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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 30 JULY 2020

Chair: H.E. Ambassador Xolelwa Mlumbi-Peter (South Africa)

Addendum

The present document contains the information provided during the Council for TRIPS meeting held on 30 July 2020.

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INDEX OF THE INFORMATION PROVIDED AT THE MEETING OF COUNCIL FOR TRIPS 30 JULY 2020*

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

1 ELECTION OF CHAIRPERSON

1. No statements were made under this agenda item.

2 NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

2.1 WTO Secretariat

2. The Council has received the following notifications from Members since its meeting in February 2020:

Under Article 63.2

3. The European Union has notified

a. Regulations relating to the implementation of the Regulation on the European Union trademark; and

b. a Regulation and a Council Decision relating to the European Union's accession to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.

4. Japan has notified consolidated versions of its Design Act, Patent Act, Trademark Act, and Copyright Act.

5. Mexico has notified its declaration of protection of the denomination of origin "PLUMA".

6. The Kyrgyz Republic has notified Government decrees, regulations and rules relating to traditional knowledge, and to patenting rules for selection achievements, electronic computer programmes and databases.

7. Chinese Taipei has notified its Trade Secrets Act.

8. Canada has notified Bill-13, providing for certain measures in response to COVID-19.

9. Thailand has notified consolidated versions of its Trade Secrets Act, the Copyright Act and the Trademark Act,

10. The Kingdom of Saudi Arabia has notified its amended Copyright Law and related implementing regulations.

11. Hungary has notified a Government decree on public health compulsory licences and transitional rules regarding epidemiological preparedness.

12. Hong Kong, China has notified an amended trademark Ordinance and its National Anthem Ordinance of 2020.

Under Article 69

13. Belize, Qatar, the Kingdom of Saudi Arabia, and Tonga have provided information on contact points for the exchange of information and cooperation on trade in infringing goods under Article 69.

14. Chile has notified a contact point for technical and financial cooperation under Article 67.

15. Let me briefly say that some of the above-mentioned notifications are also included in the list of IP-related COVID-19 measures. This non-exhaustive list of IP related measures is compiled and maintained by the WTO Secretariat from official sources and from Members' inputs. The most recent inputs were received from Greece, Switzerland, and the Russian Federation. It represents an informal situation report and an attempt to provide transparency with respect to measures related to IP taken in the context of the COVID-19 crisis. The list is updated continuously, and the most recent version can always be accessed on the WTO website.

16. Let me also draw your attention to the following two developments in the area of documentation procedures:

a. A new document series has been created for the circulation of Members' reports to the TRIPS Council. The IP/C/R/[MEMBER]/- series from now on comprises reports and reviews submitted by individual Members to the TRIPS Council from 2020 onwards. This includes reports and responses relating to geographical indications (TRIPS Article 24.2), biotechnology patenting and related issues (TRIPS Article 27.3(b)), incentives for technology transfer (TRIPS Article 66.2), and technical cooperation (TRIPS Article 67).

b. The second development relates to the administration of reminders by the Secretariat's Central Registry of Notifications (CRN). The CRN sends out annual reminders to Members identifying unfulfilled annual notification obligations across all WTO agreements. In the context of TRIPS, the notification obligations under Articles 63.2, 67, and 69 - namely to notify legislation, responses to the Checklist of Issues on Enforcement, and information on contact points, are ongoing obligations which require action whenever new legislation enters into force, or when the contact point details change. In light of this, CRN reminders will from now on be sent to all Members covered by these obligations - indicating that these notification obligations apply "as appropriate".

17. By sending such regular reminders, CRN invites Members covered by these provisions to regularly verify that they are up to date with their ongoing notification obligations under TRIPS Article 66.2, Article 67, and Article 69.

2.2 Australia

18. Australia is not listed under this agenda item. We submitted a notification on 24 July, after the agenda was circulated, and I would like to take this opportunity to briefly outline the notification.

19. In response to recommendations in the Productivity Commission's report on its review of the Australian IP system, certain amendments were made to Australia's crown use and compulsory licensing measures. These amendments came into effect on 27 February 2020.

20. Neither of the amendments apply to compulsory licensing for export purposes.

21. The crown use provisions were amended to improve and clarify their operation, specifically to:

a. make it clear that crown use can be invoked for the provision of a service that any Commonwealth, State or Territory Government has the primary responsibility for providing or funding; and

b. require that Governments first seek a negotiated outcome with the patentee, such as a licence to use the patent.

22. The requirement to first attempt to negotiate does not apply in an emergency.

a. if negotiation is unsuccessful, or access to a patented invention is required in an emergency, Ministerial approval for invoking Crown use must be sought.

23. If approved, the patentee must be notified of the reasons for the decision. The reasons must be given to the patentee prior to exploitation under the Crown use provisions, or if an emergency, as soon as practicable.

24. The compulsory licensing provisions were amended to replace the 'reasonable requirements of the public' test with a 'public interest' test when the Federal Court considers an application for a compulsory licence.

a. The court is also required to consider the public interest when specifying the terms of the licence, including remuneration.

2.3 Canada

25. On 25 March, Canada amended its *Patent Act* to expand the authority of the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another specified person to supply a patented invention to the extent necessary to respond to the COVID-19 pandemic. Canada has notified this measure under document IP/N/1/CAN/30. So far, no authorizations have been issued pursuant to this measure.

26. This amendment empowers existing manufacturing capacity to address market failures as necessary; for example, when the patent holder is not in a position to produce the invention for use in Canada or if demand exceeds supply during a health care emergency.

27. These amendments include safeguards to protect the interests of patent holders; for example, including ensuring that a patent holder receives adequate remuneration for the use of the patent and placing limitations on the duration of the authorization.

28. Canada would continue to welcome timely notifications on similar measures taken by other Members as well as concerning any compulsory license authorizations on patented inventions related to COVID-19 before the next meeting of the TRIPS Council.

2.4 European Union

29. The European Union has notified two acts concerning EU accession to the Geneva Act of the Lisbon Agreement. The first act is:

- Regulation (EU) 2019/1753 of the European Parliament and of the Council of 23 October 2019 on the action of the Union following its accession to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications

30. This Regulation ensures the legal framework for effective participation of the EU in the WIPO Lisbon Union after the EU's accession to the Geneva Act. It lays down rules allowing the EU to exercise the rights and to fulfil the obligations laid down in the Geneva Act, on its behalf and on behalf of the Members which ratify or accede to that Act.

31. In particular, it provides that, as a rule, Members may request the European Commission, as the Competent Authority under the Geneva Act, to register in the International Register under the Geneva Act GIs that originate in their territory if these are protected and registered under EU law.

32. The Regulation also sets out a procedure for the assessment of geographical indications (GIs) of third country origin for which protection in the EU under the Geneva Act is sought. Moreover, it contains transitional provisions for appellations of origin originating in EU Members and already registered under the Lisbon Agreement as well as for appellations of origin originating in a third country and registered under the Lisbon Agreement before the accession of the Union to the Geneva Act.

33. The second act is:

- Council Decision (EU) 2019/1754 of 7 October 2019 on the accession of the European Union to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications

34. This Decision of the Council of the European Union contains the Council's authorisation for accession of the EU to the Geneva Act. It also authorises Members to ratify the Geneva Act or accede to it.

35. The EU has also notified a delegated and an implementing regulation on trademarks, which were adopted in 2018 (Delegated Regulation 2018/625 and Implementing Regulation 2018/625). The delegated regulation updates and simplifies EU trademark applications. The implementing regulation updates and replaces implementing rules on trademark applications.

Hungary

36. The notified Government Decree on public health compulsory licences for exploitation within Hungary created the possibility to issue a public health compulsory licence for exploitation within Hungary. The Government Decree laid down the preconditions to issue a compulsory licence in an emergency public health situation, like the current COVID-19 pandemic. The Government Decree implements Art 31 of the TRIPS Agreement. The Government Decree ceased to have effect and its content was incorporated into Hungary's patent law. Hungary notified also another law that amended the mentioned provisions.

2.5 South Africa

37. We thank the Secretariat for the overview of notifications received under this agenda item. As rightly pointed out some of the notifications overlap with the list of verified measures which was published by the Secretariat. South Africa wishes to raise some questions on COVID-related notifications under agenda item 2. We look forward to studying Australia's notification and the short explanation of the amendment. Also, the intervention from Canada has been well noted. We have some further questions regarding Canada's notification. The EU also discussed the notification of Hungary about which we also have some questions. For brevity I will focus only on a few questions and submit the remainder in writing.

Canada: document IP/N/1/CAN/30 (Canada: Laws and Regulations)

a. Does the scope of the amendment allow compulsory licenses to be sought by the Minister of Health for purposes of importing generic versions of patented medical products to respond to public health emergencies?

b. The amendment limits the duration of the compulsory licenses to a maximum of one year. As is now apparent, pandemics and other public health emergencies can go on for much longer, how will Canada address this gap? Can the compulsory licenses be renewed or can the Minister of Health reapply for a new compulsory licenses to cover the same products? Would this not disrupt access during an emergency?

c. Do patent holders have the right to apply for an injunction or any other relief that may halt implementation of the compulsory licenses sought by the Minister of Health?

d. Why has Canada limited the right of a Minister of Health to apply for and be granted a compulsory license only in situations of public health emergencies? How will the Minister of Health address patent challenges in other situations of public health need in Canada?

Hungary: document IP/N/1/HUN/3 (Hungary: Laws and Regulations

38. The TRIPS Agreement reaffirmed by the Doha Declaration on TRIPS and Public Health recognize that each WTO Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. The right to issue compulsory licenses, be it to address public health or any other national concern, should be a common feature in national patent legislation.

a. Why has the Government of Hungary decided to rely on its emergency powers to issue a Government Decree for public health compulsory licenses?

b. Section 1(4) of the Decree states the period for which a public health compulsory license is granted shall not last longer than until 31 March 2021. Given that the COVID-19 challenge is expected to continue for a number of years, and shortages are likely, what other provisions exist in Hungary's patent law that will allow Hungary to issue compulsory or government use licenses to import or manufacture patented medical products?

c. The public health compulsory licenses decree allows exploitation of patented inventions presumably including importing from other countries. How will the opt-out of Hungary as an eligible importing country in connection with the 30 August 2003 and Article 31*bis* mechanism impact the utility of Hungary's public health compulsory license decree?

d. What circumstances informed the Government's decision to terminate the special legal order (State of Danger) on 18 June 2020?

2.6 Chinese Taipei

39. In compliance with Article 63.2 of the TRIPS Agreement, we notified the WTO TRIPS Council of our recent amendments to the Trade Secrets Act in documents IP/N/1/TPKM/26. In brief, the changes are as follows:

a. This amendment introduces a "confidentiality order for prosecutorial investigation" system to strengthen protection of trade secrets during investigation proceedings. A person who violates a confidentiality order shall be liable to imprisonment for a maximum of three years. The new law will prevent trade secret leakage during investigation, increase corporations' willingness to file a lawsuit, and enable prosecutors to effectively and quickly conclude their investigations.

2.7 Thailand

40. Thailand is pleased to inform the TRIPS Council that we have submitted three notifications through the e-TRIPS platform in compliance with Thailand's obligations under Article 63.2 of the TRIPS Agreement. The document reference numbers are IP/N/1/THA/3/Rev.1, IP/N/1/THA/4, and IP/N/1/THA/5. We would like to briefly explain some key amendments in the laws.

41. First, the Trade Secrets Act 2002 was amended in relation to the appointment and the duties of the Trade Secrets Board members and the penalty imposed on the controller of trade secrets and the revealed of facts obtained or known from the performance of work more appropriate in the current situation. The amended provisions came into force on 6 February 2015.

42. Second, the Copyright Act 1994 which was amended as follows:

a. - The Copyright Act (No. 2) B.E. 2558 (2015), which came into force on 4 August 2015, introduced the amendments to the Copyright Act 1994 on provisions related to rights management information (RMI), technological protection measures (TPMs), liability limitation of internet service providers (ISPs), and other provisions with an aim to enhance efficiency of copyright system particularly in the digital environment.

b. - The Copyright Act (No. 3) B.E. 2558 (2015), which came into force on 6 April 2015, introduced the amendments related to the prohibition of, and penalties for, illegal recording of movies in movie theatres (anti-camcording provisions), and copyright exceptions beneficial to disabled persons.

c. - The Copyright Act (No. 4) B.E. 2561 (2018), which came into force on 11 March 2019, introduced the amendments to comply with the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired, or Otherwise Print Disabled.

43. Third, the Trademark Act 1991 which was amended as follows:

a. - The Trademark Act (No. 2) B.E. 2543 (2000), which came into force on 30 June 2000, revised certain aspects of trademark registrability, the cancellation and related procedures, the collection of publication's fee, and the composition, power and duties of the Trademark Board.

b. - The Trademark Act (No. 3) B.E. 2559 (2016), which came into force 28 July 2016, expanded the scope of trademark protection and amended the provisions of the relevant part of this Act to conform with the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol).

44. Thailand will continuously fulfil its TRIPS notification obligation to ensure accessibility and the transparency of our intellectual property system.

2.8 Japan

45. This delegation is pleased to inform the Council that Japan recently amended its Patent Act, Design Act, Trademark Act, and Copyright Act. We would like to take this opportunity to briefly explain some major points of the amendments.

46. Firstly, the Patent Act was amended to enhance the patent litigation system. The amendment enables the ability to determine proportional damages beyond the scope of rights holder's production/sales capacity that are the sum of equivalence for licensing fees. In addition, the amendment clearly states that the court can consider the amount that would be determined if negotiations were made on the premise of patent infringement in calculating the amount of damages for the amount equivalent to the licensing fee. There are similar amendments in the Design and Trademark Acts.

47. Secondly, the Design Act was amended to enhance the design system. The scope of protection is expanded into "graphic images not recorded or displayed on Articles" and "building exterior and interior design". Additionally, the related design system, which allows the registration to be granted for a design even if the design is similar to one the applicant has previously filed an application for, are enhanced to protect designs continuously developed based on one consistent concept. Precisely, related designs can be registered within ten years of the initial principal design application. That had been limited to before the publication of the design bulletin for the principal design which was about eight months from the application of the principal design. In addition, provisions have been reviewed with the aim of consecutively protecting designs that are similar only to related designs. Also, the protection period for design rights are expanded from 20 years from the registration date to 25 years from the application date.

48. Finally, the Copyright Act was amended in order to be compatible with the Beijing Treaty on Audiovisual Performances. In addition, the amended Copyright Act, which introduces the compensation scheme that teachers can use works in online lessons without permission of copyright owners in principle, was to come into effect within three years from the date of promulgation, May 25 2018. However, the Government implemented this Act in this April, a year earlier than initially planned, in order to meet needs for remote education due to COVID-19. The compensation in this fiscal year is free.

49. The Government of Japan will continuously fulfil its obligation to ensure the accessibility and the transparency of the Japanese IP system.

2.9 Saudi Arabia, Kingdom of

50. IP is a key factor for the future development of Saudi Arabia's economy, and Vision 2030 stipulates targets that are directly enabled by IP. In line with this, I would like to inform you that the Kingdom of Saudi Arabia has recently submitted two notifications to the TRIPS Council concerning replacements of Saudi laws that had been notified previously under Article 63.2 of the TRIPS Agreement.

51. Saudi Arabia's Council of Ministers amended the Saudi Copyright Law, introducing two changes:

- First, replacing the Ministry of Culture and Information with Saudi Authority for Intellectual Property; and

- Second, regarding the decision-making function under the Copyright Law, replacing the Minister with the Board of Directors of the Saudi Authority for Intellectual Property. As a result, the Article currently reads: "Decisions of the Committee shall be made by majority vote, which shall be endorsed by the Board of Directors".

52. Thus, the adoption of the decisions issued by the Committee must be approved by the Board of Directors of the Saudi Authority for Intellectual Property, and no longer involve Ministerial approval. The Board is composed of a President and 15 Members of both Government and private sectors.

2.10 Mexico

53. This delegation is pleased to inform the Council for TRIPS that Mexico has issued a general declaration on protection of the appellation of origin "Pluma".

54. The declaration has been notified to the Secretariat and published on the WTO website in document IP/N/1/MEX/20-IP/N/1/MEX/G/9.

55. The general declaration provides for the protection of the appellation of origin "Pluma", in accordance with the Law on Industrial Property, in order to protect coffee products, in particular the fruits of coffee plants of the species Coffee arabica, primarily of the varieties Typica and L. Pluma Hidalgo, which are grown in 30 municipalities in the state of Oaxaca, including the municipality of Pluma Hidalgo.

2.11 Canada

56. Canada will answer South Africa's questions that they will provide in writing. Canada wishes to make clear at this point that the COVID-19 specific measure that we have notified is in addition to Canada's existing compulsory licenses regime. It does not replace the existing regime, t. It is designed to address this particular issue that we had. The notified measure is itself part of the broader set of measures that are otherwise not IP measures that aim at preventing shortages resulting from COVID-19 and demonstrates taking leadership in this regard.

2.12 European Union

57. We would also like to ask the delegation of South Africa to provide the questions in writing and we will provide the most precise answers in writing.

2.13 Hong Kong, China[1]

58. Pursuant to Article 63.2 of the TRIPS Agreement, Hong Kong, China submitted two notifications IP/N/1/HKG/35 and IP/N/1/HKG/36 to the WTO Secretariat on 3 July 2020.

59. The first notification is related to amendments to the Trademark Ordinance with a view to making essential procedural rules for implementing the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks in Hong Kong, China, and empowering local law enforcement agency to enforce the criminal provisions under the Trademark Ordinance.

60. The second notification is related to a consequential amendment to the Trademark Ordinance, following the enactment of the National Anthem Ordinance. The amended law prescribes that a trademark shall not be registered if it consists of or contains the national flag or emblem of China, or the regional flag or emblem of Hong Kong, China.

3 IP MEASURES IN THE CONTEXT OF COVID-19

3.1 South Africa[2]

61. More than 16.5 million cases and 650 thousand deaths of COVID-19 have been confirmed globally. The global community is facing an extraordinary challenge. No country has been spared the devastating effects of COVID-19. The health and human toll are substantial and expected to continue to grow.

62. In this context we recall Resolution of the World Health Assembly WHA 73.1 of 19 May 2020, which recognizes that the COVID-19 pandemic has a disproportionately heavy impact on the poor and the most vulnerable, with repercussions on health and development gains, in particular in low-income countries. It further calls on cooperation between multilateral organizations and other stakeholders and the World Health Organization (WHO) Director General to identify and provide options that respect the provisions of relevant international treaties, including the provisions of the TRIPS Agreement and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health, to be used in scaling up development, manufacturing and distribution capacities needed for transparent, equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the COVID-19 response. South Africa

[1] The delegation of Hong Kong, China requested at the meeting, that for reasons of time, its full statement be included in the record of the meeting. This record may thus contain elements that were not spoken at the meeting.

[2] The delegation of South Africa requested at the meeting, that for reasons of time, its full statement be included in the record of the meeting. This record may thus contain elements that were not spoken at the meeting.

welcomes the launch of the Trilateral Study on Access to Medical Technologies and Innovation but notes it is very thin on the issues related to COVID-19.

63. The list of verified measures prepared by the Secretariat already indicate some steps taken by Members and supplemented by views Members will express during this TRIPS Council meeting and further meetings. A further step in concretizing this commitment is to hold a workshop as requested by the ACP Group which will give Members and other participants an opportunity to further discuss IP challenges with respect to access and to explore approaches to deal with COVID-19 in the context of intellectual property rights.

64. Curbing the pandemic and limiting the social and economic fallout is dependent on an unprecedented timely roll out of sufficient quantities of medical supplies to all countries in need including masks, personal protective equipment, ventilators, diagnostic kits as well as therapeutics and vaccines as they are identified. This requires global solidarity to transfer technology and massively scale-up manufacturing globally. At present there are vast shortages of medical products within a country as well as between developed and developing countries. In light of possible second waves of the coronavirus, countries must take measures to ensure that they are able to restock medical products that will be needed to fight the virus.

65. The WHO estimates that at least 500 million tests are needed over the next 12 months in low- and middle-income countries.[3] Testing if deployed in a timely way could contribute to saving at least nine million lives and avert at least 1.5 billion COVID-19 infections. The challenge with testing is to develop new rapid diagnostic tests and to scale up the production of such reliable, affordable tests to a volume sufficient for all countries to access them. Similar shortages can be seen with respect to personal protective equipment and ventilators. Bloomberg reports that the world demand for ventilators is ten times the current supply capacity.[4] Manufacturing ventilator parts for e.g. using e.g. 3D printing raises a number of intellectual property issues such as patents, industrial design and copyright.

66. The challenge of intellectual property is most apparent in the area of therapeutics. Several of the therapeutics under investigation do have patents granted or pending in many countries. A recent case that has widely been reported is remdesivir, approved in several jurisdictions as preliminary results showed that it shortened the recovery period. Earlier this month, it was reported that Gilead had agreed to supply the United States its projected production for the next three months, raising concern about supply of remdesivir to other countries. Gilead has entered into nine licensing agreements with generic manufacturers from three countries for the supply to 127 countries.[5] These limited, non-transparent exclusive licenses seem to be an attempt to contain competition by creating an oligopoly.[6] Generic manufacturers globally that can contribute to expanding global supply have been excluded. The lack of transparency, and accountability in the present dire times is extremely worrying and dangerous. It is an indicator of the IP and access challenges ahead of us, that the WTO Members need to address effectively and swiftly. On the subject of vaccines, there are already news reports of intellectual property disputes that could hinder the development and production of COVID-19 vaccines.[7] We observe with great apprehension the rush by developed country Members to sign deals to gain preferential access to vaccines, leaving many countries behind. Vaccine nationalism may address short term political demands of a country but drastically falls short of what is required to contain this pandemic. World leaders from the North and South have referred to a vaccine as a global public good, that should be fairly and equitably available globally, leaving no one behind. Now is the time to put it into action.

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[3] WHO COVID-19 ACT Accelerator Technical Update and Virtual Press conference of 26 June 2020 <https://www.who.int/docs/default-source/coronaviruse/transcripts/act-accelerator-technical-update-and-press-briefing-26th-june.docx?sfvrsn=b88700e1_0>

[4] Bloomberg (2020), *World Ventilator Demand Now 10 Times What's Available, Says Maker*, <https://www.bloomberg.com/news/articles/2020-03-25/world-ventilator-demand-now-10-fold- what-s-available-says-maker.>

[5] See <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>

[6] See <https://www.latimes.com/world-nation/story/2020-07-01/gilead-patent-limits-access-to-covid-19-drug-remdesivir>

[7] See <https://twn.my/title2/intellectual_property/info.service/2020/ip200704.htm; https://www.fiercebiotech.com/biotech/moderna-stock-sinks-as-patent-case-spurs-concern-for-covid-19-vaccine>

67. The challenge before us is to produce an effective vaccine to meet the needs of the world population of 7.8 billion in as short a time frame as possible. This will require the sharing of knowledge and technology of successful vaccines so that the widest distribution at lowest cost can be achieved. Even the European Parliament Resolution entitled "The EU's public health strategy post-COVID-19" which was adopted on 10 July 2020 acknowledges its importance as it calls for "maximum sharing of COVID-19 health technology-related knowledge, intellectual property and data to the benefit of all countries in the context of WHO's Technology Access Pool (C-TAP).[8] It also calls for strong support for the WHO's C-TAP, while incorporating collective safeguards in favour of the public regarding public funding, such as transparency, accessibility and affordability clauses and non-exclusive licences for exploitation of final products, in all current and future calls for funding and investment. It further calls for enhanced dialogue with third countries and the issuance of compulsory licences in the event that such countries do not share their vaccines or therapeutic knowledge.[9]

68. In a July 2020 paper, MSF documented how exclusive rights and monopolies granted to pharmaceutical corporations, resulting in high prices and blocking generic competition has had a negative effect on MSF's medical actions in different countries. This has affected that ability of countries to provide access to treatment of HIV/AIDS, tuberculosis, hepatitis C and cancer for patients who need them. Beyond access to pharmaceuticals and biosimilars, the effects of patents have also hindered the introduction of affordable vaccines in developing countries, with the focus on pneumococcal conjugate vaccines (PCV) and human papillomavirus vaccine (HPV).[10] The 'fair shot' report found that the patents increase uncertainty, costs and delays in competition resulting in high prices for low-and-middle income countries. We cannot afford a similar scenario when dealing with COVID-19. In short, we are of the view that the World Trade Organization should be cognizant of IP obstacles across essential medical products needed to contain the pandemic and take urgent steps to address these barriers in a comprehensive manner. The WTO TRIPS Agreement does provide a number of flexibilities that may be utilized by Members to overcome IP obstacles. In anticipation of such barriers, some WTO Members have undertaken urgent changes to national patent legislation to make it easier to issue compulsory licenses. However, there are a number of challenges:

69. Firstly, IP barriers go beyond patents, and often flexibilities in other intellectual property such as industrial designs, copyright and trade secrets is often less understood and implemented nationally.

70. Secondly, developing countries may face legal, technical and institutional challenges in using TRIPS flexibilities. This is especially true for countries that have never utilized flexibilities such as compulsory licenses.

71. Thirdly, when an exporting country is producing under a compulsory license mainly for export, the mechanism established by the 30 August 2003 decision, and later translated into an amendment of the TRIPS Agreement as Article 31*bis*, would be applicable. This mechanism waives the condition in Article 31(f) that a compulsory license should be predominantly for the supply of the domestic market. However, experience in using this mechanism is largely non-existent. In 2006, *Medecins Sans Frontieres* (Doctors without Borders) attempted to use the procedures to export HIV medicines from Canada to Rwanda but it concluded that the mechanism is neither expeditious nor workable. We also note that implementation of the Article 31*bis* mechanism at a national level is rather limited or may not achieve its intended objectives. Further some countries have opted out of using this system as importers, which may pose a challenge to access.

72. Several voluntary initiatives have emerged since the outbreak of COVID-19 including pledges and voluntary licenses. Some of these are commendable, but these are *ad hoc* initiatives, simply inadequate to systematically and comprehensively address IP barriers. IP holders of essential technologies may also decide not to participate in such initiatives.

73. The World Health Organization has launched the COVID-19 Technology Access Pool (C-TAP) calling IP holders to voluntarily issue global non-exclusive licenses or to voluntarily surrender

[8] European Parliament https://www.europarl.europa.eu/doceo/document/TA-9-2020-0205_EN.html.
[9] Ad par. 8.
[10] The full text of MSF report 'A fair shot for vaccine affordability: understanding and addressing the effects of patents on access to new vaccines' is available from: <https://msfaccess.org/fair-shot-vaccine-affordability>

intellectual property rights, to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world. However, to date no company has committed to doing so. Instead limited, exclusive and often non-transparent voluntary licensing seems to be the preferred approached and these are insufficient to address the needs of the current COVID-19 pandemic.

74. "Business as usual" approaches are simply inadequate to tackle COVID-19. We need to consider new bold measures that will comprehensively and expeditiously address IP challenges. The following approaches can be considered:

75. Members must explore international collaborations and binding commitments to facilitate the open sharing and right to use technologies, know-how, data and global non-exclusive rights to use and produce COVID-19 medical products.

76. Members must take policy and legislative measures to ensure that patents and other intellectual property do not erect barriers to access to medicines, diagnostics, vaccines and medical supplies and devices. This includes addressing evergreening of patents by restricting the grant of secondary patents on known medicines and excluding from patentability second medical uses as being mere methods of treatment in terms of Article 27 of the TRIPS Agreement. Members are encouraged to take measures to facilitate the local manufacturing or import of essential medical supplies, devices or technologies including diagnostics, medicines and vaccines.

3.2 Nigeria

77. My delegation will like to thank you, Chair, for convening this very important meeting and we would like to extend our thanks to the Secretariat for its timely compilation of the various measures regarding trade-related intellectual property rights in the context of COVID-19, at these difficult uncertain times.

78. Allow me to highlight the effects of the pandemic from our national standpoint. COVID-19 is a supply chain and demand shock. My Government is introducing fiscal and monetary measures to stabilize demand and prevent mass business failure and job loss as is the case with many governments. Our MSMEs and other firms are currently adversely affected by a trade finance shock. Developing countries like Nigeria who lack the capacity to produce the required COVID-19-related medical supplies and equipment depend largely on importation to be able to meet demand. Given the unpredictability of this COVID-19 virus, this pandemic may remain with us for a very long time as there are no effective vaccines or cure as of yet. In order to rise to these challenges, countries should be allowed to tap into each other's growth as this would also go a long way in improving prospects for a global recovery. Similarly, the invocation of TRIPS flexibilities can certainly provide certain subsidies to local manufacturing industries.

79. Furthermore, access to medicines has been a long-standing issue for our country due to the high cost of patented drugs, and this is heightened by the COVID-19 pandemic. We call for deeper and honest collaboration among countries and the relevant international organizations as was agreed at the World Health Assembly to fight this common problem.

80. We note that the link provided under this agenda item mostly contains among other things, measures taken by countries to facilitate IP processes. However, there is need for continuous collaboration among all Members in order to cushion the negative effects of the pandemic. We encourage that; while the focus by most Members seems to be to develop an adequate response mechanism, we should not lose sight of the need to intensify in a parallel process our efforts to develop an effective vaccine and to increase access to medicines and COVID-related equipment, especially in more vulnerable countries. We may wish to recall the recent resolution on COVID-19 adopted by the WHA which, among other things, calls for the intensification of efforts to control the pandemic, and for equitable access to and fair distribution of all essential health technologies and products to combat the virus. It also calls for an independent and comprehensive evaluation of the global response, including, but not limited to, the World Health Organization's performance.

81. As we have mentioned in our previous information provided, we underscore that the mandate of the TRIPS Council includes the monitoring of the operation of the Agreement, and to ensure the balance of rights. We therefore urge the TRIPS Council to play a critical role on intensifying its trilateral cooperation with the WHO and World Intellectual Property Organization on intellectual

property and public health in order to promote innovation and access to health technologies not undermining the moral right to benefit sharing.

3.3 Brazil

82. Brazil's most relevant COVID-19 measures related to intellectual property rights are listed on the World Trade Organization's compilation, available on its website.

83. These are two initiatives undertaken by our intellectual property office.

a. The first refers to the creation of a COVID-19 technology landscape observatory. The aim is to provide innovators with information on existing technologies that might be useful for preventing, diagnosing or treating COVID-19.

b. The second measure listed is Brazil's intellectual property office decision to prioritize the examination of patent applications related to the fight against COVID-19.

84. Both initiatives can also be found in the WIPO COVID-19 IP Policy Tracker, where other information on the operation of our intellectual property office during the pandemic is available.

3.4 China

85. At the informal session held on 19 June 2020, Members recognized the importance of IP-related measures in response to COVID-19 and the unique role the TRIPS Council could play in this regard. In the complied list of IP measures in the context of COVID-19, China has confirmed two measures.

86. The first one is the Notice on Time Limits for Handling Affairs Regarding Patents, Trademarks and Layout-Designs of Integrated Circuits under the impact of the COVID-19 pandemic, which has clarified and provided relief measures for parties exceeding the time limits for handling IP-related affairs. This Notice applies to all stakeholders across all countries and regions affected by the COVID-19 pandemic. The purpose is to effectively protect their legitimate rights and interests.

87. The second measure, the one my presentation focuses on, is the Information Sharing Platform for Patents on Pandemic Prevention against COVID-19, which has been developed by the China Patent Information Centre in February 2020 under the guidance of the China National Intellectual Property Administration (CNIPA). The Platform has provided professional and public welfare patent information assistance and services for stakeholders to carry on research related to COVID-19 pandemic prevention and control. It has also made contributions to strengthening international cooperation and information sharing by means of providing comprehensive and technical patent information related to COVID-19.

88. As you can see, this is the website and home page of the Platform (https://ncp.patentstar.cn/en).

89. The Platform is built on the basis of the China Patent Research System (CPRS), which was also developed by the China Patent Information Centre. We selected more than 7000 patent documents in the key areas of technological innovation related to "fighting against COVID-19" from the database of CPRS. According to their technical relevancy and degree of importance, these patent documents are divided into nine first-level branches, 35 second-level branches and 78 third-level branches. They cover the wide spectrum of technical fields including treatment medicines, prophylactic medicines, detection and diagnosis reagents, medical instruments, etc.

90. When you access this Platform, you will find its bilingual interfaces: one is Chinese and the other is English. Take this document as an example. The Platform provides detailed information on the patent documents, such as its bibliographic data, full-text, claims, specification, and legal status. It is also possible to download the file.

91. The Platform integrates functions of retrieval, online translation, communication feedback, etc. The database affiliated to the Platform has been updated regularly. The Platform can be accessed for free without prior registration. The statistics show that, as of 26 July 2020, the Platform has received visitors from more than 60 countries and regions with 238,148 hits in total.

92. If you have any further questions or would like to get more information about the Platform, please contact us through the contact information shown on the screen (email: fuwubu@cnpat.com.cn, phone: +86-10-61073090).

3.5 Chile

93. Once again, Chile wishes to thank the Secretariat for preparing a compilation of the measures notified to the World Trade Organization in relation to the pandemic. We consider it extremely useful for Members to notify the various measures introduced, as this enables them to share their experiences while helping other Members that are assessing potential measures to tackle the pandemic. Chile's IP office has taken measures to make deadlines more flexible, and my delegation hope that the Secretariat will keep the list of measures up to date.

3.6 India

94. As visible from various interventions, a number of country Members, both developed and developing, have adopted measures to enable governments to overcome IP barriers in case they constrain access to the goods required for handling the COVID-19 pandemic.

95. The rising incidence of COVID-19 requires all countries, particularly developing and least developed countries which are disproportionately affected by the pandemic, to be able to procure and/or manufacture products required for diagnosis, treatment and prevention of COVID-19. Intellectual property rights over such products can constrain countries' ability to rapidly procure, produce and supply such goods at the required scale at affordable prices.

96. The COVID-19 crisis is a powerful reminder of our inter-connectedness, and the need for a coordinated, global strategy to overcome this unprecedented global public health crisis. No country is reliably insulated from this highly contagious virus, as long as it persists anywhere in the world. While the disease has no preventive vaccines at the moment, more than 100 candidate vaccines are in various stages of development. Similarly, many medicines are being tried for treating this disease. Though a safe and effective vaccine may still be few months away, countries are already competing to lock in assured access, which may drive up prices and crowd out others who may find it difficult to access it at affordable prices.

97. WTO Members need to work together in the TRIPS Council to ensure that IP rights do not block access to critical technology required for rapid scaling up and augmenting the manufacturing capacity for medicines, vaccines, equipment and treatments required for an effective response to COVID-19. In this regard, we also support the suggestion by the ACP Group for a workshop on IP and COVID-19.

3.7 El Salvador

98. With regard to information concerning the COVID-19 pandemic, we would like to thank the Secretariat for all its efforts to make relevant information available to Members. El Salvador has not taken any specific emergency measures pertaining to intellectual property, however, the running of our National Intellectual Property Office was affected by the general suspension of terms and deadlines because of the closure of Government offices. This information was included on the World Intellectual Property Organization's COVID-19 IP Policy Tracker webpage, a link to which has also been included on the World Trade Organization's website. We would like to report that the Decree on the state of emergency in the country expired on 15 July 2020, which meant that terms and deadlines resumed as of 16 June 2020. On the same date, the Office's intellectual property services, including the processing of applications, also resumed under special conditions. We will shortly be sending this information in writing to the WIPO Secretariat, so that it can update its important COVID-19 IP Policy Tracker tool.

3.8 Russian Federation

99. My delegation supports the inclusion of this topic to the Council agenda, and thanks South Africa for this initiative. In the context of the pandemic it is important to have an open, transparent and balanced discussion of IP measures related to the pandemic in our Council. The Russian Federation

thanks the Secretariat for establishing and maintaining the dedicated web resource. It is a very useful and easy to use instrument for all Members.

100. We would like to share with Members some of the measures taken by the Government of the Russian Federation and the Russian Federal Services for Intellectual Property related to the COVID-19 situation.

101. The first measure was the creation of a special information section in the official internet site of the Russian Federal Institute for Intellectual Property, which contains information on patents relevant in the context of a pandemic (patent documents submitted by both domestic and foreign right holders).

102. The second was the creation of a special news section on the official internet site of the Russian Federal Service for Intellectual Property "Patent of the week" to promote inventions which represent technical solutions related to the fight against COVID-19.

103. The third was the Decision of the Russian Federal Service for Intellectual Property on accelerated consideration of applications for inventions and utility models in the field of technologies for combating viruses and associated diseases (pneumonia) without charging an additional fee.

104. During the period from 15 April to 17 May, a system of full electronic interaction was applied between the Russian Federal Service for Intellectual Property and applicants.

105. The fifth is under Government Resolution of 20 June 2020, time limits for the applicant's opportunity to perform actions related to the legal protection of intellectual property (including those related to the payment of patent and other fees) was extended at the request of the applicant until 31 December 2020.

3.9 Indonesia

106. We would like to thank the delegation of South Africa for bringing this agenda item and would like to support the statement made by the delegation of South Africa.

107. We also would like to thank the Secretariat for providing important updates on Members' measures related to trade and intellectual property rights in relation to COVID-19. We see this as a positive contribution which shares good practices in providing transparency and predictability.

108. We believe that the COVID-19 pandemic warrants more specific information on Members' measures related to flexibilities under the TRIPS Agreement. Whether there are possibilities for the Secretariat to provide more updates and information in this section, we believe it would be beneficial for Members.

109. In addition, we understand that the TRIPS Agreement together with the TRIPS Council could play an important role in assisting access to technology, medical equipment, therapeutics, and vaccines for COVID-19 could be available in a timely, equitable and affordable manner.

110. Hence, we believe that the work of this Council is more crucial than ever to enhance cooperation with other international organizations and provide a better understanding to its Members on the importance of cooperation and flexibilities in TRIPS Agreement, including through workshops or other means available that may be undertaken by this Council.

3.10 Ecuador

111. Ecuador wishes to report on the work carried out in relation to intellectual property measures adopted in the context of the COVID-19 pandemic.

112. Through the National Intellectual Rights Service (SENADI), Ecuador has set up a website providing information on technologies used to treat and prevent COVID-19.

113. The aforementioned site contains: Government measures and official information issued by national bodies within their areas of competence; and details concerning the health measures taken following the declaration of a state of emergency in Ecuador.

114. It also includes information generated at the international level regarding the pandemic, which has been sourced from information sharing platforms and technological bulletins prepared by international bodies and national intellectual property offices.

115. Ecuador has also been involved in preparing the PROSUR Bulletin on Patents in the Public Domain for Technologies to Combat COVID-19.

116. This information is included in the list of intellectual property measures in the context of COVID-19 drawn up by the Secretariat.

117. SENADI prepared an Information Bulletin on patents related to COVID-19, which contains useful information related to technologies to fight COVID-19.

3.11 United States of America

118. With respect to general comments on IP measures and COVID-19, intellectual property encourages innovation, incentivizes research and development, and manufacturing and distribution. These core features of intellectual property are necessary for the global community to find and develop treatments and cures for this deadly pandemic and to support economic recovery.

119. We have the shared objective of helping to ensure the swift delivery of potential COVID-19 therapeutics and vaccines around the globe. We believe that facilitating incentives for innovation and competition to develop, test, and produce safe and effective therapeutics and vaccines for the COVID-19 response, including by respecting intellectual property rights, and supporting industry-led collaboration and voluntary knowledge sharing, will best achieve our shared objective.

120. As we have stated in past discussions, IP is an important piece, but ultimately only one piece of addressing the issue of access to any potential therapy. We believe that IP has not been an obstacle in addressing the pandemic but rather has motivated global efforts to find treatments and cures. Limits to manufacturing capacities and supply chain issues, for example, are of much greater concern, especially for vaccines, given the need to provide access to the entire global population. We also must be concerned about the pandemic creating the opportunity for the increase of counterfeit COVID-19 pharmaceuticals, which are in and of themselves a threat to health and safety. In fact, the perspective that IP is a barrier to access to medicines is often voiced by governments that have significant barriers like taxes and tariffs in places that affect access.

121. Where intellectual property rights exist, they can be licensed to companies around the world to scale up manufacturing. But if the time needed to get the required regulatory approvals is too long, and other barriers make the cost of products too high, the raw materials or labour needed are unavailable, or the market is flooded with counterfeit goods, then safe and effective access to needed treatments and equipment would be affected.

122. With respect to United States Patent and Trademark Office (USPTO) relief and initiatives due to COVID-19 noted on the WTO website, and as noted in the June informal, the USPTO considers the effects of coronavirus to be an "extraordinary situation" for affected patent and trademark applicants, patentees, re-examination parties, and trademark owners. Therefore, it has announced certain relief in the form of extended deadlines, a new prioritized patent examination pilot programme for smaller applicants for COVID-19-related treatments, and resources offered to applicants as the COVID-19 situation continues. The USPTO also announced a COVID-19 prioritized trademark examination programme for certain medical products and services.

123. For example, the USPTO launched the COVID-19 Response Resource Center to provide improved access to USPTO initiatives, programmes, and other helpful IP-related information regarding the COVID-19 outbreak, including links for consumers and healthcare workers to report COVID-19-related counterfeiting and fraud to various regulatory and law enforcement agencies, as well as tips for identifying counterfeit products.

124. In addition, the USPTO has launched Patents 4 Partnerships, which is an IP marketplace platform for licensing opportunities for patent owners who want to license their IP rights to individuals and businesses who can turn those rights into solutions to address COVID-19.

125. Further information on these measures can be found on the World Trade Organization webpage and World Intellectual Property Organization COVID-19 IP Policy Tracker.

126. The USPTO has also, with other US Government agencies, launched virtual capacity building programmes for customs, police, health regulators, prosecutors and judges focused on combatting counterfeit and fraudulent goods related to COVID-19. These goods include personal protective equipment (PPE), face masks, disinfectants, hand sanitizer, test kits and medicine.

127. With respect to a workshop request, the situation of COVID-19 is rapidly changing. Before a decision can be made on this matter, it is important to consider the intended audience, the topics, the necessary expertise, and the objective of such a web-based meeting.

3.12 European Union

128. It is clear that broad and equitable access to existing and new treatments, and ultimately vaccines, will be key to tackle the present public health crisis, including for developing countries that have no production capacities or more limited financial resources. The European Union will provide more comments on this crucial issue under agenda item 14.

129. The EU notified two IP measures that were taken in the context of the COVID-19 pandemic. Measures were also notified by Germany, Hungary, Italy and Greece.

130. The European Union Intellectual Property Office had extended the deadlines for trademark and design matters. This decision concerned all time limits in each proceeding before the EUIPO that would have expired between 9 March and 30 April 2020.

131. The European Committee for Standardization and the European Committee for Electrotechnical Standardization, in collaboration with their Members, agreed to make freely available certain copyrighted European standards for certain medical devices and personal protective equipment.

Germany

132. An amendment to the German Act on the Prevention and Control of Infectious Diseases in Humans granted the German Parliament the competence to determine the existence of an "epidemic situation of national significance". In such a situation, the Federal Ministry for Health (instead of the Cabinet) is authorized to issue orders under the German Patent Act, allowing faster proceedings.

Italy

133. The Italian Patent and Trademark Office has extended the deadlines for administrative proceedings for trademarks, patents, designs and models.

Greece

134. Greece also notified measures related to time limits in IPR administrative procedures.

Hungary

135. Hungary notified its new legislation on compulsory licenses also under the COVID-19 measures.

136. As the crisis persists, the situation is dynamic and additional notifications can be expected, especially as regards deadlines for administrative proceedings related to intellectual property rights.

3.13 Australia

137. Consistent with the 18 May WHA resolution, Australia recognizes the need for universal, timely, and equitable access to essential health technologies and products consistent with the

TRIPS Agreement. Australia stresses the vital role of IP in incentivizing the often costly and timely development of important health products, including vaccines. In this time of crisis, the TRIPS Agreement should support quick, fair, predictable and implementable access arrangements to vital health products. We recognize the need for all Members to understand their rights and obligations under the TRIPS Agreement, including its flexibilities. To this end, we support the provision of information to Members regarding key articles of the Agreement. It is our view that a harmonious, well-functioning and clearly understood international IP framework, underpinned by the TRIPS Agreement and the rights of IP holders, is crucial to ensuring that Members can address the challenges posed by COVID-19.

138. We support efforts by the TRIPS Secretariat to increase transparency around best practices during these unprecedented times. We note the World Intellectual Property Organization has established a Policy Tracker to monitor IP-related relief measures introduced by IP offices across the world.

Australia's IP-related measures

139. On 22 April 2020, IP Australia put in place a streamlined process to provide extensions of time to assist customers impacted by the COVID-19 outbreak. Under the streamlined process, extensions of time of up to three months are available free of charge. Customers can simply tick a box in IP Australia's eServices system to declare that they are unable to meet a deadline due to disruptions from the COVID-19 pandemic. No further documents need to be uploaded and the extension of time fee will be automatically waived.

140. The relief measures will be continued until at least 31 August 2020. Customers will be provided with at least one week's notice prior to the measures ceasing.

141. These streamlined, free extensions apply to most of IP Australia's fees but not to renewals.

142. Around 1500 requests for extensions of time were received through eServices from 22 April 2020 to 21 July 2020 (1204 trademarks, 255 patents, 18 designs). Most requests have been granted with some still under consideration.

143. A trademark service that provides free support and assistance for businesses impacted by the COVID-19 pandemic has also been established. The service provides information about trademark registration in the current environment. Our assistance does not guarantee registration of their trademark nor does it offer business or legal advice. For business and legal advice, customers will continue to be encouraged to contact an intellectual property attorney or a business advisor.

3.14 Switzerland

144. As a great supporter of transparency, Switzerland would like to thank the Secretariat for this compilation of measures.

145. Switzerland recently sent an update to the WTO Secretariat, informing that the premises of its IP Office are open again for visitors since early June. We thank the WTO Secretariat for updating the respective table on its website accordingly.

146. Switzerland attaches great importance to questions related to access to medicines, in particular in times of a crisis. In this respect, we believe that cooperation is important and that a voluntary approach is most effective. I will, however, come back on this in more detail under agenda item 14.

3.15 South Africa

147. This is just a very quick response to some of the issues that have been raised and then just a request to have this agenda item stand over our next meeting which is scheduled for October. South Africa attaches high importance to the protection of intellectual property rights and from this point of view, intellectual property rights are important in creating the right incentives for rights holders to benefit the right level of protection is something which is specified by the TRIPS Agreement.

148. We also have to understand that when right holders exercise these particular rights, they have to respect various parameters in the TRIPS Agreement as recognized generally in IP systems worldwide. I want to remind colleagues that Article 7 of the TRIPS Agreement addresses this issue. It reads that "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

149. In this context, we raise the possibility of IP rights being a barrier to access. We welcome the intervention by the United States and recognize the importance of the private sector in ensuring that innovative solutions are found to this pandemic. But it is not only the private sector which guarantees success in this regard. We have seen massive financial support from governments to develop various technologies and now, for example, vaccines for COVID-19. We have seen earlier in July 2020 that a private company, Gilead, had agreed to supply the United States for a projected production for the next three years of a drug called remdesivir. This raises concern about its supply to other countries. Gilead has entered into nine licensing agreements with generic manufacturers of three countries to supply 127 other countries. These limited non-transparent exclusive licenses seem to be an attempt to contain competition by creating an oligopoly. Generic manufacturers globally that can contribute to expanding global supply have been excluded. The lack of transparency and accountability in the present dire times is extremely worrying and dangerous. It is an indicator that if IP and access challenges ahead of us are not addressed, many WTO Members would fall short of the requirement to create the right conditions for access, products and technologies to address the COVID-19 pandemic.

150. On this basis, I ask that the discussion of this particular issue be continued and be held over to the next TRIPS Council meeting in October.

3.16 United States of America

151. The United States would like to comment concerning South Africa's request that this agenda item be held over to the next meeting in October. The U.S. would ask whether this would be an *ad-hoc* agenda item for the TRIPS meeting, and accompanied by detailed information, per the rules of procedure, for the fall meeting.

4 REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

152. No statements were made under this agenda item.

5 REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

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

7 PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

7.1 Brazil

153. Brazil is taking the floor to restate its position in this matter.

154. We remain convinced that the TRIPS Agreement should be amended to include a disclosure requirement of origin of genetic resources in patent applications.

155. We believe that such amendment would allow for a harmonious legal coexistence between the provisions related to the acquisition of intellectual property rights (especially in relation to patents) of the TRIPS Agreement and the obligations of the Convention on Biological Diversity (CBD).

156. We would also like to inform that the Nagoya Protocol on Access and Benefit-sharing was recently approved in Brazil's Chamber of Deputies and should soon be analysed by our Senate.

157. The imminent conclusion of Brazil's accession to the Nagoya Protocol reinforces the need, from our perspective, of a solution that leaves no doubt or grey areas about the compatibility and complementarity between of the two instruments.

7.2 Tanzania on behalf of the African Group

158. Our intervention will be in respect of agenda items 5, 6, and 7. The African Group would like to reiterate its long-standing view and position regarding the inseparable relationship between TRIPS Agreement and the Convention on Biological Diversity, and our call for the TRIPS Council to cooperate with CBD Secretariat, in order for the TRIPS Agreement to remain relevant and meaningful, particularly for developing countries.

159. Also, the African Group would like to reiterate the following:

a. TRIPS Agreement must be reviewed to take into consideration the need for protection of traditional knowledge and folklore as provided by Art 27.3 (B).

b. The Agreement needs to ensure the benefits to be shared between patent holders and the custodians/ original owners of genetic resources and traditional knowledge.

c. The Agreement should state clearly the obligations of Members in ensuring their legislations and state measures to prohibit misappropriation of genetic resources and traditional knowledge.

d. Article 29 of the TRIPS Agreement could be amended to include a mandatory equitable sharing and disclosure requirement of sources of genetic resources and traditional knowledge involved in the claimed invention.

160. Therefore, the African Group would like to urge Members to get back into discussion and particularly in considering documents TN/C/W/52 and TN/C/W/59 which had attracted significant support of Members from diverse configurations and backgrounds which can serve well as a basis of our discussion going forward. Therefore, we urge the TRIPS Council to collaborate with regional and international organizations such as the CBD Secretariat, to remain relevant to its Members.

7.3 Bangladesh

161. On agenda items 5, 6, and 7, the position of Bangladesh has not changed. In this regard, to avoid repetition, I refer to my delegation's statement made at the TRIPS Council's meeting on 6 February 2020.

162. Bangladesh stands ready to engage constructively with Members.

7.4 South Africa

163. It has become a practice to address the three agenda items together under the rubric of the 'Triplets'. However, in this discussion we often lose the relative importance of the individual components making up the 'Triplets'. The Doha Ministerial Declaration instructed the TRIPS Council as part of its work programme to review Article 27.3(b) as well as to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore. These are legitimate outstanding implementation issues which remain an integral part of the Doha round single undertaking. In recent times Paragraph 31 of the Nairobi Ministerial Declaration (WT/MIN(15)/DEC) reaffirmed the strong commitment of all Members to advance the negotiating on the TRIPS issues under the work programme of the Doha Ministerial Declaration.

164. South Africa believes that the debate in respect of the Article 27.3(b) is not a static one. South Africa requires disclosure of the use traditional knowledge or biological resources in patent applications under Sections 30 (3A) of the *Patents Act No. 37 of 1952* as amended by *Act No. 20 of 2005.* Despite this requirement and various legislative approaches to curb biopiracy, the problem continues to grow. In the absence of an internationally agreed and enforcement system, as applicable under the TRIPS Agreement, national disclosure requirements are of limited effect due to the territorial application of intellectual property rights.

165. South Africa is a non-examining patent country; any complete patent application that is filed and meets with the formal requirements (fees and correct forms) of the Patents Act will therefore be granted. The practice of non-examination gives rise to the potential of abuse, as patentees count their 'rights' safe in the knowledge that the general public does not understand the concept of non-examination and that IP litigation is expensive and time consuming. Between January 2005 and July 2015, 40,131 patents originating from all over the world were registered in South Africa; only 4064 of those patents have a South African origin. We are now attempting to fix this by introducing formal examination as envisaged in our IP Policy. The IP Policy sets out a range of proposals relating to key aspects of patent law that have an impact not only on public health but more broadly. In addition to substantive search and examination, IP Policy addresses the following issues (amongst others) - patent oppositions, patentability criteria, parallel importation, exceptions and compulsory licences. The South African patent landscape is characterized by the easy grant of patents of dubious quality and value, as well as the enforcement of a legal framework that appears to be heavily skewed in favour of patentees. What this means in practice is that in exchange for very little, market exclusivity is easily granted, and maintained, ordinarily at a high cost to society.

166. In respect of the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge, a large group of WTO Members has 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 to the TRIPS Agreement as set out in document TN/C/W/59.

167. In line with our previous information provided, it would be useful for the CBD Secretariat to brief the TRIPS Council on the CBD and other implementation issues under the Nagoya Protocol as well as any new developments.

168. We wish to raise once more the issue of the update of 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. It would be appropriate for the Secretariat to update the information contained in these notes in a neutral manner to further facilitate discussions among Members.

7.5 Zimbabwe

169. The Government of Zimbabwe reiterates its previous information provided on this agenda item. As a signatory to the Convention on Biodiversity, Zimbabwe attaches great importance to its international obligations under the CBD. We join other delegations in calling for the harmonisation of the TRIPS Agreement to the CBD as we are of the view that the TRIPS Agreement does not prevent a person from claiming patent rights on an invention based on a genetic resource or traditional knowledge.

170. Recalling Paragraph 19 of the Doha Ministerial Declaration of 2001, and reiterating that Section 33 of the Constitution of Zimbabwe inculcates a right to culture for our people, it 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."

171. 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, the TRIPS Agreement does not require patent applicants to disclose origin of GR and TK used in a claimed invention.

172. It is therefore our considered declaration that the TRIPS Agreement be amended to introduce for a mandatory disclosure requirement 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 (WIPO) is redundant as none of the WIPO treaties and discussions deal with trade-related aspects of intellectual property.

173. The delegation of Zimbabwe has noted that WIPO has recently published a study entitled, "Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions." We propose that this Council consider inviting WIPO to brief Members on its findings as this and other studies by the Organisation could benefit us immensely in our discussions.

7.6 China

174. China's position remains unchanged in two joint proposals TN/C/W/52 and TN/C/W/59. We believe that benefit sharing solely based on contractual terms and establishing a database on genetic resources are not sufficient protection measures. Instead, prior informed consent to access and fair and equitable benefit sharing ensure better protection for genetic resources.

175. I also recall three procedural suggestions made by my delegation to the TRIPS Council meeting in February 2020.

7.7 India

176. We recall our detailed interventions on these long-standing agenda items in the previous TRIPS Council meetings and reiterate the need for an international enforceable regime to end the misappropriation of genetic resources and traditional knowledge. The TRIPS-CBD linkage is important for all countries as it seeks to address biopiracy. We need to move forward in our discussions on these three mandated issues, namely, the TRIPS-CBD linkage, GI Register and GI Extension based on modalities contained in document TN/C/W/52.

177. Paragraph 19 of the Doha Ministerial Declaration mandates us to examine the relationship between the TRIPS Agreement and the CBD, as well as the protection of traditional knowledge and folklore. The TRIPS Council has regrettably failed to fulfil this mandate for almost 20 years now.

178. India would also like to reaffirm that the TRIPS Council is the appropriate forum to discuss this issue due to the fact that much of the misappropriation is a consequence of trade, and lack of legal enforceability of an outcome through the WIPO IGC process. It is unfortunate that the same countries who pressed upon the discussion of IP issues in WTO at one time are now unwilling to engage in WTO on an issue of critical importance to developing countries and showing us the door to WIPO.

179. We also support a briefing by the CBD Secretariat on the latest developments in the implementation of the Nagoya Protocol and updating of three factual briefs by the Secretariat on these issues.

7.8 Nigeria

180. Our intervention will be in respect of agenda items 6 and 7.

181. I would want to recall previous information provided by Nigeria on these subject matters and we reiterate that the need for the mutual supportiveness of the TRIPS Agreement and the Convention on Biological Diversity cannot be over emphasized. Enhanced corporation of the TRIPS Agreement and other relevant international organizations and international instruments remain a basic principle of the TRIPS Agreement. We are in support of the harmonization of the TRIPS Agreement in other to be consistent with the CBD.

182. Traditional communities continue to be negatively impacted as a result of the illegal exploitation of their biological resources or associated traditional knowledge. My delegation is of the view that 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 sustainable use in other to conserve biological diversity, and must show evidence of a fair and equitable sharing of benefits, as are the principles of the CBD. In other to achieve this, we advocate for the creation of a database and registration system to be maintained by the users of this genetic resources, traditional knowledge and folklore and which therefore contain valuable information as to the origin, source and contact details of the inventor that is accessible to the world. This will go a long way in upholding transparency and build trust among WTO Members.

183. As has been proposed in past African Group proposals, Article 29 of the TRIPS Agreement ought to be given more force to include traceability and a prior informed consent from the source, in respect of any product manufactured 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 should be made in exchange for patent protection. We call upon our trade partners who are users of the GRTKF to foster strategic collaborations with

relevant countries towards developing a mechanism where the patent applicants in their respective countries will be mandated to disclose the actual source of any genetic material or TK utilized by them during the manufacturing of their products. This will go a long way in the administration of benefit sharing with the original owners.

184. The full disclosure requirement will not only be beneficial to Nigeria in terms of access to benefit sharing, but it will also, on the other hand, improve the quality of our substantive patent examination, which will in turn ensure the validity of patent grants in our country.

185. Finally, we urge Members to consider the collaborating with each other both regionally and internationally, in other to achieve this mutually beneficial goal.

7.9 Kenya

186. The protection of biological resources, traditional knowledge and folklore is an important developmental issue and of particular interest to many Members. In this regard, Kenya fully supports the examination of the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), as the TRIPS Council was mandated by Paragraph 19 of the Doha Ministerial Declaration.

187. Kenya believes that TRIPS Agreement and the CBD should be implemented in a manner that is mutually supportive and does not run counter to their respective objectives. We therefore consider that the TRIPS Agreement should be amended to incorporate a provision for Members to require that a patent application involving the utilization of genetic resources and/or associated traditional knowledge, should disclose the source and country of origin of the biological resources and the associated traditional knowledge, in accordance with the CBD. In addition, there should also be a requirement of evidence of prior consent and equitable benefit sharing under the relevant national law.

188. We believe that to develop a sound and viable technological base in developing countries and LDCs, any utilization of local genetic resources must be in a sustainable manner in order to conserve biological diversity.

189. Finally, Kenya continues to encourage the engagement of the Director-General in his mandated consultative process on the relationship between the TRIPS Agreement and the CBD. We look forward to the outcome of these consultations and encourage other Members to engage constructively in the process, considering that this issue is of high priority for developing countries, since they are often victims of bio-piracy. These dishonest practices must be combated effectively to facilitate the sharing of the benefits gained from the exploitation of such resources.

7.10 Switzerland

190. In the interest of time, I will not repeat Switzerland's position that has not changed. I hereby refer to previous statement of my delegation under these three agenda items.

7.11 Indonesia

191. My delegation would like to reaffirm its position on the great importance on the negotiation of relationship between TRIPS Agreement and the Convention on Biological Diversity, as well as the protection of traditional knowledge and folklore.

192. We also reiterate our position that Article 27.3(b) and Article 29 of the TRIPS Agreement does 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 omission provides a room for misappropriation and misuse of genetic resources and traditional knowledge that, in the end, defeat the purpose and objective of the CBD and the Nagoya Protocol.

193. Substantive discussions of this issue should not be delayed simply because it is being negotiated in other fora, such as WIPO. The discussions to take place in this Council should reinforce what has already been agreed at the multilateral level, such as CBD, and should complement

negotiations/discussions in other fora. We believe that parallel discussions will enhance effort and understanding in achieving a fair and balanced trading system with regard to intellectual property.

194. Indonesia 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.

7.12 Canada

195. With respect to the relationship between the TRIPS Agreement and the Convention on Biological Diversity, 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.

196. 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.

197. Canada has been 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.

198. Furthermore, Canada regrets the postponement of substantive discussions at the IGC and looks forward to the prompt resumption of the IGC's important work in a mutually agreeable manner.

7.13 United States of America

199. The United States' position has not changed, and we refer to previous information provided in the TRIPS Council on the subject.

7.14 European Union

200. The position of the European Union has not changed. We refer to our previous information provided on these matters.

7.15 Japan

201. The position of Japan is unchanged. We firmly believe that the protection of GRs, TK and folklore should be designed in a manner that supports both creativity and innovation.

8 NON-VIOLATION AND SITUATION COMPLAINTS

8.1 Brazil

202. As this is a formal TRIPS Council meeting, I would like to present some of the views we have shared with Members in previous informal encounters.

203. Brazil believes that the TRIPS Council should seek the completion of the mandate assigned to it by Article 64.3 of the TRIPS Agreement, which refers to this Council's obligation to present recommendations on scope and modalities of the application of subparagraphs 1(b) and 1(c) of Article XXIII of the GATT.

204. This issue has been on the agenda for more than 20 years now, depriving this Council of precious time and energy to pursue other objectives. The moratorium determined by Article 64.2 TRIPS played a fundamental role during the consolidation process of the Agreement, and fruitful discussions were undertaken during this past 20 years.

205. We believe it is now time to move towards more concrete directions. Brazil has always the larger picture in mind – the context of WTO reform – and how we could, as Members, make our

contribution to this effort. There are elements that could bring us together in these discussions and facilitate an agreeable and reasonable outcome.

206. We are convinced that a balanced and thoughtful decision on scope and modalities of non-violation and situation complaints (NVSCs) would bring clarity and concrete guidance, further consolidating and reasserting the use of flexibilities provided for in the TRIPS Agreement. Finally, for Brazil, a mature and balanced treatment of NVSCs could even shed a light on negotiations to improve the dispute settlement system.

207. We have been engaging with Members in this past month and we plan to continue this exercise in the months to follow. We welcome your views and contributions.

8.2 Tanzania on behalf of the African Group

208. As it will be recalled, in December 2019 Members reaffirmed their commitment to continue with the exercise of examining the scope and modalities for the application of non-violation and situation complaints and make recommendations to the MC12 as mandated in Article 64.3 of TRIPS Agreement. However, our firm view is that the moratorium of non-violation and situation complaints should be made permanent in order to ensure Members' rights to TRIPS flexibilities are fully utilised.

209. Moreover, it is our understanding that expiry of Paragraph 2 of Art. 64 of the TRIPS Agreement (the moratorium), will not trigger automatic application of Article XXIII of GATT 1994 in dispute settlement, as any outcome is conditional on consensus under paragraph 3 of Art. 64 of the TRIPS Agreement.

8.3 Bangladesh

210. 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.

211. To avoid repetition, I refer to my delegation's statement made at the TRIPS Council meeting on 6 February 2020. Bangladesh reiterates its readiness to constructively engage with Members on this issue further.

212. In addition, my delegation would welcome an informal session on information sharing in this regard. Bangladesh also looks forward to hearing about Brazil's proposal on focused discussion.

8.4 Nigeria

213. We align ourselves with the information provided by the delegation of Tanzania on behalf of the African Group and wish to add a brief comment regarding this agenda item.

214. My delegation wishes to thank the Chair and the Secretariat for their continued work in trying to work out the modalities for the applicability of non-violation and situation complaints as mandated by the General Council, and we also welcome the extension of the moratorium on NVCs on 10 December 2019, however, we note that this is not a permanent solution. My delegation reiterates that in the absence of any agreeable modalities as of yet, our position remains that non-violation and situation complaints under Article XXIII subparagraph 1(b) and 1(c) GATT should not be allowed to apply under the TRIPS Agreement, as this may result in preventing our policy makers from effectively utilizing the flexibilities available in the TRIPS Agreement. Specifically, this may restrict our power to make regulations and policies for public health with the aim to increase access to medicines.

215. In terms of a possible way forward, we propose that the TRIPS Council recommend to the upcoming Ministerial Conference that non-violation and situation complaints should not be allowed to apply under the TRIPS Agreement. We believe that it is time for all Members to suggest concrete direction on this issue going forward. However, we are happy to engage with the Chair and other Members to find an amicable solution on this issue. We continue to thank you, Chair, and the Secretariat for their continued work.

8.5 India

216. 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. These complaints can not only have a chilling effect on Member's exercise of their IP regimes but also severely restrain the ability of Members to achieve public policy objectives.

217. 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. 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. Introducing such complaints into the TRIPS Agreement is, therefore, unnecessary.

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

8.6 Thailand

219. Thailand would like to reiterate that our position on this issue remains unchanged. We believe that non-violation and situation complaints should not be applicable to the TRIPS Agreement. It is important to strike an appropriate balance between IP rights protection which provides incentives for the creation of IP and innovation, and the TRIPS flexibilities which allow Members to achieve their legitimate interests.

220. We, therefore, strongly support the continuation of the NVC moratorium, at least until the 12th WTO Ministerial Conference. Thailand is willing to engage in future discussions with a view to finding a common understanding and making the NVC moratorium permanent.

8.7 China

221. Like many others, China believes that non-violation and situation complaints should not be applicable to the TRIPS Agreement and wishes that the Membership could achieve a consensus on the non-application. Specific arguments have been presented in the joint proposal document IP/C/W/385/Rev.1 submitted by many Members including China. We also look forward to Brazil's proposal.

8.8 Argentina

222. 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.

223. 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.

224. 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.

8.9 Chile

225. Our delegation's position is well-known among Members. Moreover, we welcome the decision made at the General Council meeting in December 2019 to approve the extension of the moratorium.

226. In our delegation's view, both formal and informal talks on this matter have brought to light the existence of different positions concerning the conditions and modalities applicable to this type of complaint, and it is therefore appropriate to continue discussing the various aspects contained in the mandate of Article 64 of the TRIPS Agreement. Chile believes that it is vital to continue extending the moratorium until a common understanding can be reached on this matter.

8.10 Zimbabwe

227. The Government of Zimbabwe reiterates its previous information provided on this agenda item. We recall Article 67 of the TRIPS Agreement which requires developed country Members to implement technical cooperation initiatives for developing and least developed countries (LDCs) to implement the TRIPS Agreement.

228. In light of the Coronavirus disease (COVID-19), at no time in the history of the World Trade Organisation has it been more necessary for all Members to be cognisant of their rights to exercise limitations and exceptions provided by the TRIPS Agreement. We urge developed country Members to uphold the spirit and purpose behind this provision.

8.11 Switzerland

229. My delegation's position under this agenda item and for the Council's recommendation is well-known.

230. For the sake of brevity, I thus confine myself to confirming that Switzerland is ready to examine and discuss any proposal from other Members on modalities for non-violation and situation complaints under the TRIPS Agreement, should they consider such modalities necessary in addition to those contained in the DSU.

8.12 Canada

231. Canada's longstanding position on this issue remains unchanged: the availability of NVNI claims under TRIPS would create legal uncertainty for Members.

232. Canada recognizes that the current moratorium exists thanks to consensus, and we trust 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.

233. We wish to express our continued interest in participating in any consultations that take place on this issue amongst other interested Members.

8.13 United States of America

234. The United States' position on this issue remains unchanged. We reiterate our support for allowing the current moratorium to expire so that Members may bring NVNI complaints in the future, as appropriate.

235. 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.

8.14 Indonesia

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

237. Moving forward for MC12, Indonesia supports the permanent moratorium of NVSCs for the TRIPS Agreement. However, we will engage if any Member puts any proposal on the table.

8.15 European Union

238. As Members will know, the European Union supported extending the moratorium of 13 December 2017 on TRIPS non-violation and situation complaints.

239. However, the EU remains open to hear and discuss any possible solutions for the future, including proposals on scope and modalities. We are ready to engage constructively in these discussions.

8.16 Jamaica on behalf of ACP Group

240. The ACP Group wishes to congratulate you on your assumption of your role as the Chair of this very important Council and to reassure you of the Group's support during your tenure.

241. The moratorium provided for under Article 64.2 of TRIPS has played an important role during the conclusion of the TRIPS Agreement. This provision avoided the hasty use of a device on which further discussion was needed, as well as afforded time for more clarity in Members' positions.

242. The ACP Group wishes to underscore the continued importance to WTO Members of the examination of the applicability of non-violation complaints to the TRIPS Agreement. While the views of Members may vary on whether to allow for such complaints, Members have consistently agreed to continue examination of this issue; most recently at the WTO General Council meeting in December 2019, where Members agreed to:

> take note of the work done by the Council for Trade-Related Aspects of Intellectual Property Rights pursuant to the Ministerial Conference decision of 13 December 2017 on "TRIPS Non-violation and situation complaints" (WT/L/1033).

243. Members further agreed that the TRIPS Council would:

> continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the 12th Ministerial Conference. It is agreed that, in the meantime, Members will not initiate such complaints under the TRIPS Agreement.

244. Consistent with this General Council Decision, the ACP Group recommends that the Council keeps the agenda item open and reconvene once further work is sufficiently mature, with a view to agreeing on a recommendation to the twelfth Ministerial Conference.

8.17 Kenya[11]

245. The examination of the scope and modalities for non-violation and situation complaints made pursuant to the TRIPS Agreement, as envisaged by Article 64.3, should also involve an examination of whether such complaints should apply to the TRIPS Agreement, and if so, to what extent.

246. We believe that the agreement by Members on the moratorium should be viewed without prejudice to the question on the availability of such complaints to the TRIPS Agreement. This is a matter that ought to be determined in the course of the examination of scope and modalities by the TRIPS Council.

247. We are, therefore, of the view that the Ministerial Conference should grant a moratorium to the effect that non-violation and situation complaints shall not be applicable to the TRIPS Agreement until the issue of scope and modalities is resolved by consensus. In the meantime, we urge the TRIPS Council to carry out its mandate under Article 64.3 and as reiterated in subsequent Ministerial Decisions.

[11] The delegation of Kenya requested at the meeting, that for reasons of time, its full statement be included in the record of the meeting. This record may thus contain elements that were not spoken at the meeting.

8.18 South Africa[12]

248. The possibility of bringing complaints on otherwise GATT-consistent measures was introduced into the GATT 1947 to address situations where the concessions or benefits obtained in a tariff negotiation could be easily frustrated by non-tariff measures, such as domestic subsidies, that the GATT 1947 did not regulate. As the original GATT did not require Contracting Parties to make substantive commitments on many such non-tariff measures, non-violation complaints were introduced as a remedy that could address any impairment of the benefits of tariff concessions as a result of such measures.

249. Thus, the basic function of Article XXIII:1(b) was to protect expectations that arose out of tariff concessions negotiated by parties to the GATT. It was to ensure that a GATT Contracting Party could obtain compensation, or a right to the compensatory or retaliatory withdrawal of concessions, where another Contracting Party introduced a measure subsequent to the negotiation of a tariff concession that frustrated the achievement of those concessions. In effect, non-violation complaints are a fall-back remedy designed to prevent circumvention of GATT obligations through measures that are not themselves GATT-inconsistent. We should however note that the non-violation remedy is an "exceptional" remedy. There has been no successful recourse to the non-violation remedy in any of the WTO disputes in which Article XXIII:1(b) has been invoked. In over 70 years of the existence of multilateral trading system, reports were adopted by the GATT Contracting Parties in only the remaining three out of the eight cases.[13] Even in those disputes in which non-violation complaints have been successful, there was agreement by the parties involved that it was an exceptional remedy to which "a cautious approach" should be taken.[14]

250. This experience with non-violation complaints in GATT/WTO jurisprudence suggests that the evolution of the multilateral trading system, and the expansion in the provisions of WTO Agreements regulating non-tariff measures, may have had the effect of making non-violation complaints largely redundant as a remedy. Nonetheless, my delegation is not a proponent of the application of NVSCs and the proponents of the application of such complaints under the TRIPS Agreement have not provided concrete examples of the kind of scenarios under which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations set out in the Agreement. Thus, as we previously suggested, it may be useful to clarify what situations proponent Members wish to avoid by having a non-violation remedy available under the TRIPS Agreement and, on the other hand, to ensure that a non-violation remedy in the TRIPS context would not be so broad as to have the effect of expanding the existing TRIPS obligations.

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

251. No statements were made under this agenda item.

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

252. No statements were made under this agenda item.

11 TECHNICAL COOPERATION AND CAPACITY-BUILDING

11.1 Bangladesh

253. The delegation of Bangladesh welcomes the reports on technical cooperation and capacity building under Article 67 of the TRIPS Agreement in favour of the developing countries and the LDCs, from the developed country Members and other international organizations and the report of the Secretariat. These reports provide us information on a wide range of programmes and activities

[12] The delegation of South Africa requested at the meeting, that for reasons of time, its full statement be included in the record of the meeting. This record may thus contain elements that were not spoken at the meeting.

[13] See Report of the Working Party on Australia - Ammonium Sulphate, Panel Report on Germany - Sardines and Panel Report on EEC - Oilseeds I.

[14] See, for instance, EEC- Oilseeds I, where both the US and the European Community made statements to this effect.

customized for the beneficiary Members. These programmes are critically important particularly for the LDCs.

254. Bangladesh sincerely thanks and encourages the developed country Members and the international organizations to continue their valuable support for developing countries, LDCs and the graduating LDCs.

11.2 South Africa

255. We wish to thank the Secretariat for its ongoing commitment to assist developing countries to make maximum use of the multilateral system. Due to COVID-19 the cooperation and capacity building activities may have been affected as reported by ITTC in its briefing to the CBFA. Face-to-face training in most cases have been postponed until the next financial year while some online activities have taken place. South Africa attaches importance to the use of the online mode during this time to continue technical cooperation and capacity building. Technical assistance and capacity-building must always respond to Members' needs, at this time many Members may have a need for technical assistance and capacity building to respond to the COVID-19 pandemic. In the context of the Biennial Technical Assistance and Training Plan 2020 – 2021 (WT/COMTD/W/248/Rev.1), emphasis has been placed on improving eLearning programmes. Expanding access to materials is also envisaged under the plan, this would be valuable for the public at large.

11.3 WTO Secretariat

256. Also on behalf of my colleagues from WHO and WIPO, I am pleased to share some excellent news with you: on 29 July, the second edition of the Trilateral Study on Access to Medical Technologies and Innovation has been presented to the public in a virtual launch event. Together with video messages by the three Directors-General, the publication is now available on each organization's webpage.

257. Encouraged by the strong and positive feedback that the study has received since its initial launch in 2013, we trust that the second edition will make its contribution to an informed policy debate about what is needed to foster innovation that is responsive to pressing needs and to secure equitable access to essential medical technologies. Its aim is to build capacities in Governments to deal with those and other challenging questions.

258. For this purpose, the revised study addresses all the key determinants for innovation and access to vital medical technologies, from research to development to manufacturing and delivery to those in need. And it maps out the close and complex linkages between health, intellectual property and trade.

259. To do so, this new publication draws practical lessons from experience, including from our joint technical assistance activities, with the interaction of those distinct policy dimensions. It sets them within the broader perspective of the human rights dimension and the Sustainable Development Goals.

260. What is new in the revised edition? We have seen numerous significant developments since 2013 that are covered by the new publication. To give you a few examples: efforts have stepped up to achieve universal health coverage. The fast-evolving pattern of the disease burden and emerging global threats to public health pose new challenges, as demonstrated by the current pandemic. Antimicrobial resistance pushes us to adapt existing innovation models. And we have also addressed the emergence of new health technologies, an increasingly diverse medical technologies sector, and strengthening innovative and production capacity in developing countries.

261. The second edition offers an improved empirical foundation for informed priority setting, resource allocation and policy decisions, through the integration of more comprehensive and accessible data on prices, access, patents and trade. This said, the Study is descriptive, aiming to build a firm empirical foundation for policymaking, rather than endorsing or advocating any particular approach.

262. What has the WTO in particular contributed to this revised edition? Among many other things, contributions include a detailed analysis of trade in health technologies, based on a completely

revised methodology to measure trends in trade in health products; second, a detailed analysis of provisions in FTAs which bear on innovation and access in the pharmaceutical sector; and finally a comprehensive review of the role of competition law and policy for the public health sector.

263. I should mention that the main text of the Study was completed before the outbreak of the COVID-19 pandemic. To take due account of the unprecedented challenges, we have opted to add a section providing a factual overview of the developments and measures taken to address this extraordinary public health crisis. As many of the issues that have arisen during the pandemic are not new, the purpose of this section is to guide the reader to those parts of the Study that provide essential background on those issues. This ensures its practical relevance to today's most urgent needs. So, while the section on COVID-19 may appear to be thin, the fact is that responses to the pandemic span such a wide range of technical areas that nearly every section of the Study is of relevance to the global response to COVID-19.

264. The pandemic has brought into sharp relief the fundamental need to co-operate internationally and to bring together diverse areas of expertise to effectively address global health challenges.

265. I would therefore like to use this opportunity to address our special thanks to colleagues and friends from WHO and WIPO, as well as the many colleagues from the WTO and other key stakeholders for their excellent collaboration and the significant contributions they have made to this publication.

266. Let me conclude with a brief quote from the DGs' foreword: "Global collaborative efforts are required now more than ever before" - it is in this spirit that we have launched the Trilateral Study.

11.4 World Health Organization

267. This is to present the second edition of the trilateral study promoting access to medical technologies and innovation – intersections between public health, intellectual property and trade.

268. As you may know, the three organizations have been working closely together to support global endeavours to improve health outcomes, to strengthen the capacity of developing countries to respond to needs in the areas of health innovation, access to health, and intellectual property. The objective of the trilateral study is to provide an up-to-date platform for sharing practical experience and understanding of a wide range of policy instruments. We count on this document to support and inform the ongoing technical cooperation and policy discussions, in particular at a time when the world grapples with the multi-dimensional challenges of the response to the COVID-19 pandemic.

269. The COVID-19 pandemic is a tragic and powerful demonstration of the importance of innovation and access for public health. Innovation is essential, but it is only part of the answer to this pandemic. Together, we must all ensure that vaccines, diagnostics and therapeutics for COVID-19 are global public goods, not more reasons that more people are left behind.

270. The trilateral study integrates lessons from diverse experiences regarding how public health, IP, trade and competition rules all interact with each other in the broader context of the human rights dimension of health and the united nations' sustainable development goals. We tried to include comprehensive and accessible data and information on prices, access, patents and licensing.

271. The insert at the beginning of the study summarizes issues that have come up in the context of COVID-19, the pandemic has brought extraordinary challenges to peoples' health, economies and societies at large. Countries are also seeking at extraordinary solutions to respond.

272. Global collaborative efforts are required now more than ever before to respond to challenging situations, not only for COVID-19 but also for other diseases, like HCV, cancer, HIV, etc.

273. WHO pledges continuing commitment for further collaboration among our three agencies, together with other UN agencies, the private sector, funders, and civil society organizations, whose insights have contributed much to the study, only this will support our work towards the shared objectives of universal health coverage, better health outcomes for all, fulfilment of the Sustainable

Development Goals (SDGs) and, first and foremost, the design of effective and lasting responses to public health crises.

11.5 World Intellectual Property Organization

274. I am pleased to join my colleagues from WHO and WTO and to add a few words on the second edition of the trilateral study.

275. Since the launch of the first edition of the study in 2013, considerable relevant work has been undertaken in WIPO that has informed the update of the study.

276. For example, comprehensive studies have been prepared for, and have been discussed in, the WIPO Standing Committee on the Law of Patents (SCP), particularly under the agenda item patents and health. These include studies on: The Role of Patent Systems in Promoting Innovative Medicines, and in Fostering the Technology Transfer necessary to Make Generic and Patented Medicines available in developing countries and least developed countries (SCP/21/8); Constraints faced by developing countries and least developed countries (LDCs) in making full use of Patent Flexibilities and their lmpacts on Access to Affordable Especially Essential Medicines for Public Health Purposes in those Countries: (SCP/26/5 and SCP/27/6); and the Feasibility Study on the Disclosure of International Non-proprietary Names (INN) in Patent Applications and/or Patents (SCP/21/9 and SCP/28/5).

277. The WIPO Global Innovation Index 2019 Creating Healthy Lives – The Future of Medical Innovation has informed the sections on economics of innovation and access to medical technologies.

278. At the same time, patent information systems have made significant progress and we now have much more sophisticated search tools to find relevant patent information, for instance through useful features in the WIPO Patentscope database.

279. The new WIPO Standard ST.27 (Recommendation for the exchange of patent legal status data) aims at improving worldwide availability, reliability and comparability of patent legal status data and we hope that the acceptance of this recommendation by patent offices leads to an improved understanding about patent legal status events across different jurisdictions.

280. There is, of course, much more in the study, such as updated and enhanced sections on copyright and trademarks. The study is comprehensive, and it takes a holistic perspective when it presents the intellectual property system in its health and trade contexts. Importantly, the study benefits from the expertise and close collaboration of the three Secretariats.

281. The COVID-19 pandemic requires that we stand together in solidarity and collaborate. The work done by the three Secretariats to produce this second edition is a small, and successful, instance of such collaboration.

282. We trust that this second edition of the trilateral study shall have many readers.

11.6 Chile

283. Chile considers that these types of tools are those that allow Members to better understand the complexities between intellectual property, trade, public health and give them greater clarity when taking public policy measures in these areas.

11.7 Zimbabwe

284. Zimbabwe thanks the WTO, WHO and WIPO for the publication and for the interventions made.

11.8 Tanzania on behalf of the African Group

285. The African Group would like to register its appreciation to Members who have timely submitted their annual reports in relation to the implementation of Article 67 of the TRIPS Agreement. On this note, we call other Members that have not yet done so, to do.

286. Similarly, we would like to urge developed country Members to continue to adhere to the obligation of providing upon request the needed financial and capacity building support to developing countries and least developed countries. We would also like to encourage intergovernmental organizations such as WIPO, WTO, UNCTAD, ITC and others, to intensify capacity building activities on IP management and transfer of technology.

12 LDC GROUP PROPOSAL ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

12.1 Bangladesh on behalf of the LDC Group

287. On this agenda item, the delegation of Bangladesh makes this statement on behalf of the LDC Group. For time constraint, I am not going into the detail for which I particularly refer to the information provided by Chad and Bangladesh at the TRIPS Council on 6 February 2020.

288. LDCs always appreciate the contributions of developed country Members and their annual implementation reports under TRIPS Article 66.2. However, many reports do not clearly give information on incentives provided to enterprises and institutions in the territory of the developed country Members. Instead, these reports contain a mixture of technical assistance programmes under Article 67 and a few technology transfer initiatives under TRIPS Article 66.2.

289. The LDC Group's proposal contained in document IP/C/W/664 contains a template for annual reporting under TRIPS Article 66.2. This may be noted that the proposal is built on the room document RD/IP/37 circulated on 5 February 2020, which was basically developed from Members' feedback. In this regard, the LDC Group acknowledges the contribution of the participating delegates, from the LDC and developed country Members, and their capital-based colleagues who provided suggestions on improving the annual reporting process during the WTO workshops on the implementation of TRIPS Article 66.2 held in 2019 and 2020.

290. The current proposal is self-explanatory. The proposed template does not demand any new information that developed country Members are already providing in the annual reports following the TRIPS Council decision contained in document IP/C/28 dated 20 February 2003 and the existing reporting format proposed through document IP/C/W/561 dated 6 October 2011. The proposed template has just reorganized the columns and rows of the existing reporting format to bring clarity and simplification. The additional contribution in the new template is the appendix, expected to specify the incentives and the details of the enterprise and institution receiving the incentives from the developed country Members and transferring technology to LDCs. It is also possible to adjust and accommodate this template with the e-TRIPS Gateway. The proposed template with appendix is expected, as has been stated in the proposal, to help simplify reporting process, synchronize the current reporting variations, and acknowledge the substantive contributions of the developed country Members with evidence and precision.

291. It may also be noted that LDC Group earlier submitted a proposal (document IP/C/W/640) dated 16 February 2018 requesting the TRIPS Council to specify the meaning of 'incentives to enterprises and institutions'. The LDC Group further submitted a room document RD/IP/24 dated 14 June 2018, to discuss and agree on developing an illustrative list of incentives for the purpose of technology transfer to LDCs. Till date there is no agreed list of incentives, however, many reporting Members are currently following the non-exhaustive illustrative list, as contained in RD/IP/24, as a guide while submitting annual reports. LDC Group sincerely appreciates those Members. The Group also encourages Members to actively engage in discussion to specify the illustrative list of incentives to technology transfer to LDCs.

292. To create a sound and viable technological base in the LDCs, the LDCs need support from the developed country Members. This is also a commitment of obligatory nature for the developed country Members. The LDC Group invites Members to reflect on the annual reporting template for TRIPS Article 66.2 contained in the proposal and explore further how to utilize this template for future reporting purpose. Members are also encouraged to discuss and deliberate on the meaning of incentives and develop an illustrative list of such incentives for the purpose of annual reporting under TRIPS Article 66.2.

293. In this regard, the LDC Group stands ready to engage constructively with Members.

12.2 Nepal

294. My delegation would like to associate with the statement made by Bangladesh on behalf of the LDC Group.

295. Among the various provisions of special and differential treatment laid down in the WTO laws, TRIPS Article 66.2 with specific provision of technology transfer to LDCs has become an important and more relevant in the context of technology led world economy of the 21st century.

296. In this context, my delegation would like to extend sincere appreciation to all developed country Members for their support and cooperation through various means of technical assistance.

297. I would like to recall the various initiatives and efforts towards implementation of the TRIPS Article 66.2 provision and its reporting mechanism.

298. The LDC Group has made three submissions over time to make the reporting mechanism clear and uniform under this Article.

299. My delegation appreciates the annual reports by developed country Members and the engagement of those Members in the reviews and workshops devoted to the TRIPS Article 66.2 implementation.

300. The clear objective of TRIPS Article 66.2 in terms of implementation is to promote and encourage transfer of technology in LDCs so that we can develop a sound and viable technological base.

301. However, there is still gap between the spirit and letter of the TRIPS Agreement mandate and its real implementation while providing assistance to LDCs under TRIPS Article 66.2.

302. Further clarification on incentive as per the spirit of the provision, its modality and coverage of enterprises and institutions to collaborate may also be required to facilitate the implementation effectively.

303. LDCs submitted a room document of an illustrative list, RD/IP/24, containing possible incentives that resonate for LDCs and could indicate what to provide and what to report to the TRIPS Council.

304. My delegation would like to thank Switzerland for its report in 2019 indicating that the LDC illustrative list served as a guide.

305. We believe that the responsibility to provide incentives may falls on the developed country Member Government and not on the private sector entities and enterprises. Therefore, it may need a clear mechanism of incentivizing enterprises and institutions in developed country Members to motivate them to transfer technology in LDCs.

306. My delegation would like to extend sincere appreciation to all developed country Members for their continued support to LDCs and expect further enriched cooperation in future particularly in technology transfer under Article 66.2 of the TRIPS Agreement.

12.3 Nigeria

307. We support the proposal provided by Chad on behalf of the LDC Group on the implementation of Article 66.2 of the TRIPS Agreement, and we would like to highlight that in view of the economic, financial and administrative constraints of the LDCs and also their need for flexibility to create a viable technological base, we urge our developed country Members to continue in their efforts in providing incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed countries so as to fulfil their mandate under Article 66 of TRIPS. Particularly, we underscore the importance ensuring that the notification under TRIPS Article 66.2 is done in a transparent and inclusive manner, and it is made in the proposed format which is fit for purpose on behalf of the LDC Group.

308. Furthermore, we thank the developed country Members in their technical support to developing and least developing countries already provided, and we urge our developed country partners to deepen their kind technical and financial cooperation and collaborations in favour of developing and least developed countries in fulfilment of their obligations under Article 67 of the TRIPS Agreement to assist our governments regarding the establishment and reinforcement of domestic IP offices and capacity building. However, we urge that such assistance should be made in a manner that is fit for purpose in accordance with the specific requirements of the beneficial countries so as to adequately facilitate the implementation of this Agreement.

12.4 Tanzania on behalf of the African Group

309. The African Group thanks the LDC Group for the proposal contained in document IP/C/W/664 which relates to the implementation of Article 66.2 of the TRIPS Agreement. We would like to commend Members who have consistently provided reports in relation to the implementation of the provision. However, LDCs have on several occasions expressed their concern that the majority of reports lacks the direct relevance to the implementation of Article 66.2 which obliges developed country Members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs, in order to enable them to create a sound and viable technological base.

310. On this note, the African Group supports the LDCs' proposed reporting template for consideration and adoption by the Council; and we urge other Members to positively consider it.

12.5 Zimbabwe

311. The Government of Zimbabwe reiterates its previous information provided on this agenda item. We support and appreciate the proposal (document IP/C/W/664) presented by the Delegation of Chad on behalf of the least developed countries (LDCs) Group.

312. We believe that this proposal is in line with the 2001 Doha Ministerial Decision on Implementation-Related Issues and Concerns. Members agreed that the TRIPS Council would put in place a mechanism for ensuring the monitoring and full implementation of the obligations.

313. There is need for specificity in the reports submitted in terms of TRIPS Article 66.2 with clear terms of reference and measurable outcomes. The current unsystematic approach in the compilation of the reports makes it very difficult for the Council to monitor compliance with this Article.

314. We call upon Members of the Council to recall that technology transfer is an essential element of Articles 7, 8, and 66.1 of the TRIPS Agreement. Support for this proposal would go a long way in fulfilling our obligations.

12.6 South Africa

315. Thank you to LDC Group and the African Group. Transparency is an important aspect of the mandate of this organisation. The simplified template will go a long way in facilitating the work of this Council and comply with the Doha Declaration. The appendix is an important addition in this paper and will enable a more accurate reflection of the recipients of incentives. We would also agree that the definition of 'incentives' should be agreed so as to enable a better understanding of what types of measures will constitute such incentives.

12.7 India

316. Article 66.2 of the TRIPS Agreement mandates that the developed country Members provide incentives to their own enterprises and institutions in their territories for promoting and encouraging technology transfer to LDCs.

317. In this regard, India supports the LDC Group's proposal, which suggests templates to provide details on the specific enterprise receiving the incentives and transferring technology to LDCs. The LDC Group believes that proposed templates will help simplify the reporting process, synchronize the current reporting variations, and acknowledge the substantive contributions of developed

country Members with evidence and precision and improve overall transparency in the context of this important provision.

12.8 China

318. We would like to thank the LDC Group for tabling the proposal. China believes that developed country Members should continue to take active measures to encourage enterprises and institutions to transfer their technology to LDC Members in accordance with the Article 66.2 of the TRIPS Agreement, thus to help the LDC Members to create a sound and viable technological base.

12.9 United States of America

319. The United States continues to support 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.

320. It is quite an undertaking each year to take stock of the programmes we report to the TRIPS Council. The relevant agencies or entities involved in the programmes are identified. As you can see from our recent reports, there is not one coordinating body that undertakes these programmes. We therefore view it best to continue to implement these programmes and these reports as we have.

321. We are always willing to meet with interested Members to discuss ways to ensure that our programmes and reports are as helpful as possible.

12.10 Switzerland

322. Switzerland thanks the LDC Group for presenting document IP/C/W/664.

323. A series of workshops and extensive discussions have taken place over the past years in which developed country Members have discussed with their LDC counterparts how to best adjust the contents and format of their reporting under 66.2 to the needs and preference of the LDC Group.

324. Developed country Members have undertaken considerable efforts to respond to those proposals when writing or revising their reports.

325. We are still in the process of examining the LDC document. Switzerland is open to look into additional proposals from the LDC group, as long as we can accommodate them.

326. As a preliminary reaction to the presented document, it seems to this delegation that this is not the case with at least some of the additional information that is now asked by the LDC Group from developed country Members

327. As document IP/C/W/664 recalls, the obligation of developed country Members under Article 66.2 is to provide incentives to enterprises and institutions in their territories so that these enterprises and institutions may, if they wish to do so, transfer their technology to LDC Members.

328. Developed country Members have, however, no obligation under Article 66.2 to ensure that the enterprises and institutions on their territory make use of these incentives or actually transfer their technology to LDCs. This is the autonomous decision of each enterprise and institution.

329. Information as to what company or institution transferred what technology to which LDC country Member is not information that developed country Members regularly have at their disposal. Nor may they demand companies and institutions to systematically provide such information under Article 66.2, not least because such information may qualify as business confidential information.

330. That said, Switzerland will make maximum efforts in its future reports to provide information on the incentives it provides under Article 66.2 in a manner as transparent, consistent, clear and comprehensible as possible.

12.11 Canada

331. Canada would like to thank Chad and the LDC Group for circulating communication document IP/C/W/664 on the proposed new template for annual reporting under Article 66.2 of the TRIPS Agreement and welcomes further discussion on this topic.

332. Canada continues to encourage constructive dialogue on the implementation of TRIPS Article 66.2, including through the recent annual workshops on this topic, which have allowed for an in-depth exchange between least developed country (LDC) and developed country Members on incentives for the purpose of promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base.

333. In addition to the valuable discussion on technology transfer incentives and LDC needs and priorities, we have also benefitted from hearing LDCs' views on how to refine and enhance the annual reporting template, in order to ensure that information on technology transfer is conveyed in a clear and user-friendly format.

334. Canada is open to hearing proposals from LDC Members on revising the reporting template in this regard, and notes that we currently follow the template previously proposed by the LDC Group in document IP/C/W/561.

335. As Canada will be preparing its annual report on the implementation of TRIPS Article 66.2 in the coming weeks, we would propose that any discussion on a standard reporting template be finalized as soon as possible, to facilitate our timely reporting on this important issue.

12.12 Japan

336. Regarding the proposal of a standardized reporting format, it should be noted that the content itself of the report is an important element and it would vary depending on the type of project by each Member. From this point of view, the format for reports should be flexible to accommodate the varying types of contents. This delegation will continue to contribute to discussions on this matter.

12.13 Indonesia

337. Indonesia thanks the LDC Group for this proposal. We support the proposal and believe it is useful for synchronizing and simplifying reporting process under Article 66.2 of the TRIPS Agreement. This proposal will also enhance transparency in WTO as called on by many Members in other committee/Council meetings.

12.14 European Union

338. The EU thanks the delegations of Chad and the Group of Least Developed Countries for having submitted this communication on a new proposal for a template for annual reporting under Article 66.2 of the TRIPS Agreement.

339. The EU and its Members take their commitment under Article 66.2 of the TRIPS Agreement very seriously and annually provide a detailed update on their respective technology transfer programmes. The EU and its Members provided proof of having promptly and attentively reacted to natural, social, health, climate and economic changes by implementing projects specifically tailored to the current needs of LDCs and their regional organisations.

340. The EU has always supported efforts to simplify the reporting process and to synchronise the reports in order to guarantee their user-friendliness and broad accessibility by LDCs. The EU and its Members have been using the previous template provided by LDCs from the moment it was officially submitted to the TRIPS Council by the LDC Group. Motivated by the aim of improving the reporting process even further, in 2019, the EU started using the e-TRIPS Portal developed and promoted by the WTO Secretariat.

341. As Members will know, the e-TRIPS Portal guarantees the full harmonisation of the reports as well as accessibility and searchability for LDCs and others. The EU intends to continue using the e-TRIPS Portal, also for the preparation of its next submission in 2020.

342. As for the new proposed template from the LDC Group, the EU is open to engage constructively in the discussion on the use of the new template and the consequent adaptation of the e-TRIPS Portal where it helps promote objectives such as accessibility and searchability. We would like to make a couple of comments regarding the proposed template.

343. Technology transfer refers to the ways and means through which companies, individuals and organisations acquire technology or know-how from third parties, irrespective of whether such technology is IPR-protected or not.

344. More often than not, technology transfer is just 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 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 prevailing local economic conditions.

345. Therefore, factors such as 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 tells us that the mere transfer of technology - without the training of local employees - does not enable the recipients to achieve the internalisation of the technology provided and to reduce the technology gap as compared with developed country Members. Accordingly, several projects implemented by the European Union and its Members are aimed at providing such training and education.

346. It also warrants highlighting that the EU actions usually target groups of countries or regions. The reason is that the EU strongly supports regional integration. That is why our technology transfer projects sometimes target regions including both LDCs and also other developing countries.

347. The EU proposes that any discussion on revised or new template takes these issues duly into account. The EU stands ready to discuss the matter further.

12.15 Bangladesh

348. The LDC Group thanks the delegations of Nepal, Tanzania, Nigeria, Zimbabwe, South Africa, India, China, and Indonesia for their support to the LDC proposal. The Group also thanks the delegations of United States, Switzerland, Canada, Japan, and EU for their encouraging words and willingness to engage with LDC Members on this issue.

349. The LDC Group welcomes the proposal from developed country Members and looks forward to engaging constructively for deciding the illustrative list and the reporting template for future reporting.

13 INTELLECTUAL PROPERTY AND THE 1998 WORK PROGRAMME ON ELECTRONIC COMMERCE

13.1 South Africa

350. The Work Programme on Electronic Commerce (WT/L/274) in Paragraph 4.1 provides that "the Council for TRIPS shall examine and report on the intellectual property issues arising in connection with electronic commerce. The issues to be examined shall include:

- protection and enforcement of copyright and related rights;
- protection and enforcement of trademarks; and
- new technologies and access to technology."

351. In order to reinvigorate the 1998 Work Programme on Electronic Commerce in line with the General Council Decision of December 2019, this delegation proposes an intensification of discussions under Paragraph 4.1 of the Work Programme. Since this area of engagement is mandated, the TRIPS Council should inscribe this agenda item as a standing item on the agenda.

352. This will facilitate a deeper discussion of issues that could be based on a catalogue of themes that could be agreed by Members. Initially the issue of electronic commerce was a standing agenda

item on the TRIPS Council; Members should return to this practice.[15] Members are encouraged to submit further proposals, share information and national experiences, pointing out how the 2030 Sustainable Development Goals may be achieved through an effective framework for technology transfer.

353. Intellectual property can have an impact on development so the link between intellectual property (IP) and development, as well as the relationship with the various SDGs, needs to be mainstreamed into the discussion of the TRIPS Council. In order to meet the SDGs, new technology needs to be harnessed and accessed by developing countries and LDCs.

354. The United Nations Conference on Trade and Development Digital Economy Report of 2019[16] captures the transformative effect of digital technologies as follows: "The world economy is transforming fast as a result of the rapid spread of new digital technologies, with major implications for Agenda 2030 on Sustainable Development. Greater levels of digitalisation of both economies and societies are creating new means for tackling global development challenges; however, there are risks that digital disruptions will favour mainly those that are already well prepared to create and capture value in the digital era, rather than contribute to more inclusive development." At the cusp of this digital revolution are technologies such as key software-oriented technologies such as blockchain, data analytics and artificial intelligence.

355. The rapid deployment of smart devices and digital interfaces to 3D printing, wearables, automation, robotics and cloud computing are all contributions to a notable digitization of the world economy, a trend which has been accelerated by COVID-19. In this context the digital divide impedes the participation of developing countries in digital value chains, while digital transformation is disrupting traditional sectors with severe socio-economic consequences.

356. On this basis UNCTAD concludes that: "The current trends of new technologies being concentrated in a few countries and controlled by relatively few companies have implications for the ability of both developing and developed country Members to participate in the technological learning processes needed to catch up and thrive in the digital economy.[17]

Discussion

357. The preamble of the TRIPS Agreement emphasizes the underlying policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives. These objectives should be read in conjunction with Articles 7 and 8 of the TRIPS Agreement. The Secretariat in its Background Note on the Work Programme on Electronic Commerce[18] recognizes that "[t]he traditional objectives of the system as reflected in the current international norms, including in the TRIPS Agreement, would appear to remain valid even in 'cyberspace'."[19]

358. Article 7 of the TRIPS Agreement provides a context to interpret access to technology by emphasizing that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner that is conducive to social and economic welfare, and to a balance of rights and obligations.

359. In order to industrialize, it is clear that developing countries would need more access to technology; however, it is also clear that as many developing countries pursue industrialization, they do so in the context of an international IP regime that is more constrained than it was in the 19th century. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes extensive standards of IP protection that are almost without exception legally binding on all WTO Members.

[15] WTO Secretariat Background Secretariat Note: The Work Programme on Electronic Commerce Addendum IP/C/W/128/Add.1 of 15 May 2003, *ad* par. 8.
[16] UNCTAD/DER/2019 ad p. 1.
[17] UNCTAD (2019) ad p. 21.
[18] IP/C/W/128 of 10 February 1999.
[19] *Ibid ad* par.13, p. 3.

360. Furthermore, Article 8 recognizes the right of WTO Members to adopt national measures to promote public interest in sectors of vital importance to their socio-economic and technological development subject that such measures are 'consistent' with the TRIPS Agreement. When considering consistency of measures, the in-built TRIPS flexibilities need to be taken into account across the entire spectrum of the TRIPS Agreement. It is also important to take account of the cross-cutting impact of proposals in other WTO bodies or plurilateral initiatives that may impact intellectual property rights.

361. Some Members have proposed disciplines to prohibit national localization requirements and governments' access to data; this may have unintended consequences for settled practices in Members' IP regimes and affect exceptions and limitations that are well-established under the TRIPS Agreement. The link between localization and IP is not clear and since it is silent on the implications for trade secrets on transparency of algorithms and access to copyrighted works in the digital economy, these issues should be approached with caution.

362. A South Centre paper[20] posits that "…localization requirement policies, which are in full compliance with WTO provisions and which may also have national security implications, are seen as a trade barrier *per se*, they may substantially impede the development of certain data-intensive industries and also favour those who already hold large amounts of data."

Summary

363. Article 7 broadly captures the need for balance between private property rights and public interest in respect of socio-economic and technological development. This links the TRIPS Agreement directly with the 2030 SDGs and requires the promotion of technological innovation, transfer and dissemination in a manner that will achieve the SDGs.

364. Further bolstered by Article 8 and Article 66.2 of the TRIPS Agreement, technology transfer is central to address development issues, including the digital divide. Both demand and supply side issues are covered in these provisions, with TRIPS Article 66.2 imposing a mandatory obligation on developed country Members to provide a favourable environment and incentives to their enterprises and institutions to promote transfer of technology to LDCs.

365. On the other hand, Article 8 recognizes demand-side imperatives that allow Members to promote public interest in sectors of vital importance to their socio-economic and technological development.

Questions

366. Questions that can frame the discussion under this agenda item include:

1. How can exceptions and limitations, including compulsory licenses in the IP system, be used as tools to ensure that the patent system contributes to the promotion of innovation in a competitive environment and to the dissemination and transfer of technology, meeting the objectives of the system and responding to the public interest at large? What are Members' experiences in this regard?

2. Article 40.1 of the TRIPS Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights, which restrain competition, may have adverse effects on trade and may impede the transfer and dissemination of technology. Read with Article 40.2, Members may address adverse effects of anti-competitive practices through appropriate measures. Such measures may also be applied to digital platforms that could potentially use their dominant position to restrain competition, including through the use of intellectual property rights. How can more effective access to technologies, especially in the digital economy, be secured for developing and least developed countries in an inclusive way?

367. In closing, I would like to stress that technology transfer is not only associated with Art. 66.2 but is a theme that should be taken account in every aspect of the TRIPS Agreement and specifically

[20] Policy Brief No.62: *Intellectual Property and Electronic Commerce: Proposals in the WTO and Policy Implications for Developing Countries* (June 2019), p. 5 *et seq*.

in how we enable the environment for developing and least-developed countries to have access to appropriate technologies in order to overcome the developmental divide.

13.2 India

368. We thank the delegation of South Africa for their timely intervention on crucial issues pertaining to intellectual property in connection with electronic commerce. The submission rightly notes that the 1998 Work Programme on Electronic Commerce mandates the TRIPS Council to examine and report on such issues. In fact, e-commerce regularly featured on the agenda of TRIPS Council meetings from 1998 to June 2003, and the Council had also produced three reports to the General Council on this issue. We, therefore, support the request by South Africa to inscribe this issue as a standing item on the TRIPS Council agenda.

369. The rapid deployment of digital technologies has increased substantially during the COVID-19 crisis, indicating that the ongoing digitalization possesses new means of tackling global development challenges. However, the pace of such digitalization is different in different trading economies. Therefore, it is imperative that the requisite technology is made available to the developing and least developed countries so as to create a level-playing field. Discussions on e-commerce will lack meaning if the gaping digital divide, partly arising out of lack of access to technologies and furthered by the pandemic, continues to exist.

370. The TRIPS Agreement, in consonance with Article 7 and Article 8, enumerates several flexibilities. These flexibilities are not limited to a particular sector or technology. It remains open for Member countries to utilize these flexibilities as per their socio-economic conditions. However, India has had very limited experiences in this regard. As of now, India has not invoked any such flexibilities in the case of e-commerce.

371. The advent of e-commerce has led to erosion of geographical boundaries, and has facilitated the entry of buyers and sellers in markets from around the world. The ongoing digitalization of the economy, however, is also throwing certain specific challenges in respect of competition policy. In this regard, the paper from South Africa rightly points out that Article 40.1 of the TRIPS Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights, which restrain competition, may have adverse effects on trade and may impede the transfer and dissemination of technology, and read with the provisions of Article 40.2, Members may address the adverse effects of anti-competitive practices through appropriate measures which may also be applied to digital platforms.

372. It is of utmost importance for developing countries to adopt e-commerce and IP policies that are mutually supportive and in line with their developmental goals and policy specificities. Therefore, we support the suggestion to maintain this issue as a standing item on the TRIPS Council agenda.

13.3 European Union

373. The EU and its members take note of the communication submitted by South Africa on operationalizing technology transfer in the context of Articles 7, 8, 40 and 66.2 of the TRIPS Agreement.

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

375. The digital economy has developed remarkably in the past decades. Our practices have evolved accordingly to capture those developments, but only limited progress has been achieved in the WTO.

376. The EU also supports the General Council Decision of December 2019 to reinvigorate the 1998 Work Programme on Electronic Commerce and is ready to continue and intensify work on the three areas that fall under the competence of the TRIPS Council.

377. As to the issues raised in the communication by South Africa, the EU believes that voluntary technology transfer has the capacity to boost international economic relationships. Therefore, it is an important tool that helps foster innovation and development. It can create win-win situations in international business.

378. A reliable and predictable system of protection and enforcement of IPRs is a necessary condition for technology transfer to occur on market-based and voluntary contractual terms and therefore a key driver of technology transfer.

379. Licensing plays a crucial role in promoting the dissemination and further development of technologies by licensees, thereby facilitating the commercialization of innovative products.

380. Enforcement of IPRs provides for transparent procedures that permit effective action against infringement of IPRs as well as the opportunity for review of final administrative decisions by a judicial authority.

381. The patent system is a key driver of innovation and research also in the area of the digital economy. Patents are an important and up-to-date source of technological information, which often cannot be found elsewhere.

382. The disclosure requirement set out in Article 29.1 of the TRIPS Agreement allows innovators and researchers, including in developing countries and LDCs, to access this information and to reach the same knowledge level, as well as to continue the momentum with further technological development of the patented technology.

383. Besides disclosure, there are many ways to support technology transfer, notably collaboration and links between researchers and industry, transparency on licensing conditions or special support to SMEs. The EU's Research & Innovation Framework Programmes are good examples of initiatives promoting cross-border collaboration, including with non-EU countries in different sectors, also e-commerce.

384. The EU and its members also contribute and implement numerous cooperation and capacity building projects to support the services trade and the development of regulatory frameworks under the Aid for Trade programmes, including with regard to digital solutions.

385. The EU has presented this and other initiatives in more detail in the context of exploratory discussions on supporting the digital capability of businesses and consumers that are taking place in the Council for Trade in Services.

386. It is also important to underline that in many cases access to technologies in the field of electronic commerce is dependent on issues outside the IP regime, such as lack of institutional capacity to absorb technologies, preferences of local suppliers, infrastructure deficiencies and restrictions on inward technology.

387. Competition law and intellectual property systems are not contradictory, but complementary systems of law, which both strive to further welfare and growth. The TRIPS Agreement recognizes the possibility of the application of competition policy measures while setting clear limits, as such measures have to be consistent with the provisions of the TRIPS Agreement.

388. Competition policy plays an important role in controlling and sanctioning anti-competitive market behaviour in any sector, including the area of electronic commerce.

389. Abusive IPR-related conduct, as any other abusive practices, can violate competition law and can be considered an anti-competitive practice, but only in clearly defined circumstances, and provided that all rigorous legal requirements are met.

390. At the same time, the number of competition cases that are related to the use of the intellectual property framework clearly underscore that it is not the IPR system as such that raises competition issues. In fact, competition issues which are related to the use of the IP framework originate from the unlawful conduct of companies, which go against the objectives of the IPR system. For example,

contractual clauses that lead to allocating markets or customers or restricting the exploitation of the licensee's own technology.

391. Finally, we would like to emphasise that existing international cooperation in the field of competition, for example the International Competition Network, facilitates the dissemination of expertise and best practices and has a large potential to strengthen the fair and appropriate enforcement of competition law and contribute to better functioning of the markets around the globe.

13.4 Zimbabwe

392. The delegation of Zimbabwe extends its appreciation to the delegation of South Africa for the submission of document IP/C/W/665 on "Operationalizing Technology Transfer in the Context of Articles 7, 8, 40 and 66.2 of the TRIPS Agreement".

393. Zimbabwe believes that the emergence of the coronavirus disease of 2019 (COVID-19) makes it incumbent upon us to resuscitate a conversation on intellectual property (IP) in e-commerce. The emergence of new technologies has added a new dimension to the world of IP, particularly in artificial intelligence, blockchain, and digitalization.

394. The only way in which we can face the existential threats we face in climate change, health and other hazards is to harness technology for our common benefit.

395. We support the proposal to restore on the agenda of the Council the agenda item on "Intellectual Property and the 1998 Work Programme on Electronic Commerce".

13.5 United States of America

396. The United States thanks South Africa for its paper.

397. Under the Work Programme on Electronic Commerce, the TRIPS Council is to examine the protection and enforcement of copyright and related rights as well as trademarks and new technologies and access to technology.

398. While there is renewed attention on the Work Programme, the TRIPS Council has never really stopped focusing on the issues identified by it. Indeed, ensuring widespread access to new technologies through protection and enforcement of copyrights and related rights and trademarks is at the very core of the work this Council does.

399. Presentations by developing countries and numerous international organizations in other bodies, such as the Working Group on Trade and Transfer of Technology, have emphasized roles of both developed and developing economies in ensuring access to technology. Developed country Members have discussed their extensive capacity building programmes and technology transfer initiatives, including as related to intellectual property protection and enforcement, designed to build the absorptive capacity of developing countries and LDCs. Meanwhile, Members have recognized the important role of the developing economy in creating an environment conducive to technology transfer. In particular, international organizations such as the World Bank, the United Nations Conference on Trade and Development, the Organization for Economic Cooperation and Development and the United Nations Food and Agriculture Organization have emphasized the importance of investment protection, removal of trade barriers to technology and strong intellectual property protection in creating an environment in which technology transfer can thrive.

400. In light of this background, as called for by the Work Programme on Electronic Commerce, this Council should focus on how the TRIPS Agreement ensures protection and enforcement of copyright and related rights as well as trademarks, and how that protection and enforcement relates to new technologies and access to technologies. Accordingly, the questions South Africa poses to frame the discussion, narrowly focused as they are on abusive anti-competitive practices and the measures governments may seek to use to remedy such specific, fact-dependent behaviour, constrain this mandate. An appropriate examination would focus on the application of the TRIPS Agreement to new technology, and how protection and enforcement of intellectual property rights can promote access to technology.

401. We do not support adding this issue as a standing agenda item. Nothing prevents Members from raising this or any issue in particular meetings.

13.6 Canada

402. Canada thanks South Africa for circulating document IP/C/W/665 on the topic of intellectual property and the 1998 Work Programme on Electronic Commerce.

403. Canada takes note of the 1998 mandate of the Work Programme, as outlined in document WT/L/274, which identified TRIPS as one of several relevant bodies to examine the trade-related aspects of e-commerce. As directed by ministers in that document, the TRIPS Council shall examine and report on IP issues arising in connection with e-commerce, including: protection and enforcement of copyright and related rights; protection and enforcement of trademarks; and new technologies and access to technology.

404. As Members of this Council may recall, in May 2016, Canada proposed, under document IP/C/W/613, an exchange of national experiences in these areas, with a view to informing our respective policy efforts at the intersection between IP and e-commerce, and to help Members understand emerging developments in this area.

405. As e-commerce continues to rapidly develop internationally, with implications for IP protection and enforcement, and pursuant to ministerial direction on this topic, Canada remains open to sharing national experiences in these areas.

406. We take note of the specific IP topics set out in the 1998 Work Programme, and would encourage an exchange of national experiences in these areas. For instance, in 2017, Canada presented on an innovative law enforcement initiative on e-commerce and trademark rights, entitled "Project Chargeback", and would similarly be pleased to share its experiences on the other IP topics contemplated by ministers at a future session.

407. Given that these topics often involve coordination across domestic government ministries, we would also encourage that topics for discussion be notified in advance of TRIPS Council meetings, to facilitate our engagement and sharing of national experiences on these important issues.

13.7 Chile

408. We wish to thank the delegation of South Africa for submitting this document and for facilitating discussion on the existing relationship between intellectual property and electronic trade as provided for under the General Council mandate of 2019 and the Work Programme on Electronic Commerce.

409. In Chile's view, Articles 7 and 8 of the TRIPS Agreement make it clear that intellectual property is not an end in itself, but a tool for development. Accordingly, the minimum standards of protection and flexibilities provided for in the Agreement enable Members to establish or adapt intellectual property systems in line with their own national realities, favouring and safeguarding their areas of particular interest in an appropriate manner.

410. Chile believes that the work of this Council in the area of electronic commerce should entail sharing experiences and best practices so as to further our understanding of how Members have used IP in conjunction with electronic commerce to strengthen SMEs and other businesses. Sharing experiences and best practices will lead to a better understanding of how IP and electronic commerce interact and how policies aimed at fostering the use of IP for development are implemented in this area.

13.8 China

411. China would like to thank South Africa for the proposal. As IP enforcement in the digital environment has been emphasized a lot in the past, South Africa provides us with the perspective of IP and development in the digital era. We recall that the General Council adopted the Work Programme on Electronic Commerce in September 1998 and mandates Members to discuss issues related to electronic commerce in the General Council and four WTO bodies, including the TRIPS

Council. The Work Programme mandates the TRIPS Council to examine new technologies and access to technology. It also requires the Committee for Trade and Development to take into account the needs of developing countries, including the use of information technology. These issues are all related to IP and development in the digital era.

412. In recent years, we have witnessed a rapid development of electronic commerce around the world. E-commerce effectively helps enterprises, especially medium and small-sized enterprises, to reduce the cost of participating in the globalization process and provides more commercial, trade and investment opportunities for enterprises so that they can better integrate into the global supply chain. The COVID-19 pandemic further highlighted the importance of e-commerce to the global economy.

413. Meanwhile, we recognize that the challenges brought by e-commerce and new technologies have aroused worldwide attention. It is important to explore how developing countries could make better use of e-commerce to expand trade and investment opportunities. China thinks that we should work to increase developing countries' involvement in world trade through appropriate measures and access to digital technologies on commercial terms, especially in a digital environment.

13.9 Australia

414. Australia recognizes the role of the 1998 Work Programme in seeking to ensure IP-related issues arising in connection with electronic commerce are approached in a manner that promotes sustainable development.

415. Efforts to reinvigorate the 1998 Work Programme should be done in a manner that does not duplicate the work of the TRIPS Council or WIPO, but rather supports existing obligations (i.e. TRIPS Article 66.2 reporting).

416. We recognize the importance of continuing to create conditions that encourage voluntary technology transfer which is mutually beneficial and supports global development.

13.10 Switzerland

417. Switzerland thanks the delegation of South Africa for introducing its submission.

418. E-Commerce is a topic Switzerland attaches much importance to. We believe that the World Trade Organization has a central role to play in shaping a legally safe and reliable international regulatory framework that is conducive - and adequately responds - to the exponential growth that we have seen in e-commerce over the last two decades.

419. My delegation agrees that the objectives of the TRIPS Agreement as set out in its Article 7, including the balance of rights and obligations, apply to intellectual property protection in both the analogue and the digital environment.

420. As in analogue business, adequate and effective IP protection and enforcement is instrumental in e-commerce, whether it concerns goods or services. Switzerland is thus happy to participate in a discussion of the Council on e-commerce from the perspective of trade-related aspects of intellectual property rights.

421. We agree that the General Council mandate must guide us in this discussion. This mandate has however, in our view, its limits. The General Council instructs the TRIPS Council to examine the e-commerce-relevant aspects of the protection of copyrights and related rights as well as of trademarks and enforcement against their infringement, which in the world of e-commerce means, above all, counterfeiting and piracy activities.

422. With its reference to new technologies and access to such technology, the General Council recognizes in its mandate that the protection and enforcement of IPRs in e-commerce matters not only for copyright and trademarks, but also for patents, utility models and designs.

13.11 South Africa

423. Thanks to Members who intervened. Just noting a few points that have been made. As this particular submission focuses on new technologies and access to technology, it does not undermine previous discussions. The main focus of previous discussions was on counterfeits, piracy, technologies to enforce particular types of technologies and IPRs, etc. From that point of view, we see that our discussion is complementary and we certainly agree with China that the issue of access to technology and the link to development is something that we need to take into account. In terms of the timing of the communications, we agree they should be made available ahead of time, given the constraints that one faces in the current scenario and the limitations that many developing countries face during this difficult time. Going forward, proposals related to the 1998 Work Programme will be made available in good time. We are also encouraged by the intervention of many Members and the introduction of certain ideas that we could explore.

424. I believe that the impact on SMEs, for example, is noteworthy given the fact that the digital revolution primarily reduces the cost of doing business. But whether or not SMEs, especially from developing and least developed countries, may benefit from this reduction of costs is certainly an open question. But if I go back, for example, to the Trilateral Study (this has become somewhat of a bible for me, the 2013 version in particular since I have not had the opportunity to look at the updated version yet in any amount of detail), I believe that the cross-cutting issues that were brought up previously will benefit from the updated study. This will enable us to certainly make proper linkages between issues as we always recognize that the topic of technology transfer is not as simple as its seams. We recognize from our previous interventions that there are both demand and supply constraints, and any legitimate system must be enforceable, transparent and predictable. But in any system where there are differences in levels of development and capabilities, we must take advantage of the flexibilities to assist developing and least developed countries. The submission also focuses on possibilities to use flexibilities in a pro-development way in order ensure that we do have a level playing field for every Member to benefit from digital technology and to ensure that IPRs do not become a barrier to the equal access and enjoyments of the benefits of the digital revolution.

13.12 Nigeria

425. Let me start by thanking the delegation of South Africa for this very informative paper while we are still considering the proposal at capital, we would like to state our preliminary observations of some similarities of some of the elements of the paper with our national approach in operationalizing technology transfer under the TRIPS Agreement.

426. We are of the view that the discussions around the 1998 work programme on e-commerce should be continued. We also agree with Paragraph 4 of the proposal which implies that intellectual property can impact on development, therefore it is pertinent to foster discussions on this regard at the TRIPS Council. The need for developing countries' and LDCs' access to new technology cannot be overemphasized.

427. Furthermore, we agree, as was provided under Article 7 of the TRIPS Agreement, that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in other to ensure the balance of rights.

14 INTELLECTUAL PROPERTY AND PUBLIC INTEREST: BEYOND ACCESS TO MEDICINES AND MEDICAL TECHNOLOGIES TOWARDS A MORE HOLISTIC APPROACH TO TRIPS FLEXIBILITIES

14.1 South Africa

428. A main focus at the WTO has been how to facilitate access to medicines in the context of the Doha Declaration on TRIPS and Public Health. The Amendment to the TRIPS Agreement entered into force in 2017. In the usual way, the term 'TRIPS flexibilities' has been emphasised in the context of access to medicines and medical technology through compulsory licenses or Government use and even in that context remains under-utilized.

429. The High-Level Panel Report on Access to Medicine observes that: "…WTO Members retained important public health flexibilities that can be used to adapt their intellectual property law, policies and practices to meet human rights and public health objectives. These include the ability to determine patentability criteria, issue compulsory licences, authorise parallel importation, apply general exceptions and employ competition laws to limit and remedy the abuse of intellectual property rights in domestic legislation."[21] In this regard, there are still a significant number of countries that do not make full use of available flexibilities under the TRIPS Agreement.

Towards an integrated approach to TRIPS flexibilities

430. The use of TRIPS flexibilities to address a public health concern is usually seen as a matter concerning patents. However, the COVID-19 pandemic requires a more integrated approach to TRIPS flexibilities that include other various types of intellectual property (IP) rights including copyrights, industrial designs and trade secrets. The use of TRIPS flexibilities in other areas of intellectual property, beyond patents, is less understood at the national level. In fact, in other fields of IP, national IP laws may not even provide for sufficient flexibilities to address issues of access. A variety of IP rights are relevant in the fight against COVID-19.

431. The COVID-19 crisis created the need to produce essential equipment and medical supplies, there is a growing need to be able to manufacture essential medical devices such as masks, ventilators and other personal protective equipment. As the debate over COVID-19 moves beyond medical issues, the nature of the pandemic requires non-medical approaches to detect, diagnose and trace the coronavirus. Studies have found that levels of neutralizing antibodies against SARS-CoV-2 remain high for a few weeks after infection, but then typically begin to wane.[22] So far, only one infectious disease comparable to COVID-19 in its broad geographic distribution has been eradicated: this disease is smallpox.

432. According to GAVI, even if eradication of COVID-19 is ultimately technically feasible, it will likely be extremely challenging.[23] It cautions that given the uncertainty around the technical feasibility of eradicating COVID-19, the global community also needs to plan for the possibility that COVID-19 will be in global circulation indefinitely. In the absence of prophylaxis through a vaccine and more effective treatments, non-medical measures have been an important priority in dealing with the devastating impacts of COVID-19.

433. Other goods and services that are needed to tackle the epidemic include protective equipment such as masks, face shields, and hand sanitizers. Such equipment and material remain in critical shortage in many countries around the world. Many WTO Members lack domestic manufacturing capacity and would be dependent on imports to meet their medical needs.

434. When an exporting country is producing under a compulsory license mainly for export, the mechanism established by the 30 August 2003 decision, and later translated into an Amendment to the TRIPS Agreement as Article 31*bis*, would be applicable. This mechanism waives the condition in Article 31(f) that a compulsory license should be predominantly for the supply of the domestic market. It should be noted that the implementation of the Article 31*bis* mechanism at a national level is very limited and may not achieve its intended objectives.[24] In any event, many developing countries may also face legal, technical and institutional challenges in using TRIPS flexibilities. This is especially true for countries that have never utilized flexibilities such as compulsory licenses.

435. The World Health Organization has launched the COVID-19 Technology Access Pool (C-TAP) *inter alia* calling on intellectual property holders to voluntarily license such rights on a "non-exclusive and global basis to the UNITAID-established and supported Medicines Patent Pool and/or through other public health research and development mechanisms, consortia or initiatives that facilitate

[21] Report of the United Nations Secretary-General's High-level Panel on Access to Medicines - *Promoting innovation and access to health technologies (2016)*, at p. 22.

[22] Ling Ni, Fang Ye, Meng-Li Cheng et al *Detection of SARS-CoV-2-Specific Humoral and Cellular Immunity in COVID-19 Convalescent Individuals* Immunity *52*, 971–977, June 16, 2020.

[23] See the GAVI Vaccine Alliance <https://www.gavi.org/vaccineswork/could-covid-19-ever-be-eradicated>

[24] WIPO CDIP/5/4 Annex II Categories of Different Provisions on Specific Flexibilities: <https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex2.pdf#page=1>

global and transparent access; and/or voluntary non-enforcement of intellectual property rights, as appropriate, during the COVID-19 pandemic, to facilitate the widescale production, distribution, sale and use of such health technologies throughout the world". However, to date no company has committed to doing so. Instead limited, exclusive and often non-transparent voluntary licensing is the preferred approached of pharmaceutical companies, which will be insufficient to address the needs of the current COVID-19 pandemic.

Some Examples

Example 1: Big data outside of the health system

436. Smartphones, mobile data, artificial intelligence, databases and algorithms have been used in the COVID-19 pandemic to leverage the detection and control and control of the virus. Different types of IP rights are relevant to protect AI algorithms, some may be protected by copyright and trade secrets while other technology is protected by patents while database rights and trade secrets may also be relevant.

437. While these approaches help with efforts to contain the spread of the virus, they can raise issues about the right to privacy and personal freedoms. National security concerns may also arise in the context of Article 73 of the TRIPS Agreement.

Example 2: 3D printing technology

438. During this COVID-19 outbreak, an Italian hospital ran out of ventilator valves (which cost USD 11,000 each) and their regular supplier could not produce them on time. A duo after scanning an existing valve, 3D printed replacement valves which only cost about USD 1 each, saving ten lives as of the time of the Article.

439. According to a news report, the original manufacturer was actually approached by the duo in hopes to ask for the valve's blueprints in an urgent attempt to save them time and produce the valves to instantly save the critical COVID-19 victims but they were declined.[25] The pair then proceeded to manufacture the replicas by manually measuring the valves and 3D printing three different versions to see which one worked best.

440. According to another news report, "potential legal and medical issues have stopped Fracassi from distributing the digital design file more widely, despite receiving hundreds of requests for the 3D-printed valves".[26]

441. Following this case, a law firm warned "…manufacturers should be aware of the complex intellectual property issues concerned with this 3D printing technology. Parts such as valves or other medical devices and equipment are capable of protection by patent and/or registered design. Unregistered design rights and copyright will also apply to the part itself and/or the digital model or CAD file. Some or all of these rights might apply in respect of a single component".[27]

442. The firm cautioned "In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts)".[28] Furthermore the firm advises that any person or company intending to manufacture parts using 3D printing should carry out some due diligence to identify:

- who ultimately holds the intellectual property rights in the component;
- whether the part is protected by patent or registered design; and
- whether the rights holder is willing to permit the parts to be manufactured in return for a small or nominal royalty for the wider public benefit; and

[25]< https://www.techtimes.com/articles/248121/20200317/maker-ventilator-valves-threatens-sue-volunteers-using-3d-printedcoronavirus.htm>

[26] <https://www.forbes.com/sites/amyfeldman/2020/03/19/talking-with-the-italian-engineers-who-3d-printed-respirator-partsfor-hospitals-with-coronavirus-patients-for-free/#1529841378f1>

[27]https://www.shoosmiths.co.uk/insights/articles/3d-printing-social-responsibility-vs-legal-risks

[28] Ibid.

- whether any regulatory approval is needed for supply of the parts.

443. This case clearly demonstrates the interface between IP and new technologies such as 3D printing and may require a better understand of how a balance may be achieved between rights holders and third parties. More collaborative approaches have been achieved through various pooling mechanisms for access to medicines, this is also true for more generic IP pledges that covers a broad range of equipment, software, network and device applications useful in healthcare, containment, tracking, diagnostics, emergency response and social distancing. Such approaches nonetheless are limited and may require action on the side of national authorities to ensure access to such technologies where pledges or voluntary licenses cannot be secured on commercially reasonable terms.

Example 3: Trade Secrets

444. Trade secrets encompass vast quantities of information needed to discover, test, create, and manufacture diagnostics, treatments, and vaccines.

445. Potential trade secrets include manufacturing processes, test data, medical formulas, and more. For vaccines and other biologic medicines, cell lines, genomic information, and other biological material can also be held as trade secrets. Data about the effectiveness of medicines and vaccines are trade secrets. Even so-called negative information — information about what does not work — can be a trade secret.

446. Article 39.2 of the TRIPS Agreement requires Members to protect undisclosed information, which is secret, has commercial value and has been subject to reasonable steps to be kept secret. Both voluntary and compulsory licenses, though common in other forms of IP are unusual in trade secrets.

447. Professor David. S Levine[29] posits that: "Clearly, there should be times when trade secrecy's ability to lock down information gives way to broader national and international information sharing concerns. If there were ever a case for re-examining trade secrecy's unquestioned dominance, a public health crisis on the scale of COVID-19 would be the time." He concludes by saying: "What seems initially like a narrow issue involving intellectual property law and innovation may actually be a critical barrier to our ability to rapidly, effectively, affordably, and safely solve the COVID-19 pandemic. The time is now to examine, and re-examine, trade secrecy's hold on information and our collective health."[30]

Questions

1. To what extent are TRIPS flexibilities embedded in areas outside patent protection well understood? If so, how are Members implementing such understandings in their national and regional laws?

2. What are the likely difficulties that Members may face in dealing with a changing technology landscape where embedded IP rights may affect the dichotomy between IP rights as private rights and the public interest dimensions recognized in the TRIPS Agreement?

3. What are the benefits and limitations of initiatives such as voluntary licenses and pledges to access much needed technology to deal with the COVID-19 pandemic?

4. Are there circumstances where trade secrets can be shared more broadly? If so, what are those circumstances? Would national or international health pandemics fall within this category?

14.2 Nigeria

448. In response to the questions framed after paragraph 20 of the proposal, the applicability of the exceptions and limitations of the TRIPS Agreement particularly compulsory license may be a

[29] 'Covid-19 should spark a re-examination of trade secrets' stranglehold on information.' < https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/>

[30] Ibid.

useful tool in ensuring that the patent system contributes to innovation and technology transfer, where Governments put in place policies that are against patent non-use and technology suppression. However, our country experience is such that it is difficult for such a tool to spark innovation as many private parties lack the technological know-how and the financial capacity to be able to finance such innovations which if achieved could foster development in Nigeria.

449. Under the Patent Act of Nigeria, a flexibility exists for compulsory licensing system that serves to promote a balance between patent protection and public interest. Nigeria is also working on a national policy and strategy which links the other parts of the economy with IP.

450. Another application of the TRIPS exceptions is the provision of fair use. Nigeria, as a common law nation, authorizes fair use as is provided for in our laws to include any use that is for personal consumption or for educational purposes. This provision is contained in our Copyright Act and aims at promoting innovation.

451. We reserve our right to come back on this agenda after due consideration from capital. We are also willing to hear other member`s experiences and approach under this agenda item.

14.3 Indonesia

452. We thank the delegation of South Africa for coming up with this important communication. We see this as timely reminder on the importance of WTO in discussing the implication of IP rights over the broad range of products, technology and medical supplies that desperately needed for responding to COVID-19 Pandemic.

453. Most of our domestic IP regimes were crafted with compartmentalized approach. In doing so, IP rights laws, excluding patent and maybe trade secret, does not include flexibilities that could address public health policy objectives.

454. This is also true with regional trade agreements. The IP chapters are among the most delicate issues in the negotiation process. In fact, the inability to narrow the gap of interest in IP matters, made some of our regional trade agreements omit the IP Chapter completely in favour of TRIPS Agreement.

455. There is room for improvement in understanding and incorporated flexibilities provided by the TRIPS Agreement in national laws of Members, especially for developing countries. The Doha Declaration on the TRIPS Agreement and Public Health reaffirms the right of WTO Members to protect public health. While the interpretation of this Declaration is covering all spectrum of IP-rights, the application of this principle is inadequately understood at national level.

456. The coverage of intellectual property rights protection for products, medical supplies, technology, therapeutics, and vaccines during this COVID-19 pandemic is indeed broad. The delegation of South Africa rightly pointed out some cases that highlighted the potential impediment mass production of products and technologies highly needed by Members. In addition, we also note increasing legal disputes involving IP-rights on vaccines development that could further complicate vaccines development that badly needed.

457. There are two issues that we would like to share in addressing question number two.

458. First, given the scale of infection of COVID-19 globally, scaling-up production of products, technology, medicines, and vaccines will be a key issue in ensuring no countries left behind in access to health for COVID-19. The absence of effective global cooperation in ensuring collaboration in IP-rights, makes the scaling-up production depends solely in the industry's policies and strategies.

459. Second, even if some Member has enabling law to ensure application of flexibilities of patents, there are no guarantees of straightforward production due to the fact that a patented product or technology could consist of several IP-rights.

460. We are pleased to learn from the WHO vaccines landscape that many developing-country Members are also in advance stages of developing vaccines for COVID-19. At the same time, cooperation between developing countries in ensuring mass production is also increasing.

461. But we understand that we are still facing huge limitations in access for advanced technology, therapeutics drugs, even vaccines, despite such cooperation. We are hopeful that voluntary licensing schemes, as initiated by a few international organizations could help narrow down these challenges. However, as this scheme mostly leans into the premise of global solidarity from multi-stakeholders, certain barriers, including possible decreasing incentives from monopoly of supply, make voluntary IP pool a wishful thinking.

462. On the issue of trade secrets, we believe that Article 39 Paragraph 3 of the TRIPS Agreement provides legal justification on disclosure of trade secrets where there is a necessity to protect the public. We are convinced that protection of the public also includes national and global pandemic.

463. However, to ensure the effective implementation, national IP law must also regulate the submission of undisclosed test or other data as part of condition of approving the marketing of certain products.

14.4 Chile

464. We wish to thank South Africa for including this agenda item. Chile wishes to reiterate that the TRIPS Agreement is based on intellectual property not as an end in itself, but as a tool for development. The minimum standards of protection and flexibilities envisaged in the Agreement therefore enable Members to establish or adapt intellectual property systems in line with their national realities, ensuring an appropriate balance at local level between IP rights and obligations.

465. Chile continues to encourage the use of flexibilities when designing balanced intellectual property systems that act as a tool to foster innovation while addressing the needs of society as a whole. In the case of the COVID-19 pandemic, we have witnessed how all of mankind has joined forces to address and overcome COVID-19 as a shared problem.

466. At the multilateral level, Chile and other Members have agreed on initiatives such as the WHO's C-TAP and the expansion of the Medicines Patent Pool's mandate, which encourage voluntary approaches to ensure that in the future we do not face the same problems that occurred at the beginning of the year and that continue to affect many Members. We have also seen how this pandemic has inspired an innovation exercise at the global level, one that is not necessarily based exclusively on IP, but rather on solidarity.

467. In Chile, the pandemic has generated an important discussion at the legislative level on the use of the various flexibilities of the TRIPS Agreement, and we are therefore interested in engaging in dialogue to share experiences of how IP has fostered innovation in the different areas mentioned in South Africa's document and in others, and of how flexibilities have been used to address problems such as the one we are currently facing.

14.5 Tanzania on behalf of the African Group

468. The African Group thanks South Africa for their paper contained in document IP/C/W/666 as communicated by South Africa. We think this communication comes at a critical time when discussions on TRIPS flexibilities are more relevant than ever, considering the situation WTO Members are going through in relation to COVID-19.

469. The African Group has on several occasions reiterated the importance and need to intensifying discussions on TRIPS flexibilities particularly in line with the fight against COVID-19. The Group has been calling for solidarity and cooperation to ensure that treatment for COVID-19 is accessible and affordable to the world as a public good. In this connection, we recognize that the TRIPS Council has a significant contribution to play in the achievement of this objective.

470. COVID-19 has exposed the deficiencies of our public health systems, particularly for the developing and LDCs. For instance, Africa has been overdependent on imports of medicinal and pharmaceuticals, a situation that has subjected our public health systems to systemic vulnerabilities, which were fully exposed during COVID-19 outbreak when global supplies fell short on essential medical supplies such as ventilators, diagnostic devices, protective gears and equipment (PPEs) and medicines.

471. It is against this background that the African Group has raised its concerns on the COVID-19 impact and outlined them in document WT/GC/219 and TN/C/20. With our submission, together with that by South Africa, we believe we can meaningfully contribute to discussions on the COVID-19 impact and the requisite trade policy tools to build our capacities and support our resilience to crises such as COVID–19.

14.6 Colombia

472. Colombia is very interested in this discussion. We consider it a priority for Members to coordinate on how to address the implementation of the flexibilities provided for in the TRIPS Agreement, while continuing to uphold the principles established in the Agreement and seeking alternative measures that safeguard public health, without disproportionately and unduly affecting intellectual property rights.

473. More specifically, regarding the use of the exceptions provided for in the TRIPS Agreement, Colombia has, until now, been able to address its public health requirements through direct dialogue with intellectual property right holders. In this way, we have managed to find solutions jointly and consensually, without any need to use the flexibilities provided for in the TRIPS Agreement.

474. The current global health crisis is a different scenario, however. Colombia cannot rule out the possibility of implementing the various TRIPS flexibilities in the future, particularly in the context of a health crisis such as this one, where it has become necessary to safeguard the primary objective of protecting public health.

475. Nevertheless, Colombia reiterates its commitment to respect intellectual property rights, and we reiterate that if it becomes necessary to use the flexibilities provided for in the TRIPS Agreement, the country will remain committed to complying with the principles set forth in that Agreement, and do its utmost to strike a balance as regards the measures taken.

14.7 China

476. Once again, we appreciate South Africa's proposal. COVID-19 seriously threatens human health and safety, causes huge negative effects to the functioning of global supply chain and poses grave challenges to the normal supply of relevant medicines, medical equipment and PPEs. China thinks that in the current situation, Members are fully entitled to utilizing flexibilities in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health to maintain public health.

477. In China's domestic laws, patent is the major field where TRIPS flexibilities are employed to ensure access to medicines and medical technologies. China's Patent Law has a special chapter on compulsory licensing. It stipulates that in emergency or extraordinary situations, or for public interest objectives, the Chinese patent administrative agency can issue compulsory licensing of inventions and utility models. In 2012, China issued Measures for Compulsory Licensing for Patent Exploitation and operationalizes the application and granting procedures of compulsory licensing. Besides, China's Patent Law also allows parallel imports.

478. China always holds the view that a right balance should be achieved between IP right holders and public interest. The protection of IP rights should go in parallel with legitimate use of TRIPS flexibilities. We support an open and inclusive discussion of IP and Public Interest so that Members can freely exchange views and experiences in utilizing TRIPS flexibilities.

14.8 Malaysia

> 1. To what extent are TRIPS flexibilities embedded in areas outside patent protection well understood? If so, how are Members implementing such understandings in their national and regional laws?

479. TRIPS flexibilities as to the method of implementing TRIPS obligations allow WTO Members different ways to transpose into national law that the TRIPS Agreement simply articulate but does not define. For example, in the field of enforcement the TRIPS Agreement allows WTO Members to resort to their own legal system and practices to implement enforcement obligations.

480. TRIPS flexibilities with regard to standards of IP protection in Malaysia include exceptions and limitations provided for, but not limited to, under the copyright and industrial property laws in Malaysia. For example, copyright protection incorporate flexibilities where it allows exceptions for visually and hearing-impaired people.

> 2. What are the likely difficulties that Members may face in dealing with a changing technology landscape where embedded IP rights may affect the dichotomy between IP rights as private rights and the public interest dimensions recognized in the TRIPS Agreement?

481. The relevant IP laws on protection of technology provide sufficient flexibility in dealing with a changing landscape where embedded IP rights may affect the dichotomy between IP rights as private rights and public interest.

482. The main challenge is generally to strike a balance in providing an IPRs framework that can assure adequate protection of IPRs that is not considered, as under- or over-protection of IPRs which may undermine the larger economic strategy of a country. However, in certain circumstances, there may be cases in which private interests in IPRs must be subordinated to more compelling public interests. Many countries, for example, are facing increasing social and financial difficulties a consequence of public health and epidemic disease.

483. Another difficulty that Members may face in dealing with a changing landscape is that the impact of IPRs itself is dependent on the types of technology. For example, the role of IPRs in the process of development in the pharmaceutical industry is very different to the role of IPRs in the mobile phone industry.

> 3. What are the benefits and limitations of initiatives such as voluntary licenses and pledges to access much needed technology to deal with the COVID-19 pandemic?

484. When patent holder companies issue voluntary licences for patented medicines, they enable other manufacturers to develop generic versions of these medicines. This helps to support supply, increase affordability and improve access to ensure an inclusive and sustainable healthcare to our wider society. In Malaysia's view, the limitation of voluntary licensing which is based on countries economic developments. Due to COVID-19, many countries are faced with challenges in addressing the high cost of medicines and technologies required in mitigating this pandemic.

485. Malaysia welcomes discussion among WTO Members on the implications of intellectual property rights over the technologies and products required for mitigating COVID-19 pandemic with the aim of ensuring that IP rights including patents, industrial designs, copyright and trade secrets do not create barriers to scaling up research, development and supply of technologies necessary to mitigate COVID-19.

> 4. Are there circumstances where trade secrets can be shared more broadly? If so, what are those circumstances? Would national or international health pandemics fall within this category?

486. WTO Members have a considerable flexibility to define which situations trade secrets can be shared, provided that such situations are consistent with the WTO TRIPS Agreement.

14.9 Zimbabwe

487. Zimbabwe extends its appreciation to the delegation of South Africa for submission of the document IP/C/W/666 on "Intellectual Property and Public Interest: Beyond Access to Medicines and Medical Technologies Towards a more holistic approach to TRIPS flexibilities."

488. Zimbabwe believes that the emergence of the Coronavirus disease 2019 (COVID-19) makes it incumbent upon us to re-invigorate the discussion on intellectual property and public health. The search for a COVID-19 vaccine and treatment is of utmost importance and it is necessary for Members to be cognisant of the limitations and exceptions open to them to ensure universal access to quality and affordable treatment once a suitable vaccine is found.

489. Zimbabwe has noted that discussions on TRIPS flexibilities and access to medicines have largely delved on limitations and exceptions to patent rights. We are aware of the efforts by pharmaceutical companies to protect their medicines through trade secrets as opposed to patents.

490. We have also noted the increased reliance by pharmaceutical companies on other forms of IP such as trademarks and industrial designs to protect medicines. Therefore, this proposal is essential for Members to fully explore the limitations and exceptions which are afforded by the TRIPS Agreement to the full spectrum of IP.

491. We call upon all Members to support this very important proposal and look forward to participating in the ensuing discussions.

14.10 India

492. We thank the delegation of South Africa for their submission.

493. The TRIPS flexibilities have stood out as important policy space for Member Countries to enable them to create an IPRs regime that ensures compliance with the obligations set out in the Agreement while taking into account their developmental priorities. These flexibilities include fair use exception (copyright), research exceptions (copyright and patent), compulsory licensing (patent), parallel import, transition periods for developing and least developed countries. While patent law flexibilities are widely discussed owing to the fact that they deal with the extremely sensitive area of public health, deliberation on flexibilities in other IP areas has been somewhat limited.

494. As rightly pointed out by South Africa in its communication, battling with a pandemic like COVID-19 requires a more integrated approach to TRIPS flexibilities in all IP regimes including those in copyrights, industrial designs and trade secrets etc. Ongoing COVID19 crisis further highlights the urgent need to initiate discussion and deliberation on the flexibilities available in these IP regimes.

495. India has incorporated some of the flexibilities outside the patent protection regime that come within the scope of TRIPS Agreement in its domestic legislations. For example, the provisions related to fair use, statutory licensing and compulsory licensing in Indian Copyright Act, 1957 and parallel imports under Indian Trademark Act 1997.

496. However, the changing technology landscape with embedded IP rights have led to new challenges. Emerging technologies like 3D printing, artificial intelligence and their wide use in response to COVID-19 outbreak, including in manufacturing of ventilator valves, the AI algorithms used in identifying the outbreak and modelling travel patterns, screening passengers and predicting possible reinfections - may be protected by IP rights other than patents, like copyright, trade secrets, database rights underlying importance of flexibilities in those IP areas.

497. The COVID-19 pandemic is an unprecedented crisis, which continues to cripple economies. Its impact is particularly disastrous for the developing and least developed countries, as they lack requisite tools such as strong economy and medical infrastructure to counter the crisis. As these countries lack the capability to develop high end vaccine at short notice, the need for technology transfer and dissemination of necessary undisclosed information, trade secrets and sharing of patent has intensified. Due to lack of legal enforceability, the success of voluntary licenses and pledges will ultimately depend on the goodwill of IP holders. Moreover, as the voluntary licensing agreements are kept secret and their terms and conditions are un-known, large markets may remain unserved and monopoly situations could continue. More transparency in this regard would help in balancing the issue of IP rights and affordability.

498. Members need to deliberate upon how broader sharing of information under the trade secret regime can help in addressing a global health pandemic of the scale of COVID-19. In this regard, it is important to note that Paragraph 1 of Article 39 of the TRIPS Agreement sets down the context in which the protection to undisclosed information needs to be provided. The context is to ensure against unfair competition as provided under Article 10*bis* of the Paris Convention which mandates Members to provide effective protection against acts of competition contrary to honest practices in industrial or commercial matters.

499. In conclusion, we believe that further discussion on the flexibilities available in various IP regimes under TRIPS Agreement is required so as to counter the pandemic.

14.11 Chinese Taipei

500. We understand that according to Articles 7, 8, and 13 of the TRIPS Agreement, besides patent protection, there are flexibilities among WTO Members, in formulating and amending respective laws and regulations to adopt measures necessary to protect public interest as well as provide limitations or exceptions to copyright and related rights.

501. Hence, given the impact of COVID-19, students may be kept out of schools due to temporary school closure. We have drafted amendments to the Copyright Act to provide limitations and exceptions in relation to the use of works for distance learning in order to protect significant public interests such as knowledge dissemination and cultural development.

502. As pointed out in the Doha Declaration on the TRIPS Agreement and Public Health in 2001, the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health. Particularly, as the COVID-19 is still raging, it is worth placing emphasis and deep thinking by all WTO Members as to how to more holistically use the TRIPS Agreement's flexibility to balance between safeguarding IPRs protection and the interests of public health.

14.12 Canada

503. Canada would like to thank South Africa for circulating document IP/C/W/666, under the *ad hoc* agenda item of "Intellectual property and the public interest", on the topic of access to medicines and TRIPS flexibilities.

504. The discussion of these issues is particularly timely, as all countries are working to develop effective treatments for COVID-19.

505. Canada's longstanding view is that the multilateral framework under TRIPS, as well as the flexibilities affirmed under the Doha Declaration on the TRIPS Agreement and Public Health, already establish an appropriate balance between protecting IP rights and promoting access to medicines.

506. Ensuring this appropriate balance will remain important as the timing and availability of promising COVID-19 treatments and other technologies becomes clearer in the months ahead.

507. Canada also reminds that IP rights are one part of a broad discussion informing the availability and accessibility of medicines and relevant technologies. As the Doha Declaration emphasizes, the TRIPS Agreement is part of the wider national and international action to address public health problems.

508. With respect to TRIPS flexibilities more specifically, Canada is always open to sharing its own national experiences and lessons learned in implementing the Paragraph 6 system, as well as on our more recent amendments to Canada's Patent Act, as notified earlier this session, under document IP/N/1/CAN/30.

509. Similarly, we continue to be interested in learning more about the practices of Members in this area and invite other Members to share their national experiences in this regard.

14.13 United Kingdom

510. We would like to thank South Africa for introducing this agenda item and giving the Council an opportunity to discuss this important issue.

511. Intellectual property rights provide incentives to create and commercialise new inventions, such as life-changing vaccines. They keep innovators innovating, creators creating and investors investing.

512. The UK believes that a robust and fair intellectual property system is a key part of the innovation framework that allows economies to grow, while enabling society to benefit from knowledge and ideas.

513. Multiple factors need to be considered to ensure equitable access for all to COVID-19 vaccines. These include increasing manufacturing and distribution capacity, measures to support or incentivise technology transfer, ensuring global supply chains remain open, and ensuring that effective platforms are utilised to voluntarily share IP and know how.

514. There are existing mechanisms that facilitate the sharing of IP. For example, expanding the mandate of an existing organisation such as the Medicines Patent Pool to cover COVID-19.

515. The UK has long supported affordable and equitable access to essential medicines, including in low and middle-income countries.

516. The world urgently needs access for all to safe, effective, quality, and affordable vaccines, diagnostics, medicines, and other health technologies to enable an effective response to the COVID-19 pandemic.

517. The UK has played a leading role in financing the global effort and working with our international and national partners, to identify end-to-end solutions that ensure affordable access for all, such as such as mechanisms to support the voluntary sharing of IP and know-how, manufacturing at scale and ensuring no-one is left behind, including the poorest and most vulnerable.

518. We are committed to collaborating with public and private partners in the UK and internationally, including exploring voluntary arrangements and approaches such as non-exclusive voluntary licensing which promote affordable access for all while also providing incentives to create new inventions, to accelerate development and equitable access in all countries to affordable health technologies for responding to COVID-19.

519. We encourage active dialogue between industry and governments to explore how best to work together to facilitate access to medicines, including TRIPS-compliant licensing models in developing countries.

14.14 European Union

520. The EU would like to thank South Africa for introducing this agenda item.

521. The world quickly needs to develop and deploy effective diagnostics, safe and effective treatments and vaccines, which are available and accessible everywhere, at an affordable price. This is the only way to make sure we can jointly defeat the virus.

522. It is clear that broad and equitable access to existing and new treatments, and ultimately vaccines, will be key to tackle the present public health crisis, including for developing countries that have no production capacities or more limited financial resources.

523. It is with this objective in mind that the EU has led "The Coronavirus Global Response" pledging initiative with the WHO and global partners to accelerate the development, production and deployment of vaccines, diagnostics and therapeutics, and to strengthen national health systems against COVID-19. The EU has also led the work on a Resolution on COVID-19 Response, adopted by the 73rd World Health Assembly on 19 May 2020. This resolution represents a strong commitment of the global community to international cooperation in fighting the pandemic and ensuring access to COVID-19 treatments and vaccines.

524. Global cooperation is essential to accelerate the development and scale-up the production of safe, effective, quality diagnostics, medicines and vaccines for the COVID-19 response, including through arrangements with industry and existing mechanisms for voluntary pooling of rights and licensing.

525. Pooling of rights and other voluntary licensing arrangements allow to accelerate the development of diagnostics, medicines and vaccines for COVID-19 and scaling up their production. These mechanisms benefit everyone as they drive both access and innovation.

526. The TRIPS Agreement provides various avenues to address potential IP matters in the case of health emergencies should voluntary mechanisms fail, not only with regard to patents, but also with regard to other IP rights. These include general clauses on exceptions or provisions on compulsory licensing.

527. In the European Union these provisions are implemented either at regional or national level. For example, the areas of copyright, trademarks, designs and trade secrets are largely harmonised at regional level, including provisions on exceptions and limitations. On the other hand, the granting of compulsory licences in the area of patents is regulated at national level - each EU Member State has relevant legislation and is able to issue a compulsory licence at national level.

528. The EU has consistently supported the use, where necessary and justified, of the flexibilities provided under the TRIPS Agreement and the Doha Declaration with the objective of ensuring effective access to medicines.

529. We also recall that the TRIPS Council Secretariat has, regularly and consistently, offered its services to any WTO Member that sees itself in the need of getting help to manage the process of Article 31bis of the TRIPS Agreement.

530. The innovation model, based on patents, has delivered consistent progress in global public health, continuously leading to important new and improved treatments as well as much extended life expectancy, tackling the global health challenges humanity faced so far. The EU considers that on the basis of the current system, with the necessary IP tools and arrangements in place, existing and new treatments, and ultimately vaccines, can be made available and effectively deployed rapidly across the globe.

531. A well-functioning ecosystem for the protection and enforcement of intellectual property rights remains a crucial incentive for innovation, the research and development of new vaccines, medicines and treatments.

532. Let us also recall that evidence shows that indeed there are many different significant causes of lack of access to medicines. It is no different in the case of COVID-19. There are no simple solutions to the current crisis. We need the necessary expertise in production of new treatments or vaccines, we need sufficient manufacturing capacity and access to resources needed to produce such treatments or vaccines.

533. It is the view of the European Union that in order to ensure equitable and affordable access to the required treatments and vaccines, we must work collaboratively with industry and with each other, incentivise innovative solutions to COVID-19, ramp up manufacturing capacity and pool resources.

534. There is another aspect in the fight with COVID-19 that we would like to highlight in this discussion.

535. A report by Europol titled 'Viral Marketing – counterfeits, substandard goods and intellectual property crime in the COVID-19 pandemic' shows that organised crime groups quickly adapt to the new trade environment and find their way to infiltrate the legitimate supply chain of pharmaceutical products and equipment. A study of the European Union Intellectual Property Office and the Organisation for Economic Cooperation and Development on Trade in counterfeit pharmaceutical products shows the economic and social costs of trade in fake medicines and the threat to public health.

536. The surge in demand for anti-COVID-19 products poses heightened risks to public health, because fake and substandard products, such as unproven and fake treatments, test kits and medical equipment and supplies – masks, ventilators, gloves, etc. – have flooded the market and this is bound to get worse when the new COVID-19 treatments and vaccines will be available.

537. Due to the global nature of these crimes, global cooperation is necessary.

538. Public health in light of the pandemic is a clear and undisputed priority. No effort must be spared to obtain effective and affordable treatment, vaccines, tests and medical devices necessary to fight this pandemic and to ensure that these products are safe for our citizens. These efforts have to be sustained for as long as needed.

14.15 Ecuador

539. Ecuador wishes to thank the delegation of South Africa for including this agenda item. Its inclusion is timely in a context where we should be joining forces and coordinating activities to re-establish our present and future global health security.

540. We wish to reiterate our commitment to the Doha Declaration on the TRIPS Agreement and Public Health (the amendment to which entered into force in 2017), which contributes by ensuring that Members have the right to protect public health and, in particular, to promote access to medicines for all.

541. Examining the issue raised by South Africa will most certainly help us to better understand the extent to which different forms of intellectual property rights allow or prevent access to the various types of technologies and products needed to tackle COVID-19.

542. The need for access to treatments, diagnostic methods, and medical devices and supplies, as well as the search for a vaccine, are concerns that must be taken into consideration by the international intellectual property system.

543. It is important to take into account that the flexibilities set out in the Agreement are not limited to patents, and we must therefore consider all the various forms of intellectual property in order to address this issue in a holistic manner.

544. In this context, adopting a multilateral cooperative approach that seeks to foster innovation, creation and technology transfer will ensure that the intellectual property system constitutes a key tool for providing answers to countries in their efforts to combat this pandemic.

14.16 Australia

545. Australia thanks South Africa for its communication.

546. Consistent with the 18 May World Health Assembly COVID-19 response resolution, Australia recognizes the need for universal, timely and equitable access to essential health technologies and products, consistent with the TRIPS Agreement.

547. Australia stresses the vital role of IP in incentivising the often costly and timely development of important health products, including vaccines we continue to believe that voluntary pooling and licensing initiatives that respect private rights are effective tools in driving innovation and facilitating widespread access.

548. We also wish to highlight ongoing international initiatives to finance, access and equitably distribute COVID-19 treatments and vaccines in a manner that respects international IP rules and the rights of IP holders and note that close and practical collaboration between Members will be critical to achieve this.

549. In accessing the personal protective equipment and other tools necessary to address COVID-19, Australia reminds Members that beyond intellectual property rules, it is other trade-related measures have an important role to play in supporting widespread access for example, APEC and the G20 have already made a number of commitments on the need to maintain trade in essential goods and Australia underscores the need for all Members to continue to guard against protectionism and support open supply chains.

550. In this time of crisis, the TRIPS Agreement should support quick, fair, predictable and implementable access arrangements to vital health products we recognize the need for all Members

to understand their rights and obligations under the TRIPS Agreement, including its flexibilities to this end, we support the provision of further information to Members regarding key Articles in the Agreement.

551. It is Australia's view that a harmonious, well-functioning and clearly understood international IP framework, underpinned by the TRIPS Agreement and the rights of IP holders, is crucial in ensuring Members can address the challenges posed by COVID-19.

14.17 Switzerland

552. We thank South Africa for their submission. The question of access to medicines and medical technologies is particularly relevant in a crisis such as the COVID-19 pandemic.

553. Switzerland is committed to ensure global equitable access to COVID-related medical products including vaccines.

554. Considering the global toll which the pandemic has already claimed, all the suffering and the heavy impact on each country's and the world's economy, there is no doubt that the international community and Governments face a unique challenge these days.

555. How can we enable and ensure access to COVID-19 relevant technologies?

556. In spite of the magnitude of the challenge, there is also some light, albeit it may not yet be the light at the end of the tunnel.

557. The pandemic triggered an unprecedented collaboration between major actors who have come together at the international level to do everything possible to contain the crisis and, *inter alia*, provide the medical technology needed.

558. The intellectual property system is one of the key components leading to access to quality of medical products. The IP system has contributed to making this extraordinary and continued collaboration effort at a global scale possible.

559. Partnerships, whether private-private or public-private, are essential to developing a vaccine and effective treatments against the novel coronavirus.

560. Within a reliable overall legal framework, IP is a foundation for stakeholders, for the public and private actors, it spurs their interaction and makes them willing to share information, knowledge and data, to aliment the global databases, license in and out technology, and to do what is necessary to scale up capacity.

561. The latter will be the crux when it comes to specific COVID-19 technologies and a vaccine in particular, and when ensuring populations' access.

562. Multilateral and global initiatives such as the COVID-19 Vaccine Global Access facility (COVAX) and the Gavi COVAX Advance Market Commitment (AMC) will consider IP issues as part of the negotiation package with private providers.

563. South Africa raises the question of the dimension of TRIPS flexibilities in the current pandemic. We agree with South Africa that the aspect of IP relating to COVID-19 and public health issues certainly go beyond patent rights, and goes beyond medical products in the strict sense.

564. Switzerland acknowledges countries' right to use the TRIPS flexibilities as they were reaffirmed in the Doha Declaration on TRIPS and public health.

565. However, measures disincentivising efforts and investment undertaken by relevant stakeholders, including in R&D, we should clearly avoid.

566. We firmly believe that measures need to build on voluntary approaches and that promoting the use of exceptions and limitations of rights will rather hamper technological, as well as any other

kind of, innovation efforts. Voluntary measures, and especially voluntary licenses, are preferable because they are faster, provide legal security and are as such more promising approaches than coercive measures. There is ample proof of success of such partnership-based approach, from looking back before the present year, and a fortiori now during the COVID-19 crisis over the past months in 2020.

567. The various platforms such as the ACT-Accelerator, the COVAX facility (and the Gavi COVAX AMC are important evidence of this. They are the results of this collaborative approach.

568. The Medicines Patent Pool (MPP), promoting voluntary licensing, is another example of a platform that successfully builds on voluntary approaches, where several companies manufacture the respective product at reduced price; without weakening the patent law and without compromising the quality of the products.

569. IP protection lies at the heart of a functioning innovation cycle and remains key for the health system. In this time where we need to confront the coronavirus, collaboration will be more important than ever to deliver on the high expectations our people have. IP is part of the solution to overcome this challenge.

570. Besides all the efforts undertaken at the international level and by the international community, governments have an important role to play by investing into their public health system and the infrastructure needed to ensure a fair and equitable access to essential medical products.

14.18 United States of America

571. Intellectual property encourages innovation, incentivizes research and development, and manufacturing and distribution. These core features of intellectual property are necessary for the global community to find and develop treatments and cures for this deadly pandemic and to support economic recovery.

572. Innovation is complex and risky, as we are witnessing with respect to the development of new COVID vaccines and treatments. Intellectual property rights are necessary to promote innovation in the face of that risk. Moreover, intellectual property rights help to ensure that there is a robust innovative ecosystem in place that encourages all relevant actors to participate in the complex process of drug discovery for new and improved treatment options in the future

573. Investment in research and development for innovative products has contributed to powerful improvements in public health outcomes, and IPRs has played a key role in facilitating this innovation, including more than 550 new therapies developed since 2000.

574. Support for innovation and intellectual property is essential, and there can be no access to drugs that have not been developed.

575. In fact, in this crisis, many right holders have voluntarily pledged or given access to intellectual property, whether it be access to key scientific journals or open source designs for personal protective equipment, or design specifications for ventilators.

576. In addition, the USPTO's platform Patents 4 Partnerships lists COVID-19 related inventions that are available for licensing to individuals and businesses. To date, there are over two hundred inventions listed.

577. As we have stated in past discussions and under agenda item 3, IP is an important piece, but ultimately only one piece, of addressing the issue of access to any potential therapy. We believe that the IP system has not been an obstacle in addressing the pandemic but rather has motivated global efforts to find treatments and cures.

578. As affirmed in the Doha Declaration on TRIPS and Public Health, the United States respects its trading partners' right to protect public health and, in particular, to promote access to medicines for all and supports the vital role of the patent system in promoting the development and creation of new and innovative lifesaving medicines.

579. Consistent with this view, the United States respects the rights of its trading partners to grant compulsory licenses, in a manner consistent with the TRIPS Agreement, including with the requirements in Article 31.

580. The United States encourages its trading partners to consider ways to address their public health challenges while maintaining intellectual property systems that incentivize the investment and research necessary to develop innovative new medicines.

581. The United States continues to encourage all WTO Members to promote a stable and predictable patent system that can nurture innovation. WTO Members can and should ensure supportive environments for innovators to achieve success and make significant contributions to economic growth in their country.

582. Many pharmaceuticals have their origins in countries with strong patent systems.

583. Robust and predictable patent systems provide interested parties with incentives necessary to encourage them to invest many years and significant financial resources into worthy endeavours without a guarantee of success.

584. Compulsory licensing diminishes the exclusivity of the patent grant and undermines the incentive for innovation and investment that is a critical component of technological progress.

585. We urge other Members to exercise caution and careful deliberation on issues related to compulsory licensing, as they have significant implications that could negatively affect investment in research and development for the treatments of tomorrow and restrict investment into new markets, including investments in new manufacturing facilities.

14.19 Sri Lanka

586. We thank the delegation of South Africa for bringing this important issue to the attention of this Committee through their submission.

587. There is a need for a focused discussion among WTO Members on the implications of intellectual property rights over the technologies and products required for responding to COVID-19 health issues. In the context of this global pandemic, it will be important for WTO Members to work together to ensure that IP rights including patents, industrial designs, copyright and trade secrets do not create barriers to scaling up R&D, manufacturing and supply of technologies and products necessary to combat COVID-19 health challenges. Sri Lanka, therefore, views that the proposal by South Africa is extremely relevant in this current global context.

588. The discussions in response to the guiding questions raised in the proposal can be useful in many ways, particularly to understand:

a. the extent to which different forms of IP rights impact the rapid development and affordable access to the various kinds of technologies and products required for responding to COVID-19;

b. the flexibilities available under the TRIPS Agreement to ensure that such IP rights do not constrain timely, equitable and affordable access;

c. the constraints to the use of such flexibilities; and

d. the adequacy of mechanisms that have been put in place to ensure global access.

589. In the light of this discussion, WTO Members can come to an informed view on the kind of IP-related measures that could be adopted at the multilateral level to support the need for ensuring rapid, equitable and affordable access to the products and technologies required to respond to similar unprecedented health crisis, such as the COVID-19.

590. The understanding of Doha Declaration is predominantly in the context of patents, though it's not the only area of IP which should be covered under this. The use of TRIPS flexibilities in other areas of IP beyond patents is less understood. In this context and the relevancy of variety of IP

rights in the fight against COVID-19, we see immense value in proposed discussion and invite Members to constructively engage in this dialogue.

14.20 Japan

591. The delegation of Japan would like to reiterate the importance of "Access to Medicine and medical technology", 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 manufacturing capacity, distribution networks as well as regulatory framework.

592. On countless occasions, humanity has overcome crises throughout history by the development and promotion of innovation. In this regard, medical technologies used to fight the pandemic have been created due to inventions throughout time. This type of development has been made possible by robust intellectual property systems that incentivize and protect innovation.

593. In addition, there are a number of voluntary initiatives to deal with the COVID-19 pandemic. We believe that voluntary basis approach is essential for such initiatives, because it provides possible options for right holders to find solution on the basis of each situation and does not impede the incentive for innovation.

594. Finally, the delegation of Japan would like to mention that the Doha Declaration, which confirmed the TRIPS flexibilities, its relevant statements, and the resulting Amendment to the TRIPS Agreement all rest on an intricate balance between importance of IP protection and protection of public health.

14.21 South Africa

595. South Africa thanks all Members who contributed to this discussion. I am very encouraged by the level of engagement that we are seeing on this particular topic it has not seen like this for a long time and it is a good precedent going forward. So, from that point of view, we also watch with interest as we develop further topics on the intersection between IP and public interest.

14.22 World Health Organization

596. We have seen over the past months how countries have mobilised unprecedented investments in collaborative, not-for-profit R&D. The COVID-19 pandemic is showing what we can do when we come together to face a shared global health threat. That is the kind of collaboration that can save lives and transform the health of billions of people globally. That is what the nations of the world agreed on SDGS and SDG 3 "ensure healthy lives and promote wellbeing for all at all ages".

597. WHO would like to thank the initiative of the Government of South Africa to open the discussions on this topic related to the interfaces between access to medicines and medical technologies and intellectual property. WHO understands the reference in the communication (contained in document IP/C/W/666) to the who recently launched "COVID-19 technology access pool" (C-TAP) and the South African concern as one of the 40 WHO Members that launched "the solidarity call to action: to realize equitable global access to COVID-19 health technologies through pooling of knowledge, intellectual property and data", one month ago, together with who director general and the president of Costa Rica.

598. South Africa mentions that "to date no company has committed to doing so. Instead limited, exclusive and often non-transparent voluntary licensing is the preferred approached of pharmaceutical companies, which will be insufficient to address the needs of the current COVID-19 pandemic".

599. WHO Secretariat would like to take this opportunity to inform the TRIPS Council that this knowledge, IP and data sharing platform, C-TAP, is meant to provide equitable access to life-saving technologies by promoting through voluntary means open innovation models and technology transfer, as well as promoting equitable global access through access-oriented licensing to fast-track product development and mobilizing additional manufacturing capacity.

600. WHO calls on WTO Members to join "the solidarity call to action" and support C-TAP initiative, which is a complementary tool to the access to COVID treatment Accelerator (ACT-A) and in line with the global strategy and plan of action on public health, innovation and intellectual property, as well as in accordance to the most recent WHA resolution on COVID-19 response that, among other aspects, "calls on international organizations and other stakeholders: (…)(2) to work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response, including, existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access to them, consistent with the provisions of relevant international treaties, including the provisions of the agreement on trade-related aspects of intellectual property rights (TRIPS Agreement) and the flexibilities within the Doha Declaration on the TRIPS Agreement and Public Health".

15 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

15.1 Dispute Settlement Developments Relevant to the TRIPS Agreement

601. No statements were made under this agenda item.

15.2 TRIPS Amendment

602. No statements were made under this agenda item.

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

15.3.1 WTO Secretariat

603. As in previous occasions and for Members' information, 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.

604. Since the last TRIPS Council Meeting in February, the Trade Policy Reviews of the European Union, Australia and Japan have taken place. These three reviews covered a very wide range of intellectual property and related trade policy issues. Developed and developing-country Members actively registered their continuing interest in TRIPS-related issues. In particular, they sought details on:

- Composition of IP assets;
- Reform of the copyright regime;
- Protection of Indigenous Cultural Intellectual Property;
- Modernization of the trademark regime and the protection of olfactory or taste marks;
- Geographical indications and the GI regime for non-agricultural products;
- Patent regime, supplementary patent certificates and patent extension;
- Compulsory licenses;
- Implementation of the Protocol Amending the TRIPS Agreement;
- Protection of test data;
- Regulation applicable to genetic resources accessed in Parties of the Nagoya Protocol;
- Protection of trade secrets;
- Enforcement, online and at the border;
- Anticompetitive practices;
- Technical assistance and cooperation programmes implemented in the framework of Article 66.2 of the TRIPS Agreement;
- Programmes to support IP management by Small and Medium Enterprises; and

- Accession and implementation of WIPO instruments.

605. The Secretariat has also contributed to the G20 and WTO wide Director-General Roberto Azevêdo's Monitoring Reports. The G20 report was circulated on 29 June 2020 and the WTO-wide report has been available since 24 July 2020. The WTO-wide report covers developments on trade-related aspects of intellectual property rights (TRIPS), including the information on developments in domestic legislation and administrative issues submitted for the monitoring exercise by Australia, Azerbaijan, Canada, Chile, India, Indonesia, the Kingdom of Saudi Arabia, Singapore, Chinese Taipei and Ukraine.

606. On this occasion, the reports also include a sub-section on the specific IP-related measures aimed at facilitating the development and dissemination of COVID-19-related health technologies, as well as at relaxing procedural requirements and extending deadlines for administrative IP matters. The table containing these measures is regularly updated and available on the WTO website, as was discussed under agenda item 3 [when a number of these COVID-related measures were described by Members].

15.3.2 Canada

607. International cooperation and coordination are essential to facilitate the cross-border movement of critical goods, services and personnel by maintaining open and connected supply chains.

608. Canada has led on, contributed to, and supported a number of statements in multilateral fora (e.g. G20, WTO, APEC) and in other groups of likeminded countries committing to open supply chains and minimizing disruptions to trade during the pandemic.

609. Here at the WTO, that includes statements that underscore the importance of open and predictable agricultural trade, a Friends of the System statement outlining the critical importance of the rules-based multilateral trading system during this unprecedented global crisis, and the MSME Working Group statement highlighting the importance of supporting MSMEs in the time of COVID-19.

610. We have advocated, and will continue to stress, that emergency measures – if necessary, to address COVID-19 – be targeted, proportionate, transparent, temporary, and consistent with WTO rules.

611. Canada continues to work with like-minded partners to turn these bold declarations into concrete, collective, and tangible actions.

612. As conveners of the Ottawa Group, our objective is to provide leadership, ideas and proposals on possible actions the broader WTO Membership could take to respond to the pandemic. This includes developing and promoting trade rules and policies that will contribute to a sustainable, inclusive and resilient international economic recovery, as well as guide our responses to future global crises.

613. Canada also remains determined to continue achieving progress in longstanding priorities in WTO reform, to help ensure a strong WTO that is modernized and relevant to 21st-century trade realities.

16 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

614. No statements were made under this agenda item.

17 OTHER BUSINESS

17.1 Annual Review of the Special Compulsory Licensing System

615. No statements were made under this agenda item.

17.2 18th Annual Review under Paragraph 2 of the Decision on the "Implementation of Article 66.2 of the TRIPS Agreement"

616. No statements were made under this agenda item.

17.3 Other Planned Activities for the Benefit of LDCs

617. No statements were made under this agenda item.

17.4 Date of Next Meeting

618. No statements were made under this agenda item.