allison shared a Nobel Prize in Medicine in 2018 for his discovery on how to fight cancer using the body's immune system.

459. Federally funded university research also ignited the innovative engines of Qualcomm, Symantec and Netscape, among many other companies.

460. The United States' experience with public-private collaborations in innovation has been a positive one.

461. Important legislation such as the Bayh-Dole Act, the Stevenson-Wydler Act and the Federal Technology Transfer Act, created a policy and legal framework that encourages, facilitates and promotes public-private partnerships and the transfer of technology developed with public funding or in federal research institutions to private industry for further development and commercialization.

462. It is important to keep in mind the main objective of this framework - public benefit in the form of new products and technologies, jobs and local economic development. We are proud of our achievements and happy to share our experience with others.

463. We look forward to hearing from other Members on this topic.

13.3 Chinese Taipei

464. A nation's competitive edge and economic development depend on the establishment of a national innovation system, which can facilitate more efficient production, faster accumulation, and broader proliferation of knowledge. Generally, universities and research institutes have a large number of innovation and R&D talents. However, they do not necessarily have commercialization resources and experiences. On the other hand, the industrial sector has the ability to manufacture but may lack innovation and R&D talents. Therefore, the research and industrial sectors can complement each other through collaboration. Over the past decade, we have been actively

promoting academia-industry R&D collaboration in hopes of bringing about a major improvement in our industrial competitiveness.

465. Currently, our academia-industry cooperation programmes on IP commercialization include the "PIONEER Grants for Frontier Technologies Development by Academia-Industry Cooperation (the Major Alliance Projects)," the "Academia-Industry Technological Alliance Projects (the Minor Alliance Projects)," and the "Chinese Taipei Industry Innovation Platform Programme (TIIP)." Each programme runs from three to ten years.

466. Take the Major Alliance Projects for instance, it is led by the industry sector to encourage domestic corporations to form alliances and submit R&D proposals. The programme also promotes cooperation between corporations and universities and research institutes to jointly engage in the R&D of innovative technologies so as to narrow the industry-academia gap, strengthen key patent portfolios, develop standards or system integration, as well as assist corporations in long-term R&D talents cultivation in key technologies and industry upgrade. Since its launch in 2013 until September 2019, the Major Alliance Projects had drawn 70.6 million USD from the industry investing in R&D, with up to 545 patent applications being filed domestically and abroad, as well as nearly 1,000 job opportunities being created.

467. Take the "Project on the Establishment of an Intelligent Platform for Integrating Key Driving Modules of New-Generation Vehicles" under the Major Alliance Projects for instance, it is led by eight universities and corporations, and is aimed at developing intelligent motor systems for electric cars. So far, the project has successfully developed the globally-competitive, high-quality wafer-thin electrical steel sheet, which has been used in the supply chain of world-renowned electric vehicle brands.

468. Also, the "Pioneer Next-Generation Mobile Terminal Key Technology Project," jointly led by four universities and corporations, is by far our largest academia-industry project focusing on 5G and AI. So far, a total of 69 patent applications associated with this project have been filed domestically and abroad. In addition, for the first time, two universities joined in the project have participated in the International Organization for Standardization (ISO) as educational institutes and submitted 55 proposals associated with key technologies.

469. IP and innovation are the integral driving forces of economic growth. However, how the government may help innovators develop their businesses through comprehensive strategies remains an important lesson. We welcome Members sharing their measures and experiences.

13.4 European Union

470. The European Union is happy to contribute once more to the important debates that have been taking place in the TRIPS Council on different aspects of "IPR and Innovation".

471. The IP is most of the time generated from collaborative research. The results of research and innovation are, more often than not, protected by IP in order to reimburse costs related to the research and development carried out.

472. Of course, the right-holders are then responsible for the level of licensing they grant to third parties and the future sharing of benefits if an innovation becomes a product sold on the commercial market.

473. The IP portfolio is beneficial to all parties and thus also a good development tool for developing countries.

474. In general, collaborative research agreements are governed by four principles:

- The parties will mutually notify each other the IP generated and will undertake to protect the IP within a period of time;

- The parties will exploit effectively the IP generated;

- The parties will not exercise any discriminatory treatment; and
- The parties will protect confidential information.

475. The EU has supported partnerships among Universities all over the world for many years.

476. During the ongoing research and innovation (R&I) Framework Programme, Horizon 2020, the Commission has been promoting public-private collaboration for IP commercialization and academic entrepreneurship through a dual-pronged approach by fostering seamless approach from Open Science to Open Innovation.

477. In fact, for the multiannual financial framework of the EU budget (2021-2027), we have proposed an ambitious €100 billion research and innovation programme, Horizon Europe, that will boost the scientific, economic and societal impact of EU funding and ultimately increase the prosperity and well-being of Europeans.

478. Innovation is a key driver for the EU to continue delivering prosperity to its citizens and meeting challenges of the future. Implementing it requires a systemic, cross-cutting and multifaceted approach. The quest for acceleration of new ideas, products and processes is driving Horizon Europe objectives and implementing modalities.

479. Horizon Europe builds on lessons learned and on experience gained under the previous framework programme. It follows a three-pillar approach addressing fundamental science, global challenges and innovation. One of the pillars of the programme is called Innovative Europe that will help the EU become the frontrunner in market-creating innovation. This pillar provides for the launch of the European Innovation Council (EIC) that will mainly promote breakthrough and disruptive technologies and innovation by serving as a one-stop shop for innovation to help small companies to innovate and scale up.

480. Through Horizon Europe the Commission will support Universities to develop i.a. entrepreneurship, in particular by fostering the integration of universities in innovation ecosystems, and enabling the entrepreneurial aspirations of researchers at all career stages with adequate knowledge, skills, and resources, including IPR skills training and support for knowledge transfer capacity.

481. Horizon Europe also urge beneficiaries to use their best efforts to exploit their results, particularly in the European Union. The exploitation of results can also take place through the transfer and licensing or results, encouraging public-private uptake and valorisation of IP for wider societal benefits and economic value.

482. In addition, to further foster the academia-industry cooperation, the European Commission is considering the revision of the 2008 EC Recommendation on the management of intellectual property in knowledge transfer activities.

13.5 Japan

483. First of all, the delegation of Japan would like to thank the delegation of Switzerland for introducing our concept paper.

484. This delegation would like to share our experiences and national policies regarding public-private collaboration in innovation in Japan, especially, commercialization of academia's IP collaborating with industry.[4]

485. As the document IP/C/W/657 points out, bringing innovative goods and services to the market is often the ultimate goal of research and development (R&D) efforts. From this point of view, we would like to show briefly the history regarding tasks of Universities stipulated by Japan's law. In the past, it had been thought that the roles of universities were "education" and "academic research" in Japan. In fact, Old School Education Act was prescribed as such. After that, we started thinking

[4] The PowerPoint presentation is available in Room Document RD/IP/36/Rev.1.

"Contribution to society" i.e., "Dissemination of research outcomes" was the third task of universities. As a sign of its importance, new School Education act stated that "Universities shall teach and conduct researches to realize their aims, and contribute to the development of societies by providing the results of such teaching and research to societies." In addition, other legislations which were intended same aim have been enacted.

486. Under these circumstances, Japan has been implementing various initiatives to support universities and research institutions, in order to further strengthen academia-industry collaboration activities and promote commercialization of research results.

487. Since universities have created various new knowledge which could be valuable seeds for innovations, the importance of transferring technology among academia-industry collaborations has increased worldwide even further. This being done to successfully commercialize valuable intellectual property and knowledge created by universities and research institutions.

488. This delegation would like to talk about some of our initiatives.

489. This gives an outline of the scheme of "Academia-Industry Collaboration Advisor." The JPO and the INPIT (National Centre for Industrial Property Information and Training) send IP experts in business development to universities that are advancing academia-industry collaboration in order to commercialize their research results. The role of advisors is not only to support IP management of projects conducted through academia-industry collaboration but also to facilitate commercialization of the research results.

490. For example, advisors give advice on how to develop R&D strategies and business strategies for projects based on certain business models, and give scenarios for commercializing products. Also, they provide support to formulate commercialization projects and analyse patent information and market information in the fields of the projects. In addition, they advise how to build a better patent portfolio, which is necessary for commercialization of their research results, through evaluating advantages of their inventions and supporting patent acquisition.

491. At the 22 universities, "academia-industry collaboration advisors" have been engaged in the commercialization projects so far.

492. We would like to introduce a successful support activity. In this case, a university and its partner company were collaborating on commercializing a medical device, which they developed together. In order to start commercial production, they had to solve several issues. On the business level, the partner company did not have enough experience to file an application to the Pharmaceuticals and Medical Devices Agency (PMDA), an authorized agency, to obtain approval for manufacturing the device. Also, the company could not find sales channels for the device.

493. The Academia-Industry Collaboration Advisor conducted various support activities. Major supports include: (1) review the business model; (2) select appropriate partner companies for manufacturing and selling the device; (3) check the need for a second supplier and select it; (4) study effective filing strategies to obtain patents under the Patent Cooperation Treaty; (5) gather information on how to file an application seeking approval for manufacturing and selling medical devices and about insurance; and (6) conduct patent clearance searches. Thanks to the advisor's appropriate advice, the collaboration succeeded in obtaining the insurance for this medical device.

494. In addition to Academia-Industry Collaboration Advisers, in fiscal year 2019, the JPO started sending IP-Strategy Designers to universities, who explore outstanding research outcomes and manage IP strategies from the viewpoint of researchers.

495. In this project, IP Strategy Designers, who are knowledgeable about and experienced in handing "intellectual property" at universities, team up with persons in charge of supporting R&D activities, including research administrators (URAs), to share their expertise. This is done to explore potential research outcomes that have not been protected by IP rights. IP Strategy Designers propose future visions to researchers, which can further develop their research results, such as plans for large-scale joint researches and commercialization. Moreover, to achieve future visions that researchers hope to accomplish, the Designers forge IP strategies from the viewpoint of researchers

by focusing on research results that should be protected by IP rights and determining the timing when they should acquire IP rights. By doing so, Designers help researchers create new economic value and social value by using their research outcomes and utilizing IP rights.

496. This delegation is sure that dissemination of research outcomes to society is one of the important tasks for universities. These outcomes would have a possibility for further economic and social development.

497. In order to facilitate commercialization of research outcomes, universities, which do not have their own resources to commercialize their knowledge, need to collaborate with companies that have the capacity to commercialize the research results. Because of this situation, private sectors also have opportunities to create high-value added products. We believe that, if the government can promote such collaborative activities, this will contribute to creating innovations and further economic growth throughout the country.

498. In order for collaborations between companies and academia-industry to be successful, it is essential that they effectively protect their intellectual property and obtain enough human resources who can manage the collaborative activities and IP strategies. The Government of Japan is expected to play key roles in this regard.

499. Going forward, the Government of Japan is committed to make contributions to further promoting innovations.

500. This delegation hopes that its information helps other delegations create their own domestic policies. And this delegation is very much looking forward to hearing many experiences from other Members.

13.6 Australia

501. Australia would like to sincerely thank Switzerland for leading this discussion on IP commercialization. We were glad to join the discussion paper as a co-sponsor.

502. The Australian Government recognizes the value of encouraging linkages between companies and universities on the one hand, and investors on the other. The Department of Industry, Innovation and Science supports collaboration between universities and industry through a number of initiatives, including the Cooperative Research Centres Program, the Entrepreneurs Program, and the IC Global platform recently developed by the Commonwealth Scientific and Industrial Research Organisation , or CSIRO.

503. The Cooperative Research Centres Programme supports collaboration by providing competitive grants for industry-research partnerships aimed at solving industry-identified problems. It is a proven model for linking researchers with industry to support the transition from research and development to commercialization.

504. The Programme comprises two elements:

- Cooperative Research Centre Grants, which offer cofounding for up to ten years for industry-led collaborative research, to resolve challenges facing industry, and improve the competitiveness, productivity and sustainability of Australian firms; and

- Cooperative Research Centre Project Grants, which offer cofounding for up to three years for industry-led collaborative research, to develop new technologies, products and services.

505. The Entrepreneurs Programme is the Australian Government's flagship initiative for boosting business competitiveness and productivity. The Innovation Connections element of the Programme encourages and assists small-and-medium-sized businesses to access knowledge, engage with researchers and foster innovation.

506. Innovation Facilitators help businesses to assess gaps in their corporate knowledge and provide specialist support, which may include assisting businesses to:

- Identify critical and strategic research needs and opportunities;
- Find and access expertise, technology and advice; and
- Work with the research sector.

507. Businesses may also be eligible to apply for a matched funding grant that provides direct access to research capabilities.

508. IC Global is an integrated suite of platforms developed by CSIRO in collaboration with over 70 partners from across industry, the research sector and government. It is designed to catalyse innovation by facilitating capability discovery, problem solving and data visualization.

509. The Expert Connect element of IC Global is a publicly searchable database of Australia's research expertise, containing more than 70,000 expert profiles from over 220 research organisations.

510. Expert Connect has been designed to boost industry-researcher collaboration. Anyone can search for a topic of interest using simple, non-scientific language, and find the most relevant researcher to connect with.

511. The platform considers both academic and business nous, presenting users with a list of relevant experts that are most likely to understand the business context.

512. Turning to the forms of public private collaboration that successfully supported IP commercialization, federal government programmes such as Cooperative Research Centres and Innovation Connections both stand out. The Government is also investing in the Challenge Based Innovation program, which fosters opportunities for business, research institutes and Government to work together to solve real-world problems.

513. Australia's IP Office, IP Australia, has developed several initiatives to help individuals, companies and public institutions to commercialise their IP.

514. Source IP , for example, connects businesses with those Australian public sector research organisations that have patented technology available to license. Launched in November 2015, Source IP is focused on making it easier for businesses to access innovation and technology generated by the publicly funded research sector.

515. The platform allows Australian patent holders to include additional information about their patents, such as their potential industrial applications and commercial advantages, to promote the technology and encourage collaborative partnerships.

516. With the assistance of the Department of Industry, Innovation and Science, the "IP Toolkit" was developed to simplify the administrative management of IP in collaborations between researchers and businesses.

517. The toolkit can help researchers and businesses to:

- Develop and build effective commercial partnerships;
- Identify the important issues in developing collaborations;
- Deal with key issues before launching collaborative relationships; and
- Reduce the need for legal advice, freeing up resources to focus on partnership building.

518. The toolkit includes resources such as:

- A checklist covering the key issues that need to be considered before initiating collaboration;

- Contract, confidentiality agreement and term sheet templates; and
- Guidance and information to help collaborating parties manage their IP.

519. The Australian Government offers various forms of training and educational resources to help innovators commercialise their IP. For example, the Australian Copyright Council (ACC) provides accessible and affordable legal advice and education on copyright law for Australian content creators and consumers. It also organises customised in-house training for creators through online webinars and in-person seminars.

520. The Australian Government's Department of Communications and the Arts contributes to the educational campaigns and awareness raising efforts of WIPO. For example, the Department's Copyright Section has hosted student visits under the WIPO-Queensland University of Technology's Master of Laws in Intellectual Property Programme and presented on issues relating to copyright law in Australia.

521. Finally, experimental facilities such as science parks have largely been the responsibility of Australia's state governments . In recent years the States have developed a range of tech precincts, science parks and business parks, which appear to have been successful in boosting the volume of patent applications.

13.7 Hong Kong, China

522. Hong Kong, China would like to thank Switzerland for placing this item on the agenda and giving us an inspiring introduction. I am also thankful to previous speakers who shared their experiences.

523. Innovation is the driving force for business upgrading and restructuring of industries, while IP is the engine behind powering innovation. IP commercialisation is important for reaping the social and economic benefits of IP and innovation, and for the long-term development of modern knowledge-based economies. Hong Kong, China treasures the value of IP commercialisation and is devoted to be proactive in this area.

524. Over the years we have cultivated all the ingredients that are necessary for the growth of IP commercialisation, including a sound legal system, a robust IP protection regime, capable research personnel, world-class professional services as well as government and funding support. To further strengthen our advantages in these areas, our Government has put in place different measures and let me share with you some highlights and successful stories.

525. "SME" is a major pillar of the Hong Kong, China economy. To unleash their potential in engaging in IP commercialisation, we have been working with relevant stakeholders in taking forward some supportive initiatives. For example, the Intellectual Property Department has been collaborating with the Law Society of Hong Kong, China to provide free consultations to SME on IP commercialisation, protection and management. An IP manager scheme has also been launched to provide training for SMEs to build up their IP manpower capacity and boost competitiveness through IP commercialisation. These consultation services and trainings are well received by the business sector.

526. We are also promoting IP and innovation in a direct and efficient manner through funding support. Our Government has been providing funding support to local research institutes to promote R&D, technology transfers and commercialisation of research outcomes. Among various funding schemes, the Technology Start-up Support Scheme for Universities was introduced in 2014 to provide funding support specifically for universities in starting technology businesses and commercialising their R&D results.

527. Starting in 2019, a maximum amount of about USD 6 million is provided annually under the scheme. Each funded technology start-up may receive up to USD 200,000 each year. With the implementation of this funding scheme, we have seen a flourishing atmosphere of techno-preneurship at university campuses. More professors, students and graduates are interested

in pursuing a career in technology. The technology start-ups of the universities have started to grow and thrive, injecting new impetus to the economy.

528. We have also launched a Patent Application Grant to provide funding support to local companies and individuals in their first patent application to help them protect and commercialize their intellectual work. An approved application will be granted up to USD 30,000.

529. This kind of public-private collaboration has nurtured some successful start-ups and commercialised products over the years. For example, with funding support from the Government, a start-up associated with the Hong Kong, China Polytechnic University has successfully developed soft contact lens using the "Defocus Incorporated Multiple Segments ("DIMS")" technology for short-sightedness control. The same team has utilised the DIMS technology to produce spectacle lens comprising hundreds of micro-lenses segments which employ the natural homeostatic mechanism to regulate the size of the eyeball based on the physical characteristics of optical input. To put it in a more layman way, the lenses constantly defocus the short-sighted vision of myopia sufferers which in turn enables them to see clearly.

530. The device has been shown to slow the progression of short-sightedness in children by 60%, and even stop the progression in 20% of the subjects tested. They also significantly reduce the overall risk of associated diseases, such as retinal detachment and glaucoma. The DIMS technology is widely acclaimed by the technology sector and has won the Grand Prix of the 46th International Exhibition of Inventions of Geneva in 2018.

531. Another successful example of IP commercialisation is a face mask created and manufactured in Hong Kong, China based on a nanofiber technology. The company collaborated with the Nano and Advanced Materials Institute Limited, a research and development centre under the Government, and produced the first Nanofibrous N95 Smart Mask which was later launched in the market under the branding of "NASK" in 2016. The technology, upon further enhancement, was used in the PM2.5 Sport Mask and won a gold medal with "jury recommendation" in the 45th International Exhibition of Inventions of Geneva in 2017. According to the company, this invention has a strong capability of commercialisation, because, out of more than 30 Nanofiber product manufacturers worldwide, the company is one of only two entities that can apply this technology for mass production.

532. In conclusion, the experiences in Hong Kong, China show that public-private collaboration is effective in promoting innovation and IP commercialisation. We would like to encourage Members to provide further assistance for your public bodies and private sectors in this regard.

13.8 Singapore

533. I would like to thank Switzerland for submitting this discussion paper on "IP commercialisation", which builds on the productive discussions we had in the February and June sessions on "Public-Private Collaborations in Innovation". Switzerland's paper is useful in stimulating discussions on how public-private collaborations in innovation on IP commercialisation can bring benefits to everyone, and Singapore is pleased to co-sponsor it.

534. Singapore's efforts in IP commercialisation are guided by a national IP Hub Masterplan, which was launched in 2013 and updated in April 2017. In order to build up our reputation as an IP hub further, the revised Masterplan undertook a comprehensive review to strengthen Singapore's innovation ecosystem, and to better facilitate and encourage IP commercialisation. In this regard, allow me to share three key pillars of Singapore's efforts to support and facilitate commercialisation of IP across a wide range of industries and sectors.

535. First, the Government worked with the private sector to develop programmes and academic courses to grow domestic IP expertise to support our economy's needs. Consultations were held with IP professional bodies, industry and academia to design and introduce two new graduate certificate courses for working adults interested in IP and innovation in 2017. In tandem, a salary support programme was also introduced to encourage employers to allow their staff to sign up for IP-related training courses. In August 2019, Singapore launched a Skills Future Framework for IP that mapped the required skills and career pathways to encourage more Singaporeans to consider and enter the IP profession.

536. Second, the Government is continually working internally to update its practices and improve openness to innovation in its work. In this regard, we introduced a National IP Protocol in January 2019 to encourage government agencies in the course of their work to generate novel solutions in addressing issues faced by the citizenry. The Protocol additionally lays out options and best practices for these government agencies to work with relevant private sector bodies to commercialise these inventions while ensuring public interests are upheld.

537. Third, we also acknowledge that IP protection is a fundamental enabler in IP commercialisation. To that end, we are continually improving our IP regime, to ensure that it remains up to date with technological and commercial developments. For example, Singapore revised its Register Design laws in 2017 to allow for, among other things, the registration of virtual and projected designs as well as graphical user interfaces. It is also in the midst of a review of its copyright laws that, among other things, tries to give clarity to issues relating to the streaming of audio-visual content from unauthorised devices and exceptions for text and data mining for analytical purposes. Meanwhile, the IP Office of Singapore is also continually improving its own services based on feedback from its stakeholders. New services like a fast track application programme for Fintech and AI patents as well as a mobile phone app for Trademark applications were recently launched as a result.

538. Let me close by emphasising that IP commercialisation is not something that governments can do on their own. Public-private collaboration is essential in ensuring that the right policies are implemented in a manner that not only helps bring new products and services to the market, but also facilitates job-creation, prosperity, and societal progress. We look forward to further discussions on this important issue with Members.

13.9 Canada

539. Canada would like to thank Switzerland for drafting the paper for "IP and Innovation" theme of "Public-Private Collaborations in Innovation – IP Commercialization", under document IP/C/W/657. We would also like to thank the co-sponsors of this discussion and those TRIPS Council Members that have shared their national experiences and insights on public-private collaborations in innovation so far.

540. Moving to the topic for this current discussion, we would like to take the opportunity to present an overview of two particular initiatives, building on presentations that Canada has made on other IP and innovation-related initiatives at past TRIPS Council discussions under this agenda item. First, we will present on the "Strategic Innovation Fund", which has been designed to provide financial support to projects that will improve innovation performance while providing economic, innovation and public benefit. Second, we will briefly present on Canada's "Agricultural Clean Technology Program" which provides non-repayable, federal contributions to implement and deliver clean technology projects that support activities across the innovation continuum.

541. With respect to the Strategic Innovation Fund, the fund serves to simplify application processes, accelerate processing, and provide assistance that is more responsive and focused on results. In allocating funding, the Strategic Innovation Fund looks to accelerate areas of economic strength, strengthen and expand the role of Canadian firms in regional and global supply chains, support economic strategies, and attract investment that creates new and well-paying jobs.

542. With respect to IP, under the Strategic Innovation Fund, recipients must own the background IP or hold sufficient background IP to allow their project's activities to be carried out. Additionally, recipients must hold sufficient rights to permit them to exploit the IP resulting from their project's activities. Recipients are also required to take appropriate steps to protect the IP resulting from activities supported through the program.

543. Second, with respect to Canada's Agricultural Clean Technology Program, the Government of Canada's Budget 2017 allocated CAD 25 million (or approximately USD 18.75 million) in funding to develop a clean technology programme for the agriculture, agri-food and agri-based products sector in Canada. The Agricultural Clean Technology Programme provides non-repayable, federal contributions to implement and deliver clean technology projects that support activities across the innovation continuum, ranging from R&D and technology and knowledge transfer, to commercialization and adoption. Projects are selected as those that generate positive impacts on

land, water and air, while reducing the intensity of greenhouse gas emissions in agricultural production. For the purpose of the Agricultural Clean Technology Program, innovation is defined as an invention, significant modifications to a pre-existing technology, or improvements to an existing technology specifically noting changes to functionality, cost or performance.

544. To conclude, Canada would be pleased to discuss these and other initiatives to any interested Member on these margins of this meeting. In the meantime, we would like to thank those Members that have shared their insights and experiences thus far, and look forward to further views on the topic of public-private collaborations in innovation and IP commercialization going forward.

13.10 Korea, Republic of

545. Korea shares with other countries recognition of the great importance of linking industries and universities on the one hand and investors on the other in promoting IP commercialization. As part of efforts to facilitate the supply of much needed innovation and technology to industries, KIPO has been conducting the "IP-Plug" project since September 2015. This aims to build a human network linking investors, academia as well as the "Korea Institute for Patent Strategy Development" which serves as an IP broker. This network functions as a forum where industries share information and explore emerging demand for innovative technology and IP.

546. In addition, KIPO has been holding a series of nationwide "roadshows" to facilitate the IP commercialization of universities and public research institutions through better connecting academia and companies, with a particular focus on small and medium sized enterprises. Such efforts have resulted in the development and commercialization of numerous new technologies by universities and public research institutes.

547. KIPO has also been implementing "A project to build product-specific patent portfolio. This project aims to facilitate top notch technology and innovation developed by universities and public research institutions and to provide such technology and innovation to companies which have a real need for them. There are several unique features of this project, which have led to its success. First, taking account of market demand, patents for several different technologies which are associated with a single product are provided as a package. That way, companies that need those technologies can easily access such patents. Secondly, the Government is assisting with the "proof of concept", which makes development of a new technology less risky for a company.

548. Recognizing that financing is one of the crucial elements for IP commercialization, the Government is also seeking to expand its support for IP-based financing. What is meant by IP financing is the use of IP assets (such as trademarks, design rights, and patents) to gain access to credit. Two of the leading forms of IP-based financing are IP-based collateral and IP-based credit. In most cases, tangible assets are used to secure asset-based loans, however, the collateralization of IP can also increase the amount of available credit. Some banks also use IP assets as a credit enhancer. Given that valuation is a key tool in the process of IP financing, KIPO has designated a qualified IP-valuation institute, thereby controlling the quality of technical valuation. KIPO has also provided assistance in terms of the cost of valuation for SMEs so that SMEs can gain easy access to IP financing.

549. IP Commercialization can be promoted and facilitated through the greater exchange of information related to transactions in the field of technology and patents. In this vein, KIPO has launched a website (www.ipmarket.or.kr) through which individual companies, in particular SMEs, can have easy access to various forms of market information relating to technology and patents. In many cases, due to its unique features, such as the divergence of views on valuing of a patent, a number of obstacles are faced in carrying out a transaction in the field of IP. To better facilitate IP-related transactions, KIPO has also established a channel where SMEs can receive consulting services on IP-related transactions from government-certified experts.

13.11 China

550. China appreciates the submission of the document IP/C/W/657 and the efforts made by the co-sponsors. We also thank the previous speakers for sharing their experience.

551. In July 2019, WIPO published the Global Innovation Index 2019(GII), in which China ranked the 14th of all countries, arising in four consecutive years. At present, the amount of trademark and patent applications of China runs in the first place of the world, as the patent applications through the PCT ranks the NO.2 and the trademark applications through Madrid Agreement ranks the NO.3 globally.

552. Until late June 2019, China has registered 5,090 GI trademarks and approved 2,380 GI products. Till the end of August 2019, 24,000 layout-designs of integrated circuits have been registered in China.

553. There is another figure, which could also provide the proof to the work done by the Chinese Government in the protection of the IPR. According to a survey conducted every year in China, the satisfaction rate of the public society to the protection of the IPR increases by 13 points, from 63.69 in 2012 to 76.88 in 2018. China has made and is still making progress in the creation, protection and utilization of the IP.

554. As we all know, transformation of the IP plays a crucially important role in the whole circle of creation, protection, utilization and management of IP. Chinese Government pays great attention to the transformation of IP and its positive effect on job creation, economy development as well as public benefit. As a result, China has legislated a specific law, named "Law of the People's Republic of China on Promoting the Transformation of Scientific and Technological Achievements", which encourages the in-time transformation of the scientific and technological achievements. Especially, it emphasizes the function of universities and R&D institutions, and encourages universities and R&D institutions to cooperate with enterprises, of achieving the goal of the transformation of IP through establishing collaborative R&D platforms, technology transfer entities, and technology innovation alliances. In order to enhance the implementation of the above-mentioned law, the State Council of China has legislated relevant regulation, and the local provincial governments also made their correspondent statutes and acts. Furthermore, in the "Outline of the National Intellectual Property Strategy" of China, we also have such kind of wording, which Members that "exerting the important function of the universities and R&D institutions in the process of the creation of IP".

555. Besides positive support at the policy level, China has also taken concrete measures. Chinese Government authorities, the Ministry of Finance together with the CNIPA (China National Intellectual Property Administration), established a national public service platform for the operation of IP, promoting the transformation of IP nationwide. The website of the platform is www.sipop.cn, which provides a service platform for online IP transactions. Till now, there are more than 200 IP service agencies as well as investing and financing entities settling in the platform, and around 20,000 IP projects are listed.

556. It is worth mentioning that, in the middle part of China, the city of Wuhan, the Chinese Government is now implementing a pilot project regarding the transformation of IP, which is setting up a "spin-off" under the collaboration of the enterprise, the university, and the CNIPA Hubei centre. The approved spin-off will play a very important role in the transformation and commercialization of IP, and it also demonstrates a good model of the public private cooperation in the commercialization of IP.

557. In the recent years, the Chinese Government also held a number of training workshops, inviting the experts in the IP field to give lessons to the university professors, students and R&D institution staffs, so as to cultivate and increase their awareness of the IP rights.

558. China reaffirms the transformation and utilization of IP is one of the targets of protecting the IP, and China also welcomes other Members for sharing their good experience regarding the transformation and commercialization of IP.

13.12 Brazil

559. Brazil thanks the proponents for their communication on public-private collaborations in innovation and IP commercialization. We are very pleased to deliver this intervention, because in the following day we celebrate Brazil's Innovation Day. The date was chosen because, on 19 October 1901, the Brazilian airman Santos Dumont encircled the Eiffel Tower in his airship.

560. Effective commercialization of R&D produced in universities is fundamental to the development of an ecosystem conducive to innovation. Brazil's Innovation Act, launched in December 2004, was amended in 2016 to include "academic spin-offs" as a legal entity. In Brazil, they are known as Scientific, Technological and Innovation Institutions (ICTs). The Innovation Act also created the Technology Transfer Offices (TTOs), a structure established by one or more ICTs, whose purpose is to create innovation policies guided towards the generation of innovation and technology licencing. The goal is to transform knowledge in tangible assets, protected by intellectual property, to be incorporated into production processes or products.

561. Brazil's innovation policy also relies on incubators, science and technology parks and accelerators. Start-Up Brazil, the Brazilian Start-up Acceleration Program, is an initiative of the Ministry of Science, Technology and Innovation (MCTI) in partnership with private accelerators. The Program, created in October 2012, aims to select and support technology-based start-ups.

562. Another feature of Brazil's public-private initiative for commercialization of innovation is the implementation of open laboratories. In 2010, the first Fab Lab was established in Brazil, which propelled the emergence of different private open labs based on the provision of services for innovation. This infrastructure has spread rapidly, with a wide variety of its types installed in schools, enterprises, and other institutions.

563. Brazil also sees public procurement as an instrument of incentivizing and spreading innovation. According to Article 20 of the Innovation Act, Public administration bodies and entities, may directly contract ICTs, non-profit private law entities or companies for the realization of research, development and innovation activities that involve technological risk, to solve a specific technical problem or to obtain an innovative product, service or process.

564. Another very important institution is the National Fund for Scientific and Technological Development (FNDCT). From 1967 to 2017, the Fund sponsored more than 30,000 projects including hydrogen-fuelled buses for public transportation, the Santos Dumont supercomputer, the Brazilian Geostationary Defence and Strategic Communications Satellite and the Exoskeleton, which was demonstrated during the World Cup in Brazil.

565. Since 2008, Business Mobilization for Innovation (MEI) has brought together the main business leaders in Brazil to stimulate and streamline policies for competitiveness and innovation in the country in a dialogue between private sector, public sector and academia. Examples of companies participating in this initiative are Natura, Suzano and Whirlpool.

566. Referring to SME's, the "Brazilian Micro and Small Business Support Service" assists small businesses with solutions to boost innovation, including support in intellectual property matters and adaptation to technical standards.

567. For the future, Brazil is in the process to enact legislation that simplifies the direct funding of enterprises for research in public universities. The expectation is to lead university research to market-oriented purposes and facilitate partnerships between the private sector and academia.

568. While thanking the proponents for this important topic, and considering our future work in the TRIPS Council, we would like to shed some light in another feature of licensing technologies, which are patent law provisions that contribute for them to be effective. One of them is sufficiency of disclosure.

569. Brazil finds that sufficient disclosure requirements in the patent registration stage is of fundamental importance. A patent request should be accurate enough to enable the reproduction by a person skilled in the art without further need of consultations with the patent previous owner. Brazil believes that Members could also explore this theme further under the agenda item "IP and Innovation".

13.13 Costa Rica

570. For Costa Rica, investment in human capital, innovation and knowledge that fully translate into economic growth require a robust intellectual property right framework. In that line, our

Government aims to the implementation of policies and rules that create effective incentives for the production, appropriation and assimilation of knowledge.

571. Above all, it is critical to ensure a high level of cooperation between academia and the private sector. To foster such cooperation, the Government has created Bureaus of Transfer of Technology and University-Enterprise Linkages. While there are still many challenges, this cooperation system has already proven its usefulness, as 45 new licence technologies have been created and are ready to be implemented.[5] The Government also created an information platform[6], called Hipatia that allows universities to publicize the available research with licensing potential.

572. Allow me to cite some specific activities performed by public universities in relation to IP and innovation:

- The Unit on Management and Transfer of Knowledge and Innovation of the University of Costa Rica issued 18 different licenses in 2018, while an additional 25 were transferred through other means.

- The Institute of Technology of Costa Rica, works on intellectual property management through its Connection Center. This Centre offers guidance on transfer of technology and it is in charge of intellectual property training for researchers and students. The Connection Center also offers guidance on intellectual property protection for innovation that is developed in house.

- The Center Cadenagro[7] of the National University, supports the agricultural sector by creating distinctive signs, and offering advice on issues related to protection and registration. It has played a key role by working directly with producers on the development of geographical indications such as Turrialba cheese, Chorotega ceramics and Tarrazu Coffee.

573. The Government has also identified the need for basic IP training for innovators. Within the framework of the National Innovation System, the Ministry of Science, Technology and Telecommunications has an active role in the promotion of Intellectual Property. The Ministry created a programme to help entrepreneurs with one-on-one advice on management of intellectual property rights. Furthermore, the Ministry and the Industrial Property Registry regularly hold joint lectures and capacity building activities on the importance of IPR in innovation for entrepreneurs.

574. To conclude, Costa Rica strongly believes in strengthening the link between innovation and intellectual property, as innovation has proven to be a driver and enabler for growth and job creation.

13.14 Norway

575. Norway would first like to thank the proponents of the communication contained in document IP/C/W/657. We agree with the basic assumption that the protection and use of intellectual property rights can be an enabling component for successful commercialisation. The document touches upon many issues which the Norwegian Government is focusing on heavily in our national innovation policy.

576. The Norwegian Government recently forwarded to Parliament a White Paper on the Health Industry in April 2019 (a summary in English can be found on the homepage of the Norwegian Government[8]).

577. The main objective of the White Paper is to contribute to improving the competitiveness of the Norwegian health industry. We perceive the starting point for the Norwegian health industry to be good, with decent growth rates through the last few years. At the same time, we also see substantial potential to do even better in the future – not the least through more, and more professional use of

[5] https://www.elfinancierocr.com/tecnologia/universidades-tienen-a-la-venta-45-tecnologias/COPQEWQWG5HWXBFMTM5S2JJWEY/story/.
[6] https://hipatia.cr/dashboard/tecnologias-licenciables.
[7] www.cadenagro.org.
[8] https://www.regjeringen.no/contentassets/41435798a618491e902935a590967502/en-gb/pdfs/stm201820190018000engpdfs.pdf.

IPR. This includes both academic institutions, the public health sector (state-owned hospitals etc.) and private enterprises.

578. We see an untapped potential for increased and better commercialisation of research results and business ideas generated by both academia and the public health sector. Many Norwegian health industry enterprises, but also universities and hospitals etc. find the process of commercialisation challenging.

579. We have identified certain barriers to growth in the Norwegian health sector which the Government can help overcome; two of these are:

- Getting public health institutions to develop into being more attractive partners for private enterprises; and

- Facilitating more and better commercialisation of medical and health-related research and of ideas generated within the health and care sector.

580. In this field, public-private cooperation on the basis of sound IP portfolios will be key, and the Government aims to contribute to increased professionalization on both sides.

581. The deliberate and professional use of IPR will be a core element at the base of achieving this goal. An increasing level of competencies in this field is needed. A broad and appropriate offer of education in the field of IPR at institutions of Higher Learning is also of the essence.

582. We will look more deeply into the question of whether more measures from the part of the Government will be necessary and meaningful in order to bring this about.

13.15 South Africa

583. We would like to thank the proponents for introducing this important item. South Africa has an active policy that promotes public-private partnership models. We followed a global trend in the popularity of PPPs by establishing a more formal PPP structure within the National Treasury in 1999.

584. Industrial Policy Action Plan (IPAP) 2017/18 – 2020/21, the latest annual iteration of a continuous action plan to re-industrialize our economy, sets out the implementation tasks. The plan stresses the pressing need for structural change in the economy. The severe shortage of human resources for R&D has been identified as a fundamental constraint to economic growth and R&D. There has been a distinct, if not deliberate, change in the profile of public (government) funding for R&D in South Africa since 2003. This change reflects an international trend in the role of governments with regard to their support for R&D.

585. South Africa has a strong culture of innovation, supported by a well-established research base. In the 2019 Global Innovation Index by the World Intellectual Property Organization (WIPO), South Africa came in the 63rd place worldwide and first place in the Sub-Saharan region.[9] South African universities and research institutions have done exceptionally well in producing world-class research and publications in peer-reviewed journals. However, there is still a gap in the National Innovation System (NIS), as most of the research outputs have not translated to commercially-viable products and services and the creation of new industries.

586. In 2008 of the Ten-Year Innovation Plan. This plan proposed five 'bold interventions in critical areas', labelled as grand challenges and covering the bio-economy, space science and technology, energy security, global change science with a focus on climate change, and human and social dynamics. The Department of Science and Technology - and more broadly government in general - implemented the plan by directing at least a portion of the additional funding from the South African National Treasury to large projects with close alignment to the grand challenges. These projects included the Karoo Array Telescope (now the SKA) which in its first trail run discovered 1200 new galaxies that had never been observed and whilst 13-member countries are the cornerstone of the SKA, around 100 organizations across about 20 countries are participating in the design and

[9] https://www.wipo.int/global_innovation_index/en/.

development of the SK, the pebble bed modular reactor, the electric car (Joule), and the development of a HIV microbicide.

587. The Government via its programs and agencies will embark on an extensive skills development programme aimed at training one million young people by 2030 in Robotics, Artificial Intelligence, Coding, Cloud computing and Networking. The South African Government's commitment to ensuring greater inter-ministerial and intra-governmental coordination as well as supporting an Inventor Assistance Programme which was launched in October 2017, in partnership with WIPO to assist inventors to protect their IP with some assistance from IP lawyers and WIPO.

588. Public funding of R&D has risen from 28% to 45% of gross domestic expenditure on R&D, and is now the dominant source of funds. Much of the additional funding has been allocated to universities, whose R&D performance - as measured by higher education expenditure on R&D - has risen from ZAR 3.6 billion in 2007 to ZAR 7.3 billion in 2012. Universities now account for 34% of the total R&D performance, up from 19% in 2007. South African universities have increased their activities in applied research. They have done so by establishing closer links with the private sector, setting up technology transfer offices, pursuing the registration and licensing of intellectual property arising from their R&D, and adopting the commercialisation of knowledge within institutions as a significant component of their mandates (in addition to teaching and research). Rising levels of public-funded R&D within universities has the additional benefit of producing the necessary human resources to directly support the economy's transition from a resource-based to a knowledge intensive structure.

589. Higher education institutions are also forging links with private companies on applied research projects. The government's huge Technology and Human Resources for Industry Programme (Thrip) embraces government, industry, science councils and higher education institutions in joint ventures to develop new technology and skills for the country. PPP remain an important tool available for the South African government to promote R&D in core areas that will promote the implementation of our National Development Plan and spur economic growth and development for all our citizens.

590. In conclusions, in relation to the submission IP/C/W/657, we have a few questions:

- Could Members share best practices on measures to ensure reasonable pricing agreements for publicly funded R&D?

- What remedies do Members employ to mitigate the failure to disclose public funding on patent filings?

13.16 Ukraine

591. Ukraine welcomes the WTO document IP/C/W/657 and thanks its co-sponsors for putting the topic of private-public collaborations in innovation on the agenda of the meeting.

592. To contribute to this discussion, we would like to note that Ukraine has significant opportunities for innovative development, especially in the field of IP commercialization. The main benefits of Ukraine are advantageous geographical location, large market, the existence of a Deep and Comprehensive Free Trade Area between Ukraine and the EU and relatively high level of Human Development Index.

593. In order to stimulate innovations in all sectors of Ukrainian economy, in July 2019 the Government approved the Strategy for the Development of Innovative Activity for the Period up to 2030.

594. This Strategy determines the purpose, main elements of national innovative ecosystem, its problems, strategic goals and tasks on which the implementation of the state innovation policy is based, in particular for creation of favourable conditions to bring innovative products to the market, including possibility of its commercialization in Ukraine and abroad.

595. We expect that the implementation of the Strategy will contribute to the growing number of natural persons and legal entities engaged in inventions, research and development, especially in

the private sector; and to the growing number of business entities that provide commercialization service. It will promote the growth of the share of innovative enterprises, in particular small businesses, as well as provide the increase in revenues from sale and use of IP and high technology products.

596. The Strategy stipulates the necessity of the development of its implementation Plan for the Period of 2019-2021. This work is ongoing today with participation of different interested authorities.

597. To share some practical examples of private-public collaboration in the field of IP commercialization we would like to shortly present Ukraine`s experience in creating a network of technology and innovation support centres (TISC).

598. Establishment of such centres in Ukraine is conducted under the Cooperation Programme between WIPO and the Ministry of Economic Development and Trade of Ukraine for 2018-2019 with the main objective to provide innovators with access to locally based, high quality technology information and related services, to assist in exploring their innovative potential and to create, protect, and manage their intellectual property rights.

599. The project is being implemented through the creation of a TISC network on the basis of higher education institutions and other specialized institutions. Such network provides, firstly, territorial accessibility for stakeholders, and secondly, the specialization of TISC employees in the areas and areas of services provided.

600. The first centre was opened in November 2018 within the National Office of Intellectual Property of Ukraine and became a coordinator of the whole network. So far, eight technology and innovation support centres have been established and two new centres will open the doors in the nearest future.

601. It is expected that successful implementation of this Project will promote development of creative industries, accelerate intellectual capital of higher education institutions, put down leakage of innovative technical solutions abroad and reduce labour migration in Ukraine.

602. Technology and innovation support centres work with start-ups, inventors, innovative companies, product-based companies and export engaged companies covering inventions, trademarks, utility models and industrial design.

603. Services offered by such centres include:

- Facilitated access and assistance in scientific and technical information search, contained in free of charge and commercial patent and non-patent data bases;
- Access to hardware and software TISC's instruments to allow innovators to conduct patent search based on TISC's hardware and software resources and to get an assistance on the patent search procedure;
- Consultation on resources, necessary for the full cycle of innovation development and implementation, starting from an idea to commercialization of the idea; and
- Distance learning with NIPO programmes - to provide access to the programmes of distance learning on basics and specifics of intellectual property right.

13.17 Switzerland

604. Switzerland would like to thank Members for their highly interesting and inspiring contributions and the sharing of their experience with public private collaboration for IP commercialization with the Council.

605. We have had a rich discussion. My delegation has heard many new ideas, measures and projects from which we can learn and we feel inspired to bring this information home to discuss with

our stakeholders to see how we could promote and improve further public private partnerships in IP commercialization - for the sake of providing a more conducive innovation ecosystem.

14 INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: R&D COSTS AND PRICING OF MEDICINES AND HEALTH TECHNOLOGIES

14.1 South Africa

606. This topic is a continuation of a sustained debate regarding the intersection between intellectual property and the public interest. The public interest is a central component of the TRIPS Agreement, which recognizes underlying public policy objectives of national systems for the protection of intellectual property. The protection and enforcement of intellectual property rights is not an end in itself. Article 7 of the TRIPS Agreement recognizes that intellectual property rights must contribute to the promotion of technological innovation and the transfer and dissemination of technology to the advantage of all stakeholders, including the users of technological knowledge, and in a manner conducive to social and economic welfare.

607. In September 2015, 193 members of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) three that aims to ensure healthy lives and promote the well-being of all people of all ages.

608. The WTO is central to achieving the 2030 Agenda for Sustainable Development Goals (SDGs), which sets targets to be achieved by 2030 in areas such as poverty reduction. Trade has proven to be an engine for development and poverty reduction by boosting growth, particularly in developing countries. Target 3.b underscores the importance of support for R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries. The Doha Declaration on the TRIPS Agreement and Public Health affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health and, in particular, provide access to affordable medicines and medical technologies for all.

609. The Doha Declaration on the TRIPS Agreement and Public Health recognizes both the importance of intellectual property for the development of new medicines and concerns that intellectual property rights affect medicine pricing. The UN Secretary General's High-level Panel on Access to Medicines observed the following: "The rules governing human rights, trade and public health exist in separate but overlapping spheres; their implementation rests at different levels. An important factor behind the incoherence between trade, intellectual property laws, human rights and public health lies in the different accountability mechanisms and uneven levels of transparency." It further observes that transparency is a core component of good governance, especially where civil society and patient groups rely on transparency of information. Transparency, as further stated, can also ensure fairness during negotiations that take place between biomedical companies and procurement organizations.

610. I do not propose to read the entire paper. However, I would want to focus on one or two further areas before I turn to the questions. Pricing strategies are based on determinants such as, *inter alia*, the cost of R&D, costs of production or financial returns to incentivize future R&D programmes. The true costs of R&D for pharmaceuticals are often unknown and highly variable, while the contribution made by public and non-profit-making sectors towards the R&D of medicines is not always accounted for. The marginal production costs of medicines are relatively small compared to their market prices while a significant proportion of this expenditure might be for marketing and promotional activities, which are costs not related to the development of the product.

611. South Africa calls on Members to share their experiences of how TRIPS flexibilities have been used to address high prices and barriers to access to medical technologies and medicines in order to achieve public health and related national objectives. In the past the impact of competition and anti-trust laws on access to medicines was explored in document IP/C/W/643. The issue of abuse of IP rights remains relevant in the context of the application of national and regional norms to ensure cheaper and more effective access to medical technologies and medicine. Policies that influence the pricing of health technologies or the appropriate rewards for successful research outcomes can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information on the role of public funding and subsidies), the medical benefits and added therapeutic value of products.

612. We would like Members to share their experiences around the following questions:

- What are the TRIPS flexibilities adopted by Members in their patent laws to ensure availability of patented medicines at reasonable prices?
- What are Members' experiences with escalating prices of patented medicines and what are the policy responses implemented to address this trend through the use of TRIPS flexibilities?
- What approaches have Members implemented regarding price regulation of patented medicines such as a combination of cost-based pricing, value-based pricing, reference pricing, and/or through tendering and negotiation, and regulating mark-up levels? If any of these approaches have been used, what are the results and challenges that Members face to ensure compliance and disclosure of necessary information or their effect on the prices of medicines?
- What measures have Members implemented to enhance the publicly available information on the costs of manufacturing medicines, vaccines and health technologies, in particular information on grants, tax credits or any other public sector subsidies and incentives relating to the initial regulatory approval and annually on the subsequent development of a product or procedure?
- Can Members share their experiences to improve the transparency of the patent landscape of medical technologies to ensure that no barriers are created to generic competition through sharing complete and up-to-date information?

14.2 India

613. We support the statement delivered by South Africa.

614. At the outset, allow me to thank and compliment my South African colleague for this extremely pertinent and timely submission that attempts to facilitate sharing of experiences between countries on the steps taken by them to maintain a balance between the pricing of medicines and the public interest.

615. The National IPR Policy introduced by the Government of India in 2015 envisions an India where creativity and innovation are stimulated for the benefit of all. The policy emphasizes that a dynamic and vibrant intellectual property system must focus on enhancing access to health care, food security and environmental protection among other sectors of vital social, economic and technological importance. Our existing laws were either enacted or revised after the TRIPS Agreement came into existence and are fully compliant with it. India has incorporated a wide array of flexibilities available under the TRIPS Agreement in its Patent Law.

616. Certain specific examples of such flexibilities include-higher patentability standards to ensure a balance between the public interest and intellectual property rights protection. Prior to 2005, India prohibited the grant of pharmaceutical product patents, which had to be changed as part of the TRIPS commitment. The concern at that time was that while genuine inventions should be patented, evergreening should not be allowed. Higher patentability standards have tried to address this concern.

617. A system of pre-grant opposition that allows any third party to oppose a patent application that is awaiting a decision at the patent office has augmented the examination capabilities of our patent office so that frivolous inventions are not patented. This has helped to keep the prices under control. Robust compulsory licence provisions to address situations where prices become unreasonable or where supply of the medicine is inadequate, strong disclosure requirements and transparency provisions that require a patent applicant to disclose the status of his application in other countries and the requirement that every patentee and every licensee furnish a statement as to the extent to which the patented invention has been worked on a commercial scale in India have helped in creating an equilibrium between the obligations taken under the TRIPS Agreement and the rights available.

618. The Bolar provision is very important for entry of generics as soon as the patent expires. The Indian Patent Law allows a generic company to seek regulatory approval ahead of the expiry of the patent. This in turn facilitates the entry of the generics as soon as the patent expires, thereby ensuring that the patent monopoly does not extend beyond the required period. The patent landscape is recognized by our National IPR Policy to be critical for enabling innovation and also to know whether there is freedom to operate. The Policy mentions that efforts should be made for the creation of a public platform to function as a common database of IPRs. It states that such a platform would help in scouting the technology landscape to identify white spaces and thereby promote innovative activities in uncovered areas. In India patent landscape work is being carried out by the Unit for Research and Development of Information Products (URDIP) of CSIR. They carry out landscaping work across technologies for small and medium enterprises, start-ups, research institutions among others.

619. Lastly, we want to mention that the questions raised in the submission address the issue of access to medicines as a whole and Members need time to respond. Therefore, the issue should be kept open for inputs/experiences to be shared by Members in subsequent meetings of the TRIPS Council.

14.3 European Union

620. The European Union views critically a number of issues discussed in the communication from South Africa.

621. As previously stated in this Council, the work conducted by the United Nations Secretary-General's High-Level Panel on Access to Medicines started from an assumption that "[a]n important factor behind the incoherence between trade, intellectual property laws, human rights and public health lies in the different accountability mechanisms and uneven levels of transparency."

622. This statement is recalled in the communication.

623. As the European Union already indicated in its written contribution to the UN Panel and in various interventions in the framework of this Council, we do not share that assumption. We do not subscribe to this point of view.

624. The Commission encouraged the Panel at that time to adopt a holistic approach to the problem of access to medicines that could result in a valuable contribution to the wider debate.

625. However, due to its limited mandate, unfortunately, the High-Level Panel has focused its proposals exclusively on addressing an alleged conflict between a R&D model that (partially) relies on IPR and the possibility of providing affordable medicines. In doing so, it has missed an opportunity to advance more balanced, comprehensive and workable solutions to the problem of access to health.

626. As we all know, IP-protected medicines are only a very small fraction of the medicines that patients in need in many developing countries lack access to.

627. As already stated at the TRIPS Council of November 2018, in general, we do not consider the TRIPS Council the appropriate forum to discuss competition policy regarding pricing of medicines and health technologies. There are other international fora, such as the International Competition Network, where such international exchanges and cooperation are taking place.

628. While the submission from South Africa seems to consider the use of competition policy a TRIPS flexibility, the EU would be cautious. While TRIPS is obviously compatible with the application of competition policy measures, it clearly does not allow for an "absolute policy space". As provided for in Articles 8.1 and 2, as well as in Article 40.2, these measures have to be consistent with the provisions of the TRIPS Agreement and cannot be used as tools in avoiding the obligations under the Agreement.

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

630. The examples concerning excessive pricing as a competition law infringement in the pharmaceutical sector in the EU show that competition law enforcement in the EU is done on a case-by-case basis.

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

632. The EU seeks to ensure, on the one hand, that medicines are accessible to those in need and, on the other hand, to promote the financing of research in new and better medicines through effective IP protection.

633. The challenge is to strike the right balance between the need to promote and finance the R&D of new and better medicines, ensuring that medicines are accessible and affordable to those in need, while guaranteeing the sustainability of health systems. We believe that these goals are not contradictory and must be pursued jointly.

634. In order to be able to make innovative medicines available, these medicines have to be researched and developed in first place. The current innovation model has delivered consistent progress in global public health, continuously leading to important new and improved treatments as well as much extended life expectancy, both in developed and developing countries.

635. This model integrates a variety of tools, such as incentives for innovation based on IP, public and private financing and awards, or public research. This variety is necessary to address situations where there is a functioning market and those where there could be market failures.

636. Since, in a market economy, most medicines are created not by public authorities but by the pharmaceutical industry, which, as all industries, needs an adequate return on investments to finance innovation, the challenge is how to use all levers available to public authorities to promote affordable access to medicine without affecting negatively the investments of the pharmaceutical industry and therefore the availability of new and innovative medicines.

637. The development of new drugs requires very significant and long-term research, coupled with clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is a critical incentive for innovator pharmaceutical companies to make the necessary investments into that research and development. The often-long time period of rigorous (clinical) testing for marketing approval, which is important to ensure the new medicines are safe, limits the economically effective time of patent protection.

638. It has to be noted that the shorter that time span becomes as a result, the higher the price for new medicines will have to be to recover the research cost in the remaining time of patent protection. The higher the price, the more it will limit access to the innovative medicines and their affordability.

639. Finally, evidence shows that there are many different and significant causes of lack of access to medicines, which renders it misleading to attribute the problem merely to, or even principally, IPR-related aspects.

640. In fact, IPR issues seem to play a minor role in the problem but a disproportionately large role in the debate. This has also been echoed in a joint-report from the WHO, WTO and WIPO stating that the "lack of access to medical technologies is rarely due to a single isolated factor".

641. Additionally, I recall that, currently, most medicines on the WHO list of essential medicines (i.e. more than 90%) are available in a generic format, either because they were never protected by a patent or because protection has expired.

642. Still these medicines do not reach all in need. In fact, many developing countries apply tariffs, taxes and substantial mark-ups to medicines and lack an efficient procurement and healthcare

system, with the result that medicines are not available to the population or at least not at an affordable price.

643. I would like to recall also that, the Global Fund, distributing medicines to patients in need in developing countries with diseases such as HIV or malaria drugs, has been financed by the EU and its Members with over EUR 19 billion from 2001-2016. For the period of 2017-2019 the EU and its Members finance the Global Fund with around 17 billion (out of the EUR 29 billion pledged by all countries). According to the calculation of the Global Fund, this has allowed the Fund to save 22 million lives. The Global Fund also cooperates closely with the Medicines Patent Pool, which receives licences from some of the world's leading innovative pharmaceutical companies for free or at a dramatically discounted price. Hence, innovations such the world's latest HIV drugs can also reach patients in need in places where the countries' government are not able to provide universal health care.

644. Contrarily to the perception of some, international trade is vital for access to medical technologies, since no country can aim to be entirely self-sufficient, in particular not developing countries.

645. In trade negotiations, the EU always takes into consideration the development status and public health concerns of our trading partners. For example, we never have nor will we ever ask for provisions which would be contrary to or otherwise undermine the Doha Declaration on the TRIPS Agreement and Public Health.

646. The Declaration underlines the importance of public health measures and allows the granting of compulsory licences for the production and importation of generics where necessary and the freedom to determine the grounds upon which such licences are granted. To ensure this, the Commission proposes a legally binding provision in its trade agreements referring to the Doha Declaration to guarantee that these flexibilities granted by the TRIPS Agreement remain available.

647. In conclusion, questioning IPRs in trade for pharmaceutical products as a means to improve their affordability would not only be looking at the wrong target, but also have consequences opposite to the intended ones. It would reduce investments and the number of resulting new medicines and treatments or lead to higher prices of new medicines available worldwide.

14.4 China

648. China appreciates the efforts made by South Africa in submitting the document.

649. The TRIPS Agreement came into force in 1995, which established a comprehensive international intellectual property protection system and set minimum standards for intellectual property protection for all Members. Compared to other international intellectual property agreements negotiated before, the TRIPS Agreement has broader IP protection scope, better implementation mechanism and more extensive protection standards.

650. Strengthening intellectual property protection does not necessarily lead to the improvement of economic efficiency and the increase of social interests. The negotiators of the TRIPS Agreement recognize this point, so Articles 7 and 8 of the TRIPS Agreement clearly stipulate that "the protection and enforcement of intellectual property rights should contribute to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare; Member may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development" and relevant Articles like Articles 6 and 31 are recognized by Members as TRIPS flexibilities. The TRIPS flexibilities are considered by Members to be an important right to safeguard their public interest.

651. At the 2001 Doha Ministerial Meeting, ministers adopted the Declaration on the TRIPS Agreement and Public Health; they reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

652. China emphasizes the importance of intellectual property protection and commits to fully comply with the provisions of the TRIPS Agreement since accession to the WTO. And as many other developing Members, China attaches great importance to intellectual property and the public interest, and it was one of the first Members to accept the Protocol Amending the TRIPS Agreement.

653. At the domestic level, the compulsory licensing system is specifically stipulated in the Patent Law of China. In the event of a state emergency or very urgent situation, or for the public interest, the patent administration under the State Council may grant compulsory licenses for the implementation of inventions or utility models. In addition, the Patent Law also permits parallel imports and the Bolar exception.

654. Actually, as of now, China has not issued any compulsory license. We provide the medicines at reasonable prices mainly in two ways. First, we include some expensive patented drugs in the medical insurance catalogue through government procurement. Second, we set up a platform to help drug purchasers in different regions to buy medicines together at the same time. By those ways, pharmaceutical companies reduce the price of drugs through the increase in sales volume and profits. And government can effectively ensure the availability of medicines, and maintain public health.

655. China believes the protection of intellectual property rights should contribute to the mutual advantage of producers and users and to a balance of innovation and the public interest. When a public health problem occurs, Members should have the right to use the TRIPS flexibilities to protect their public interest. China also hopes to hear from other Members' experience in using TRIPS flexibilities to safeguard the availability of medicines.

14.5 Chinese Taipei

656. We understand that intellectual property and the public interest are central components of the TRIPS Agreement, and how to strike a balance between intellectual property protection and the public interest are important public policy objectives for Members. There are relevant provisions in our Patent Act as follows:

657. In order to implement the spirit declared by the Doha Declaration on the TRIPS Agreement and Public Health and the WTO General Council resolution, and for purposes of assisting Members with insufficient or no manufacturing capacity in the pharmaceutical sector to obtain pharmaceutical product(s) needed for treating HIV/AIDS, tuberculosis, malaria and other epidemics, according to Articles 90 and 91 of our Patent Act, when complying with certain requirements and agreeing to comply with the relevant regulations prohibiting the re-export of compulsory licensed pharmaceuticals, the Specific Patent Agency may, upon request, grant a compulsory license to the requestor to exploit a patent concerned for the purpose of producing and importing pharmaceutical product(s) to these Members.

658. Besides, according to Article 60 of our Patent Act, the effects of the patent right shall not extend to research and trials, including their practical requirements, necessary for obtaining registration and market approval of drugs under the Pharmaceutical Affairs Act or obtaining market approval of pharmaceuticals from a foreign country. It will help the pharmaceutical companies to obtain marketing approvals, so that the general public can choose and obtain more reasonable pharmaceutical product(s) as soon as possible.

659. Regarding drug prices, our National Health Insurance adopts a value-based pricing mechanism in new drug pricing when a new drug has to obtain market approval before listing. To ensure rational allocation of medical resources, a new drug has to undergo pricing review procedures prior to listing, in which the economic and therapeutic values of the new drug are evaluated, and the listing prices are decided based on the evaluation results.

660. Regarding drugs covered by our National Health Insurance, to ensure reasonable listing prices, price and volume surveys are implemented, so that price adjustments can be done by referring to the actual transaction prices and to reflect the real situation on the market. Besides, patents are taken into consideration in the price adjustments, in which listed drugs are classified into various categories based on their patent status and different price adjustment formulas are applied to different categories.

661. Our National Health Insurance adopts a value-based pricing mechanism in new drug pricing. In terms of pricing methods, a new drug is priced based on international prices of the new drug, or the listing prices or the international prices of the comparators, and may enjoy mark-ups in certain cases such as drugs with better clinical benefits. Certain drugs such as those used for rare diseases can not only be priced based on the international prices of related products, but can also be priced by cost-calculation methods.

662. The decision on new drug pricing review is made by a joint meeting composed of stakeholders including authority officials, scholars and experts, beneficiaries, employers, healthcare providers, etc. Moreover, the meeting minutes and meeting sound records are disclosed on the website.

663. Regarding the improvement of the transparency of the patent landscape of medical technologies, our Pharmaceuticals Affairs Act was amended on January 31 last year (2018) to introduce the system of patent linkage of drugs, entered into force on August 20 this year. According to the main points of the amendments, the holder of a new drug permit should submit the patent information regarding such drug within 45 days after the receipt of the drug permit. The holder of a new drug permit should also list and make public the patent information of the new drug in the Registration System for Patent Linkage of Drugs.

664. Through patent linkage, we ask the holders of new drug permits to disclose patent information of the drugs soon after market launch. By making such information public, we encourage generic drug companies to learn the patent status of the new drugs first, and carry out necessary circumvention as they develop their own drugs. This shall help to reduce risks of suspension of sales caused by infringement disputes after the drugs are put on the market and also provide more comprehensive IP protection for drugs.

14.6 Brazil

665. We thank South Africa for its communication to the Council. As a country that offers universal health and medical care, a constitutional right in Brazil, we reaffirm the importance of reaching the right balance between access to medication and the development of new treatments by the pharmaceutical industry.

666. The increasingly high prices of health products and therapies are not only the reality of several developing countries but also many developed country Members.

667. The latest multilateral initiatives on the promotion of transparency of costs of health products – such as the "WHO Technical Report on the Pricing of Cancer Medicines", the "WHO Roadmap on Access to Medicines and Vaccines", the "Transparency Resolution" adopted by the 72nd World Health Assembly, and the resolution on "Access to medicines and vaccines" adopted by the Human Rights Council, promoted or sponsored by Brazil - have relied on substantial support from a wide range of countries from different economic and geographical backgrounds.

668. While acknowledging that the matter of pricing of medicines is a complex one, involving questions relating to supply, taxation, infrastructure, or regulatory aspects, we should not refrain to acknowledge that patents, market practices and lack of data also play a significant role.

669. The WTO Multilateral Agreements and, consequently, the TRIPS Agreement were built upon a very fine balance of rights and obligations, where mutual concessions led to agreement. Therefore, discussions on the use of TRIPS flexibilities, including the provisions of the Doha Declaration on TRIPS and Public Health, which is an integral part of this fine balance, should not be considered politically sensitive.

670. Brazil remains committed to promoting access to quality, safe, effective and affordable health products, which we believe is an essential role of governments and multilateral organizations.

671. In this sense, it is fundamental that all interested actors – governments, civil society and the private sector – dialogue and contribute to creative solutions to achieve these goals.

14.7 Switzerland

672. This delegation acknowledges the importance of, and fully supports the goals contained in, the 2030 Agenda for Sustainable Development, including goal number three to ensure healthy lives and promote wellbeing for all at all ages.

673. By incentivizing research and development of new medicines, the IP system and patents play a key role in making further progress towards achieving goal number three by 2030.

674. The communication of South Africa further refers to the TRIPS flexibilities, confirmed in the Doha Declaration on the TRIPS Agreement and Public Health in 2001. Members are free to use these flexibilities in situations where they have to address a public health problem under the Declaration.

675. In addition, Members agreed on including Article 31*bis* in the TRIPS Agreement, providing for a compulsory license for export purposes to address the particular needs of WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector.

676. While these TRIPS flexibilities are there for Members to be used in appropriate circumstances, it is important to underline that the IP system and patents can only perform their function and incentivize the necessary investment needed to develop new drugs for unmet medical needs, if IP protection is the rule - and making use of a flexibility remains the exception.

677. The IP system proved to be instrumental in the unparalleled success story of modern medicines over the last 100 years, for the benefit of both developed and developing countries.

678. This said, more progress is needed to address illnesses that still today are not curable, whether communicable or non-communicable diseases. The IP and patent system will play a crucial role in mastering this challenge. Where not sufficient on their own to incentivize investment in R&D - as may be the case in areas such as neglected tropical diseases or drug-resistant bacteria - additional incentives are needed to complement the incentives of the patent system.

679. It is the essence of the patent system to grant to the inventor a time limited right for the commercial exploitation of her or his invention. The patent system is central as it addresses and remedies an economic market failure, in order to reward and promote innovative and creative activity. As any right, an IP right can be abused. In such cases competition law may provide a remedy. Beyond this, competition and or anti-trust law are outside of the field of responsibility of this Council.

680. My delegation considers also the pricing of medicines as well as the cost of research and development to be outside of the purview of the TRIPS Council. The WHO is currently examining questions in this regard, as the communication of South Africa also notes.

681. Having said this, it would be misleading in this delegation's view to imply that the price of a medicine is directly related to patents. To ask for a specific price, is not a right conferred by a patent on its owner.

682. In sum, the IP system, and for cases such as neglected diseases, complementary incentive and financing systems are needed, to ensure that innovative and more effective medicines and medical technology continue to be developed also in the future, to reach the goal of healthier lives and wellbeing for all.

14.8 Japan

683. For the purpose of having meaningful discussions under this agenda item, the delegation of Japan would like to suggest 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.

684. We all should note that the development of new and innovative medical technologies needs so much cost and takes so much time as well, and therefore Japan believes that there should be an

appropriate mechanism to incentivize the development of such technologies not only for the developed country Members but also for the whole world.

685. In addition, this delegation would also like to point out that it should not be focused on the price too much since there is a huge difference in costs between a medicine based on a new chemical entity (NCE) not previously used in any pharmaceutical product, and an incremental modification of an existing medicine. However, even for NCEs the stated costs differ widely.

686. Generally speaking, we have the need to protect intellectual property to encourage development of new and effective drugs so that new essential drugs will continuously be developed.

14.9 United States of America

687. The United States respects Members' right to protect public health and, in particular, to promote access to medicines for all, as affirmed in the Doha Declaration on TRIPS and Public Health.

688. The United States is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow trading partners to address the serious public health problems that they may face.

689. The United States supports the vital role of the patent system in promoting the development and creation of new and innovative life-saving medicines and urges Members to consider ways to address their public health challenges while also maintaining IP systems that promote innovation.

690. Pricing of medicines is a very important issue that is currently being discussed in the United States.

691. However, we do not believe that it is an appropriate topic for TRIPS Council.

692. It is important to recognize that drug pricing and drug availability are complex issues. There are many factors that play a role in it, with IP rights being just one of those factors.

693. As has been noted during this discussion, the WHO-WIPO-WTO joint study on Promoting Access to Medical Technologies and Innovation (the "Trilateral Study") highlighted many factors that contribute to the availability of medicines. Such factors include regulatory barriers; taxes and tariff policy; procurement mechanisms; increase in the production, sale and use of the substandard/fake/counterfeit medicines; complex supply chains; and the list goes on.

694. We believe that the narrowly-focused mandate of the UN High Level Panel was flawed and therefore cannot lead to outcomes that adequately address this issue.

695. While patents do play a role in the pricing of products covered by patent protection, the primary role of patents is in incentivizing the development of new drug products. Discussions on the pricing of new drug products are moot if there are no new drug products being developed.

696. In our view, a robust patent system does not prevent countries from taking measures to protect public health.

697. An effective patent system not only incentivizes the discovery of new drugs, new uses for existing drugs, and improvements on existing drugs, such as methods that improve drug efficacy, but also importantly enriches the public domain as patents expire.

698. This balance is best shown by the leading role of the United States in pharmaceutical innovation and by the strength of the generic market, with nine out of ten prescriptions being filled in the United States with generic drugs.

699. Without patent protection, especially in the pharmaceutical field, research into new drugs, new uses of existing drugs, and improvements to existing drugs would dramatically decline.

700. In terms of pricing, it is important that patents are not issued for old and obvious ideas and that the patent term is not inappropriately extended, so that generic manufacturers can make medicines available at lower prices.

701. It is necessary to look at the whole picture in order to improve the situation. A narrow focus on patent rights as ostensibly obstructing the availability of reasonably priced medicines would distort a complex and multifaceted picture and would leave out many factors that are fundamental in addressing pricing and access to medicines issues.

702. The experience of the United States shows how patent and pharmaceutical data protection stimulate an environment that promotes innovation, R&D, job creation, and the creation of new life-saving products. In turn, this environment maintains and promotes a strong generic pharmaceutical industry, which accounts for over 90% of all prescriptions filled in the US.

703. Finally, with respect to the proposal to keep this agenda item open, we request that the Council follow the agreed rules of procedure regarding how items are added to the agenda.

14.10 South Africa

704. We would like to thank all delegations that took the floor. Just a short reflection on this debate. We thank especially the European Union delegation for having intervened and having raised important points.

705. I would like to point out that this particular item does not deal with competition policy as such. It deals with price transparency and so is different in emphasis. I believe that in respect of the UN High Level Panel Report we disagree that the panel's mandate was narrowly focused on the issues that both the European Union and the US point out. We note that some of the EU member States have taken different views on the issue including in the World Health Organization related to transparency of medicine prices.

706. We would also like to address the issue of competition. The paper does not deal with competition *per se*. We would like to point out that the TRIPS Agreement is replete with references to competition. This specific Division has competition in its title. So, essentially, I think that as Members of the WTO we are competent to talk about competition. This is not to say that competition is the only issue on the table. We also thank some of the interventions which focused on the fact that access to medicines is complicated by various factors. I think we could agree. Anyone who reads the Trilateral Study which was issued fully understands that it is a complex landscape. The only purpose of putting this item on the agenda was essentially to focus attention on high medicine prices, and to also highlight the fact that transparency may be one of the main issues that we could use to look at this particular issue.

707. South Africa has been proactive in ensuring that when it comes to the pricing of medicines, all the right policy and regulatory frameworks are in place, including a single price existence which is composed of a basket of various inputs based on purchasing parity of consumers, which is revised from time to time when authorizations are given for medicine as such. We also would like to touch on one of the points raised by the EU in respect of the WHO Essential Medicines List. Many of the medicines on the list are off-patent as correctly indicated. Over the course of time also patented medicines would be added to that list. These medicines remain quite expensive and so one of the issues is that given the fact that these medicines remain expensive they do put pressure on budgets that countries have for health purposes.

708. We also would like to thank Switzerland for their intervention. We believe that prices necessarily imply that the patent exists, but pricing is also relevant in how companies essentially make a decision as to what level of pricing to introduce for that particular product or technology. As we indicate in our paper there are other factors which need to be included in this pricing decision including the fact that some of the research into medicine and high technology is from public funding, and as a result these inputs must be reflected and essentially the savings or support must be passed on in how final pricing methodologies are reached. I also recall the intervention of the United States which indicated that where public money is invested by the United States Government into the development of a product, the government usually insists on some government use license. These

are all things that we have to take into account. I think this is a useful opportunity for us to reflect on the factors that affect access to medicines, one of them being the pricing.

709. We also want to emphasize, as we have throughout this discussion on IP and the public interest, that there is no one magic bullet. We have to ensure that the system works overall. All of us have to do certain things including us developing countries getting our regulatory systems to work, ensuring that we have the right mechanism to invoke flexibilities. We emphasise this fact over and over again, and essentially also to ensure that the right balance is struck between private and public interests as maybe the case when it comes to patents. So from that perspective, I would like to thank delegations for the positive constructive interventions that we heard in this regard.

14.11 World Health Organization

710. The World Health Organization carefully reviewed the communication from South Africa contained in document IP/C/W/659 on Intellectual Property and The Public Interest: R&D Costs and Pricing of Medicines and Health Technologies, and in order to contribute to the debate of the TRIPS Council in relation to this topic we would like to share recent related information and activities from WHO.

711. During the last World Health Assembly in May 2019, WHO members, "Seriously concerned about high prices for some health products, and inequitable access to such products within and among Members, as well as the financial hardship associated with high prices which impede progress towards achieving universal health coverage", approved the so-called "Transparency Resolution", WHA72.8, co-sponsored jointly by more than 20 developed and developing countries (including South Africa), on improving the transparency of markets for medicines, vaccines, and other health products. The Resolution recognizes "that the type of information publicly available on data across the value chain of health products, including prices effectively paid by different actors and costs, vary among Members and that the availability of comparable price information may facilitate efforts towards affordable equitable access to health products". The Transparency Resolution urges members, *inter alia*, to share information on net prices of health products as well as on costs from human subject clinical trials; to facilitate improved public reporting of patent status information and the marketing approval status of health products; and to improve national capacities, including through international cooperation and open and collaborative R&D and production of health products in particular in LMICs.

712. The WHO Secretariat will continue to support members in collecting and analysing information on economic data across the value chain for health products and data for policy development towards achieving universal health coverage and SDGs. We will continue supporting efforts to determine the patent status of health products and promote publicly available user-friendly patent status databases for public health actors and procurement agencies. In the context of WHO's work on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the current week we launched a questionnaire addressed to members, which requires an intersectoral response, in particular from national public health authorities and patent offices, to collect information to facilitate implementation of the prioritized recommendations included in the global strategy. In order to provide information on and an opportunity to ask questions and/or request further clarifications on the completion of the questionnaire, the WHO Secretariat is inviting member State missions covering health and intellectual property to an information session at WHO headquarters on Tuesday, 12 November 2019.

14.12 European Union

713. I would like to thank South Africa and WHO for what they have said and also, I would like to thank other delegates for the points they have raised.

714. When it comes to transparency of the cost of medicines members of the European Union and the EU would agree that we have to provide guaranties and we have to work together so we can boost transparency in the marketplace. But the actual cost of producing medicines is relatively low or basically zero in some cases.

715. As was said by colleagues of WHO, other factors have to be borne in mind such as research and development: these costs are the highest and the most burdensome for the pharmaceutical industry.

716. If we look at the procedure for bringing to market, clinical and pre-clinical tests can take years. Public funding differs between EU Members and differs around the world. Everyone knows that such help, subsidies which vary, are quite often part of the pricing.

717. I would like to add that the communication which was shared by South Africa is very interesting but is something that we also raised during the panel discussion at the UN.

718. A patent gives you a monopoly, gives you an operating monopoly, there is no doubt of that, and a monopoly is allocated to all medicines of the same company. There are medicines, there is development, there is research but out of that research only very few medicines get to market and that costs money. Therefore, there is a transparency cost here because pharmaceutical companies are in a very competitive market and must have return on investment. We cannot leave aside those facts. Those are market facts.

719. We do not think in the EU that we confuse competition policy with this. In the EU, within a single market, competition in the pharmaceutical sector is treated in the same way as for any other sector. We recognize the actual cost of the medicine is something which is very delicate. I did not want you to be confused and let South Africa's communication say what it does not.

15 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

15.1 Dispute Settlement

720. No statements were made under this agenda item.

15.2 IPR-Related Issues in Trade Policy Reviews and the Director-General's Monitoring Reports

15.2.1 WTO Secretariat

721. As on previous occasions, the Secretariat will provide a brief update of the issues related to intellectual property policy that have come up in the most recent Trade Policy Reviews.

722. Since the last TRIPS Council Meeting in June, the Trade Policy Reviews of Canada, North Macedonia, Suriname and Costa Rica have taken place. These reviews have covered a very wide range of intellectual property and related trade policy issues. During these reviews, developed and developing-country Members have continued to actively register their interest in TRIPS-related issues, by addressing specific follow-up questions on current aspects of the IP system of the Member under review. The areas of particular interest shown by Members include:

- Implementation of the TRIPS Agreement;[10]
- Copyrights and related rights;[11]
- Trademark regime;[12]
- Geographical indications;[13]
- Patent regime;[14]
- Protection of plant varieties;[15]

[10] Suriname.
[11] Canada, North Macedonia, Suriname, Costa Rica.
[12] Suriname.
[13] Canada, Costa Rica.
[14] Canada, Costa Rica, Suriname.
[15] Canada.

- Protection of trade secrets;[16]
- Enforcement, online and at the border;[17]
- Implementation of national intellectual property strategies;[18]
- Accession to, and implementation of, WIPO instruments.[19]

723. The Secretariat has also prepared the TRIPS-related sections for the end-year G20 and WTO-wide Director-General's Monitoring Reports, which will be circulated in late November.

724. The section on "Policy Developments in Trade and Intellectual Property" in the Monitoring Reports highlights the national IP strategies being implemented by China, Myanmar and Turkey; as well as the information on developments in domestic legislation and administrative issues submitted for the monitoring exercise by Australia, Brazil, Chile, China, Indonesia, Mauritius, the Philippines, Chinese Taipei, the Kingdom of Saudi Arabia, South Africa, Thailand and Turkey.

16 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

16.1 Bangladesh

725. On the issue of observer status, the delegation of Bangladesh reiterates its position stated in earlier meetings. Bangladesh would like to support the South Centre to be granted observer status to this Council.

16.2 Venezuela, Bolivarian Republic of

726. My delegation maintains its position regarding this agenda item, that is, admitting the South Centre as observer to the TRIPS Council.

16.3 South Africa

727. South Africa would like to reiterate its previous statements in this regard.

16.4 United States of America

728. The United States cannot join the Members seeking to include the South Centre as an observer, either on a permanent or *ad hoc* basis.

729. The United States values the contributions of Members and is satisfied with the current set of *ad hoc* and permanent observers. We do not see a gap that needs filling by adding new observers at this time.

16.5 China

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

17 ANNUAL REPORT

731. No statements were made under this agenda item.

[16] North Macedonia.
[17] Canada, North Macedonia, Costa Rica, Suriname.
[18] Canada, North Macedonia, Costa Rica.
[19] Canada, Costa Rica.

18 OTHER BUSINESS

18.1 Dates for TRIPS Council Meetings in 2020

732. No statements were made under this agenda item.

18.2 Work Programme on Electronic Commerce

18.2.1 Norway

733. First, I like to admit that it is good to be back in the TRIPS Council after 19 years absence.

734. Many of the current discussions circle around the same issues as then. That shows that these issues are of great importance to the Membership.

735. But if it is one single issue that has had a major role in turning my hair grey in those 19 years, it is the Council's lack of addressing the obligation to discuss electronic commerce given to the TRIPS Council by numerous and consecutive Ministerial Conferences. It's been a while since the work programme has been on the agenda for the Council and the mandatory reporting to the General Council has reflected this.

736. The world has changed. The basic principles are still the cornerstones but technological developments have changed the way IPRs are used, misused, shared, stolen and utilized. When consumers buy the right to read an e-book on a tablet it is a far more limited right than buying a book, and the right to stream audio-visual content for listening and viewing normally does not include the right to resell or to distribute that content to others via electronic networks.

737. Norway will therefore thank you for putting this important issue on the agenda for the meeting.

738. Norway looks forward to this discussion and is ready to participate actively in discussions about how the development of the digitalized society affects trade-related intellectual property rights and the pivotal role of IPR in such a society.

18.2.2 South Africa

739. We would echo Norway's intervention in many ways. We do have a mandate and we also have a work programme. South Africa together with India has been active in trying to highlight a certain aspect of this mandate, including an approach to the moratorium. We believe that a more active discussion on these matters would enhance the overall status and understanding of matters that arise out of what we call the fourth industrial revolution. From this perspective, South Africa may put something on the agenda of the next TRIPS Council. I cannot say for certain that this would happen because I may not be here. It would depend on my colleagues who take over from me to continue this particular debate. Also, I would like to thank my colleagues for the support that I have received in the TRIPS Council and specifically from the Secretariat. I really appreciate that and I believe that there is much to talk about.

18.2.3 Mexico

740. I thank the Council for granting the exception which now allows us to include an intervention on this topic.

741. Regarding the outcome of discussions on the draft Review of the Standard for Follow up Formula at the last meeting of CODEX Alimentarius, Mexico is working on a paper that will outline its concerns with respect to the provisions of the TRIPS Agreement, and which it will present at the next meeting.