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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 14-15 JUNE 2023

Chair: H.E. Ambassador Dr Pimchanok Pitfield (Thailand)

Addendum

The present document contains the statements made during the Council for TRIPS meeting held on 14-15 June 2023.

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AT THE MEETING OF COUNCIL FOR TRIPS 14-15 JUNE 2023*

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

1 NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

1.1 WTO Secretariat

1. The Council has received the following notifications from Members since its meeting in March 2023. Under Article 63.2:

a. A number of the member States of the European Union have notified a number of primary and secondary domestic laws:

   i. Ireland has notified a significant number of laws and regulations relating to the substance and the administration of its IP system.

   ii. Portugal has notified laws on the collective management of copyright and related rights, on copyright exceptions for the benefit of blind people, on the monitoring, control and removal of protected content in a digital environment, and on formality requirements relating to applications for industrial property grants.

   iii. Slovenia has notified consolidated versions of its Copyright and related Rights Act and of its Act regulating Collective Management of these Rights.

   iv. The Czech Republic has notified an amended Act on Geographical Indications, and an amendment to its Copyright Act.

b. Ukraine has notified an amended Copyright Act, and an Act to harmonize legislation in the area of Plant Varieties and Seed Production with EU legislation.

c. Moldova has notified a law on Copyright and related Rights updating and modernizing its copyright legislation and implementing a number of international treaties.

d. Montenegro has notified amendments to its Law on Trademarks.

e. Korea has notified a number of amendments and consolidated versions including its Patent Act, its Trademark Act, its Design Protection Act, its Utility Model Act and its Copyright Act, as well as related Enforcement Decrees.

f. Costa Rica has notified a number of laws and regulations relating *inter alia* to Copyright and related Rights, on Patents, on Trademarks, on Protection of Topographies for Integrated Circuits, and on IP Enforcement, as well as the creation of an interinstitutional commission for IP protection.

g. Japan has notified consolidated versions of the Patent Act, its Trademark Act, and the Designs Act.

h. Hong Kong, China has notified its Copyright Amendment Ordinance which covers a number of areas, mainly to strengthen copyright protection in the digital environment.

Under Article 69, as regards contact points for IP enforcement under Article 69, Montenegro and Türkiye have notified such contact points since the last meeting.

2. This concludes the overview of notifications received since our meeting in March 2023.

1.2 Japan

3. This delegation is pleased to inform the Council that Japan recently amended its Patent Act, Design Act and Trademark Act. These amendments have been notified to this Council in accordance with Article 63.2. The reference numbers are IP/N/1/JPN/67, IP/N/1/JPN/68, and IP/N/1/JPN/69.

4. We would now like to take this opportunity to briefly explain the amendments.

5. Firstly, amendments were made to the Patent Act, Design Act and Trademark Act to relax the requirements for restoring those rights that were lost due to the failure to comply with prescribed time limits.

6. The revised Acts relaxed the requirements for the restoration of rights from "legitimate reasons", which corresponds to "due care" in the Patent Law Treaty, to "unintentional," under which such rights can be restored unless the delay is intentional.

7. Secondly, an amendment to the Trademark Act simplified the procedures for notifying applicants of the decisions regarding their international trademark applications. This amendment enabled the Japanese government to send certain kinds of notifications to applicants electronically via the International Bureau of WIPO, in lieu of postal mail.

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

1.3 European Union

9. Slovenia provided two notifications, IP/N/1/SVN/9 and IP/N/1/SVN/10.

10. IP/N/1/SVN/9 is a new Slovenian Copyright and Related Rights Act, which regulates the right of authors with respect to their works of literature, science and art and the rights of performers, producers of phonograms, film producers, broadcasting organizations, publishers and makers of databases, and transposes the latest EU directives 2019/789 and 2019/790.

11. IP/N/1/SVN/10 is a new Slovenian Act Regulating Collective Management of Copyright and Related Rights and it transposes EU Directive 2014/26/EU into the legislation of the Republic of Slovenia. It regulates the collective management of copyright and related rights, the procedure for granting permits to collectively manage such rights, the procedure for concluding common agreements and setting tariffs for the use of copyright works, the operation of the Copyright Board, the procedure for multi-territorial licensing of online rights in musical works, dispute settlement, and the supervision of the implementation of this Act.

12. Now let me please conclude with the presentation of the Portuguese notifications and again this is a continuation of previous notifications going back to October 2022 and March 2023 TRIPS Council meetings.

13. Portugal provided four notifications, IP/N/1/PRT/4, IP/N/1/PRT/5, IP/N/1/PRT/6, and IP/N/1/PRT/7.

14. IP/N/1/PRT/4 is the Decree-Law No 100/2017 of 23 August 2017 amending the Law regulating collective management organizations for copyright and related rights and the multi-territorial licensing of rights in musical works for online use in the internal market is the first amendment to Law no. 26/2015, of 14 April 2015, transposing EU Directive no. 2014/26/EU, on the collective management of copyright and related rights and the granting of multi-territorial licences for musical works for online use in the internal market, and amending the Copyright and Related Rights Code and the equitable compensation table attached to Law No. 62/98, of 1 September 1998.

15. IP/N/1/PRT/5 is the Order No 6142/2019 of 4 July 2019, laying down rules on the formal requirements for applications and documents for the investigation of applications for the grant of industrial property rights.

16. IP/N/1/PRT/6 is Law No 92/2019 of 4 September establishing the permitted uses of works for the benefit of blind persons and decriminalizing unauthorised public performance of commercially published phonograms and videograms. It establishes the permitted uses of works for the benefit of blind people, transposing Directive (EU) 2017/1564, of the European Parliament and of the Council, and decriminalizes the unauthorized public performance of commercially edited phonograms and videograms (Fourteenth amendment to Decree-Law No. 63/85, of 14 March 1985, second amendment to Decree-Law No. 252/94, of 20 October 1994, third amendment to Decree-Law No. 332/97, of 27 November 1997, and first amendment to Decree-Law No. 122/2000, of 4 July 2000).

17. IP/N/1/PRT/7 is Law No 82/2021 of 30 November 2021 establishing procedures for monitoring, removing and preventing access in the digital environment to content protected by copyright and related rights. It concerns inspection, control, removal, and impediment of access in a digital environment to protected content.

1.4 Ukraine

18. Ukraine is pleased to inform the TRIPS Council that despite the ongoing Russia's war of aggression and intensive missile and drone attacks we continue to improve our IP system and to fulfil our international obligations undertaken in the framework of the WTO.

19. In particular, to comply with the transparency principle we have notified the TRIPS Council on recent amendments to our main dedicated IP legislation by two submissions.

20. The first notification (IP/N/1/UKR/16) concerns the Law of Ukraine "On Copyright and Related Rights" that was adopted with the aim of regulating relations in the field of acquisition, exercise and protection of copyright and related rights, as well as *sui generis* rights. It has replaced the text of the previously notified Law of Ukraine "On Copyright and Related Rights". The new Law had been developed in the context of Ukraine's commitments on implementation of appropriate Directives of the European Union, in line with the Ukraine-EU Association Agreement.

21. The main novels of this Law include as following:

a. the range of definitions of basic terms has been revised, introducing new essential descriptions for works and specific kinds of works, performances, phonograms, videograms and *sui generis* objects as well as updating the definitions of types of use and other attributable elements;

b. distinctive legal status of copyright and related rights owners has been introduced in order to provide eligible differences from licensees of material rights;

c. legal treatment for unalienable rights to equitable remuneration for authors, performers, phonogram and videogram producers has been introduced into the Law with detailed provisions for certain terms of use of these objects;

d. means of free legitimate use of copyright and related rights objects have been extended and supplemented for specific cases;

e. the term of copyright protection has been extended to 70 years after author's life as a basic principle;

f. the method of compensation instead of claiming damages or losses has been introduced.

22. Let's now proceed with another notification (IP/N/1/UKR/17) submitted by Ukraine. It presents the Law of Ukraine amending certain legal acts in the field of plant variety rights protection to harmonize them with the provisions of the EU legislation as well.

23. The purpose of this Law is to optimize legal regulation in the field of obtaining and use of rights to plant varieties in accordance with the best international rules and practices.

24. The Law improves appropriate terminology, streamlines functions and powers of the competent authority, contains updated provisions on the rights to variety, including intellectual property rights, confirmed by the patent on the plant variety, and property right to spread the variety, certified by state registration. It also clarifies conditions and procedure of their acquisition.

25. The Law intends to improve the procedure of state registration and to simplify application process by implementing the possibility of obtaining electronic services for filing applications and cutting bureaucratic red tapes.

26. It also sets new terms of intellectual property rights validity: thirty years - for varieties of tree and shrub crops and grapes, and twenty-five years - for all other varieties, started on the day following the date of state registration of the right.

27. We expect that implementation of provisions of this Law will promote use and commercialization of new plant varieties and improve access to modern and effective seeds and planting material for agricultural producers, create state-of-the-art regulation in this field, bringing Ukrainian legislation closer to the EU legislation. Both laws have already entered into force.

28. With this in mind, let us reassure WTO Members that we will continue to comply with our notification obligations and to inform about development of our IP legislation while considering such work as of high priority and great importance, including for rebuilding and recovery of Ukraine.

1.5 Moldova

29. First of all let me thank Ukraine and commend them for their continued work and commitment to this Organization despite the ongoing war initiated by Russia on their territory and we would like to reiterate that Moldova stands in solidarity with Ukraine and their people and we will stay in solidarity as long as it takes.

30. Referring to our notifications, we would first of all like to thank the WTO Secretariat for introducing the updates of Member's notifications including Moldova's notifications which was submitted under Article 63.2 of the TRIPS Agreement under the reference number IP/N/1/MDA/18.

31. For the sake of brevity, I will present the notified changes in a comprehensive manner. Short descriptions of every notified modification are included in the document mentioned above, however, several points are important to mention, namely the purpose of the new Law No. 230 of 28.07.2022 on Copyright and Related Rights which is to ensure the protection of copyright and related rights in the Republic of Moldova. Law 230/2022 replaced the former Law on Copyright and Related Rights 139/2010. In comparison to the former Law 139/2010, the new Law no. 230/2022 seeks to improve the copyright system in Moldova, adjusting it to the technological developments and digital environment and to enhance the efficiency of the collective management system, in line with the international treaties and EU legislation in the field.

32. The new act ensures the implementation of the provisions of the Beijing Treaty on Audiovisual Performances, Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled. It also transposes a series of European directives as mentioned in the notification.

33. Concluding, my delegation would like to take this opportunity to thank the WTO Secretariat, particularly Ms Natalie Carlson and Ms Sandra Smith, Josefita Pardo de Leon and Francisco Hernández Fernández for their continued support and assistance in the process of updating our notifications through the e-TRIPS Submission System that we find very valuable.

1.6 Costa Rica

34. Costa Rica is grateful for the opportunity to discuss the notifications that we have submitted under this item on the Council's agenda.

35. I would like to reiterate that Costa Rica's regulatory developments in the field of intellectual property right protection reflect the implementation of international trade commitments and a country-wide effort that recognizes the importance of intellectual property rights as a development tool.

36. Further to our previous statement, I would like to point out that Costa Rica approved the 1991 version of the International Convention for the Protection of New Varieties of Plants (UPOV 1991) and issued a Law for the Protection of New Varieties of Plants and its respective regulations, which made it possible to establish an applicable *sui generis* system.

37. With regard to test data, the amendments to the law on undisclosed information and its regulations established a protection term of five years for new pharmaceutical products and ten

years for new agricultural chemical products. For these purposes, new products are considered to be those that do not contain chemical entities previously approved in Costa Rica.

38. On the basis of reforms to the Law on Patents and its regulations, Costa Rica established a compensation period of 18 months in the event of procedural delays in the granting either patents or commercial authorization approval. Patent term restoration applies when delays last five years or more from the patent filing date, three years or more from the request for substantial examination, or three years or more for the commercial authorization of medicines.

39. In addition, a patent linkage system was also established to ensure that a marketing permit cannot be approved for products identified as patented.

40. It should be noted that legislation on the enforcement of intellectual property rights was amended in relation to administrative, civil and criminal sanctions. Some penalties were adjusted to make the sanctions dissuasive, and a system of pre-established damages was developed for cases in which the amount of damages cannot be determined.

41. For trademark, copyright and related offences, a graded system was established, proportional to the damage caused.

42. In criminal matters, it is up to the judge to determine on a case by case basis whether pecuniary or prison sentences apply.

43. I reiterate my delegation's thanks to officials from the Secretariat's Intellectual Property, Government Procurement and Competition Division for their assistance in the submission of these notifications

44. On that note, I conclude my statement and express our readiness to respond to Members' questions.

1.7 Hong Kong, China

45. Pursuant to Article 63.2 of the TRIPS Agreement, Hong Kong, China submitted, on 12 May 2023, notification IP/N/1/HKG/40.

46. The notification is related to the amendment to the Copyright Ordinance under the Copyright (Amendment) Ordinance 2022 to strengthen copyright protection in the digital environment. The Amendment Ordinance mainly covers five key areas:

a. to introduce a new technology-neutral exclusive communication right for copyright owners to communicate their copyright works to the public through any mode of electronic transmission;

b. to introduce corresponding criminal sanctions;

c. to revise and expand the scope of copyright exceptions to allow use of copyright works in certain common Internet activities; facilitate online learning and operation of libraries, museums and archives; and allow media shifting of sound recordings for private and domestic use, etc.;

d. to introduce "safe harbour" provisions to provide incentives for online service providers to co-operate with copyright owners in combating online piracy; and

e. to introduce two additional statutory factors for the court to consider when assessing whether to award additional damages to copyright owners in civil cases involving copyright infringements.

47. Last but not least, I would like to join colleagues in thanking the Secretariat for their excellent support throughout the process.

1.8 Korea, Republic of

48. During last March and April, in accordance with Article 63.2 of the TRIPS Agreement, Korea provided a total of 13 notifications to the WTO, regarding the amendment on Copyright Act, Design Protection Act, Utility Model Act, Unfair Competition Prevention and Trade Secret Protection Act, Act on the Layout-designs of Semiconductor Integrated Circuits, and their related enforcement decree.

49. Let me just briefly touch upon the gist of each amendment.

50. The Copyright Act has been revised:

a. to establish the legal basis for public transmission of the works published in curriculum books in order to provide various contents for educational purposes through online and;

b. to regulate the procedures for registration and to introduce the *ex officio* decision on mediation.

51. Regarding the Patent Act, amendments were made on:

a. regulations regarding punitive damages compensation;

b. patent applications concerning disaster prevention, recovery, etc. became eligible for accelerated examinations in response to COVID-19;

c. a mediation committee was introduced for reasonable settlement of cases on trial;

d. and the period to petition a trial on a decision of rejection of a patent application was extended from 30 days to three months.

52. With regards to the Trademark Act, amendments were made on regulations regarding punitive damages compensation, etc.

53. Regarding the Design Protection Act, amendments were made:

a. to change regulations regarding punitive damages compensation,

b. to introduce *ex officio* re-examination after determination if there is *prima facie* evidence for rejection.

54. Regarding the Enforcement Decree of the Design Protection Act, amendments were made to expand the scope of eligibility for accelerated examinations including:

a. applications for design registration by SMEs with certification for management of intellectual property with regard to products selected as superior designs and;

b. applications for design registration of a design using technology related to the fourth industrial revolution.

55. As for the Utility Model Act, several amendments were made mainly to apply *mutatis mutandis* the amended Patent Act to utility models, etc.

56. Regarding the Unfair Competition Prevention and Trade Secret Protection Act, amendments were made to change regulations regarding punitive damages compensation.

57. Lastly, regarding the Layout-designs of Semiconductor Integrated Circuits, amendments were made:

a. to introduce regulations regarding disqualification, recusal or self-recusal of committee members, etc. and

b. to change regulations regarding the amount of penalties with regard to offences of infringement, false marking and fraud.

1.9 European Union

58. I would like to revert to the notification by Ukraine and I would like to echo you, Chair, in thanking the Ukrainian authorities for their intervention today and also for complying with their notification obligations of the TRIPS Agreement. So the EU would like to do the same, and emphasize that all this is done under the unprecedented circumstances caused by the brutal, unprovoked and illegal invasion of Ukraine by Russia. The EU can only admire the efforts by the Ukrainian authorities in a situation where the Ukrainian capital itself is under fire from Russian attacks, where Russia causes huge damage to human lives and environment by targeting critical infrastructure such as the Kakhovka Dam recently and where Russia illegally occupies of Ukrainian territory. The EU stands firmly by Ukraine and its people in this unparalleled crisis and will provide further political, financial, military and humanitarian assistance to Ukraine.

1.10 Russian Federation

59. The Russian Federation is obliged to attract your attention that political statements made by some Members and you, Chair are out of the mandate of the TRIPS Council and WTO competence. We consider such practice inappropriate. Political statements only impede the work of the Council. Russian Federation asks you as the Chairperson to take appropriate measures.

1.11 United States of America

60. Just over a year ago, Putin began his brutal and unprovoked full-scale invasion of Ukraine. The Russian Federation continues to inflict the death and destruction on Ukraine and the Ukrainian people. The United States reiterates its condemnation of Russia's brutal unprovoked and unjustified war of aggression against Ukraine.

61. The United States will continue to support Ukraine's courageous efforts to defend itself, uphold its territorial integrity and protect its population. As President Biden reconfirmed during his visit to Kiev are long-term commitment to Ukraine is unwavering, and we will work to build a coordinated approach to assistance and to help Ukraine to use the rebuilding process to achieve best practices for laws, regulations and standards across sectors.

62. We have also worked with our allies and partners to impose strict costs and sanctions on the Russian Federation's aggression against Ukraine. We call on the Russian Federation to immediately cease its use of force against Ukraine, refrain from any further threat or use of force against another Member of this Organization and immediately withdraw all of its military forces from the territory of Ukraine.

2 REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

63. No statements were made under this agenda item.

3 IP AND COVID-19

3.1 South Africa

64. South Africa would like to congratulate you on your appointment as the Chair of this very important Council.

65. We welcome that the TRIPS Council is now engaging in discussion on the MC12 Pandemic Declaration under this item. We want to emphasize that the instruction to relevant WTO bodies is not limited to analyzing lessons learned and challenges experienced during the COVID-19 pandemic but importantly, paragraph 23 states that we need to use these lessons learned and the challenges experienced during the COVID-19 pandemic, to build effective solutions in case of future pandemics including on balance of payments, development, export restrictions, food security, intellectual property, regulatory cooperation, services, tariff classification, technology transfer, trade facilitation, and transparency, in an expeditious manner. We must therefore in the context of the TRIPS Council,

consider the IP and technology transfer related issues. We also need to be aware that paragraph 24 states that a stocktaking exercise will be taken of the work by WTO bodies under this Declaration yearly at the General Council until the end of 2024, based on the reports of those relevant bodies.

66. This in our view necessitates structured discussion on a trigger ready mechanism that can be evoked in case of pandemics and avoid the need to negotiate waivers during a pandemic which has proved inadequate, as the WTO in the context of the COVID-19 pandemic delivered too little too late. We should be reminded that the objective of this is to safeguard public health rather than narrow commercial interests.

67. We therefore propose that the agenda and the annotated agenda reflect both the elements of paragraph 23 and 24 in future to enable focused discussion by the Council on our expected deliverables under this item.

3.2 Indonesia

68. Indonesia would like to congratulate you on your election as the Chair of this Council.

69. Although WHO already declared that COVID-19 is no longer defined as a Public Health Emergency of International Concern, it continues to take a significant toll on global health. There is still also the very real risk of new variants emerging that could be more transmissible and/or more severe. COVID-19 is here to stay. With that in mind, the painful lessons and experiences of COVID-19 need to inform our future strategies for preparedness and response for the next pandemic and other health emergencies.

70. The Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics (MC12 Pandemic Declaration), in this regard, could be a vehicle for the WTO to provide a rapid and effective response in our part, through a trigger ready mechanism, as mentioned by the South Africa delegation.

71. In this regard, WTO Members could consider exploring normative solutions under TRIPS to make future responses to pandemics effective and timely, instead of having to negotiate for years, in which whatever outcomes we produced would be too little and too late.

72. In this context, Indonesia would also like to suggest that the Secretariat, in cooperation with WHO and WIPO, write a country level analysis of the legal status of patents and patent applications relating to COVID-19 vaccines, therapeutics and diagnostics. Such a study may contribute to identifying and addressing potential IP-related obstacles to their local production.

3.3 United States of America

73. I would like to make a couple of interventions under this agenda item. The first being under the initial topic that you mentioned - Measures regarding Trade-Related-Intellectual Property Rights. The previous intervention that the United States made on this topic concerning IP measures in the context on COVID-19 stand. As stated previously, intellectual property plays an incentivizing role in the development of new technologies to combat this deadly pandemic and in supporting economic recovery.

74. In past meetings, the United States highlighted the US Patent and Trademark Office COVID-19 pilot programme which prioritises examination of certain patent applications claiming a product or process subject to an applicable FDA approval for COVID-19 use, and a companion fast track pilot program for appeals related to COVID-19. As of 14 June 2023, 1068 applications have requested prioritised examination status in the USPTO's COVID-19 prioritized examination pilot programme, 392 of which have this far been granted.

75. The pilot programme was originally set to expire after the USPTO accepted 500 applications into the programme, but this application limit has been removed. Further information on the USPTO's initiatives and life science technologies can be found on the COVID-19 response resource centre page of uspto.gov.

76. Also, as mentioned previously, in 2021, the USPTO launched a category of its Patents for Humanity Program for inventions that address the COVID-19 pandemic. This category was intended to provide business incentives for patent applications holders and licencees whose inventions track, prevent, diagnose or treat COVID-19. The ceremony to recognize the five winners of this program was livestreamed in February of 2023. The United States Copyright Office also made adjustments in response to the pandemic as we have mentioned previously but those measures have expired and no current adjustments are in force.

77. Separately and in response to South Africa's proposal, the position of the United States is that the scope of this agenda item should flow from the mandates in the Ministerial Decisions from MC12. We have found the discussion in previous TRIPS Council meetings regarding measures that Members have taken in the context of COVID-19 pandemic to be helpful. We are also interested in any updates on measures Members are taking with respect to the Ministerial Decision under the TRIPS Agreement for new topics under this agenda item. We ask that Members proposing any new topics, to send proposals in advance so that other Members have adequate time to prepare for a constructive discussion.

78. Regarding a proposal made by Indonesia - if I caught that correctly - in our view Council discussions are most constructive when Members have had adequate time to prepare, and discussions are based on submissions and proposals that we have been able to study in advance. So we look forward in receiving any proposals that we can take back and carefully consider.

3.4 Maldives

79. Even though WHO has now ended COVID-19 public health emergency, the WHO COVID-19 epidemiological updates show that nearly 400,000 cases have been reported daily last month. Therefore, we believe the discussion to cover the therapeutics and diagnostics should continue at this TRIPS Council with an emphasis on preparing for any future pandemics.

80. The Maldives remains committed to do its part in assisting to provide universal, equitable access to COVID-19 vaccines, including therapeutics and diagnostics. We are deeply concerned that the deliberations in the WTO have taken too long to provide a credible contribution in our fight against the pandemic. The pace of discussions in the TRIPS Council have outlined the importance of a trigger ready mechanism to deal with future pandemics. Therefore, we urge all Members to start engaging in constructive dialogue so that the WTO is prepared to respond to any future pandemics.

3.5 Djibouti, on behalf of the LDC Group

81. On behalf of the LDC Group, Djibouti would like to congratulate you on having assumed the chairpersonship of this Council. We thank the WTO for its work in the context of the health crisis. We seek to work on the database in line with the group's objectives and at this stage we would just like to note that this is up-to-date as of the first quarter of 2022, so we therefore think it may be relevant to continue updating or delete, to ask the question as we move forward. On the WTO response document from the Ministerial Conference, again we welcome up-to-date information when it comes to the application of the TRIPS Agreement in the context of the MC12.

3.6 Colombia

82. As has been mentioned on other occasions, particularly last week at the informal Council meeting, Colombia reiterates its agreement with the extension of the waiver to cover the production and supply of COVID-19 diagnostics and therapeutics, which will be addressed in another agenda item later.

83. Notwithstanding the foregoing, it is our view that we should now be starting to think about future pandemics, in line with the discussions being held in other forums.

84. We therefore feel that our efforts must be geared toward a discussion on establishing an "open trigger" mechanism that allows for the use of a waiver in future pandemics without the need to negotiate everything from scratch in the midst of a crisis. We should now be starting to think about future pandemics, involving any other pathology, including the one generically referred to as pathology X by the WHO, in line with the discussions being held there and in other forums.

85. To that end, we believe that we could build on the agreements reached thus far and focus on describing the situations that would give rise to the use of a waiver in future pandemics. Use of such an instrument should be allowed by default in the event of another health crisis resulting in another declaration of a pandemic by the WHO so that precious time is not wasted in circumstances requiring speed and urgency.

3.7 India

86. India echoes the views shared by South Africa and other co-sponsors on this issue. Inequitable access to vaccines, therapeutics, diagnostics and health products continues to pose challenges in combating COVID-19, and therefore as mandated in paragraph 23 of the MC12 WTO's response to pandemic Declaration a solution to this critical issue is imperative to build resilience for future pandemics. Thus, the protracted discussions on the TRIPS waiver proposal and its delayed and limited outcome have necessitated the importance of a mechanism to deal with future pandemics, and my delegation hopes that the TRIPS Council will engage on this issue in earnest and good faith.

3.8 European Union

87. The European Union is ready to engage in this topic in line with the mandate of the Ministerial Decision. We would like to point to the fact that notifications of National Measures that have already been provided under this item, provide for interesting material as regards to this measure, so we should not forget that we already have certain material to look into in the context of our work on this point. We would like to second what the delegation of the United States said, that, should we engage on additional aspects, it will be best to do so on the basis of submissions so that all delegations can prepare properly for such discussions.

3.9 United Kingdom

88. Firstly, I would like to state that the UK stands a solidarity with Ukraine.

89. Regarding this agenda item we would like to echo the comments made by the United States and the European Union that we welcome proposals in advance that we can give appropriate consideration to.

4 REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

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

6 PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

6.1 India

90. Traditional medicine is either the mainstay of health care delivery or serves as a complement to it. Traditional and complementary medicine (T&CM) has been an important and often underestimated part of health care. The socio-cultural practice and biodiversity heritages of traditional medicine are invaluable resources to evolve inclusive, diverse sustainable development. The contribution of traditional medicine to health systems is yet to be completely realized. The establishment of WHO's Global Centre for Traditional Medicine in India in April 2022, with estimated USD 250 million committed by the Government of India reflects the commitment and the vision to harness the latent potential of traditional medicine systems to be a catalyst in promoting global health along with sustainable development. Additionally, the launch of an informal group called the "Friends of Traditional Medicine" by India in May 2023 in the build-up to the World Health Assembly, will serve as an informal platform to discuss and seek support towards mainstreaming traditional medicine, including for achieving Universal Health Coverage, and support WHO's efforts for appropriate integration of traditional medicine into health systems.

91. India being one of the ancient civilizations has preserved a rich body of traditional knowledge associated with biological resources and the concern faced by countries with rich indigenous and traditional knowledge systems like India, is the misappropriation of this knowledge. These facts and

developments attest to the importance of the linkage between TRIPS Agreement and the Convention on Biological Diversity (CBD).

92. Article 16.5 of the CBD recognizes "that patents and other intellectual property rights may have an influence on the implementation of this Convention". It mandates that the Parties "shall cooperate in this regard, subject to national legislation and international law, in order to ensure that such rights are supportive of and do not run counter to its objectives." Furthermore, the Doha Ministerial Declaration in paragraph 19 has mandated that the TRIPS Council examine the relationship between TRIPS and the CBD, and the protection of traditional knowledge and folklore.

93. India therefore continues to call for an international enforceable regime to contain misappropriation. We must work to make the TRIPS Agreement better integrate into and complement the goals envisaged in the CBD; an important environment agreement that we often ignore, even amidst the ongoing Trade and Environment week. Despite several submissions like TN/C/W/52 submitted in June 2008 with the support of 109 Members followed by the last submission on this issue TN/C/W/59 in April 2011 proposed by a vast majority of WTO membership, it is regrettable that progress remains elusive.

94. In this regard, we note that some Members view the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) process to be the right forum for these discussions, missing the point that these discussions at the WIPO IGC process are complementary and mutually supportive of our work here at this Council. Therefore, as often heard in WTO, processes or choice of fora should not limit our engagement on substance. Given the enforceability of the TRIPS Agreement and the fact that much of the misappropriation is a consequence of trade, there is both the mandate and a strong need to build the linkage between the TRIPS Agreement and the CBD under the aegis of this Council.

95. Therefore, considering the mandate from the Doha Ministerial Declaration and the 2030 Sustainable Development Goals (SDGs), targets 2.5 and 15.6 to which we are all committed, that specifically call for promoting access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, it is crucial for us to take these discussions forward towards an outcome. To this end a formal briefing by the CBD Secretariat on the latest developments on this issue, as well as an update of the factual briefs will be useful for Members. And we hope that the votaries of external stakeholder engagement should principally have no concern with CBD briefing.

96. Lastly, India remains fully committed to continue our efforts in building momentum and achieving an outcome on these important issues.

6.2 Bangladesh

97. On agenda items 4, 5 and 6, or the so-called triplets, the position of Bangladesh has not changed. In this regard, to avoid repetition, I refer to my delegation's statement delivered during the previous TRIPS Council meetings. Bangladesh supports discussions towards a progress on these issues and stands ready to engage constructively with Members.

6.3 Indonesia

98. Indonesia's position remains unchanged, and we would like to refer to our previous statements on these agenda item respectively. Although Article 27.3(b) excludes patentability for animal and plants, our delegation further stresses the need to review this article in order to prevent misappropriation and misuse of genetic resources and traditional knowledge. Furthermore, this provision historically disadvantaged developing country Members and LDCs, particularly indigenous and traditional community, as the source of genetic resource and traditional knowledge that have not been provided with fair and equitable sharing of benefits arising from such usage.

99. Indonesia along with other likeminded Members, in this regard, has submitted a proposal - document TN/C/W/59 - on adding a mandatory disclosure requirement with a view to strengthen the effectiveness of Article 29 of the TRIPS Agreement. The proposal received broad support from developing countries. Moreover, there are more and more countries adopting disclosure requirement at the national level.

100. In this context, Indonesia would like to reiterate our request in this Council as follows:

1. that the Secretariat of the CBD be invited to present on the Nagoya Protocol, and

2. that the WTO Secretariat provide an updated background paper on state of play on the TRIPS-CBD.

6.4 Peru

101. Peru's position on these agenda items has not changed. However, we would like to refer specifically to the relationship between the TRIPS Agreement and the Convention on Biological Diversity (the CBD). We believe it is necessary to reiterate, as a first point and as a matter of principle, the need to fulfil the mandate we undertook in Doha to examine this issue.

102. The status quo of the past several years is causing significant harm to many Members. I highlight the case of my own country, which is dealing with misappropriation of its genetic resources and associated traditional knowledge, as reported by our National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples, which last year recorded the second highest number of cases since the Commission's inception, clearly reflecting the urgency of addressing this issue.

103. The solution that Peru and other countries consider most appropriate and that we have proposed here and in other forums is to include the obligation to disclose the origin of the resources and traditional knowledge. Article 29 of the TRIPS Agreement does not suffice, as it does not require patent applicants to disclose the country of origin or provide evidence of compliance with prior informed consent and benefit-sharing. We believe that including the obligation to disclose the source would prevent cross-border misappropriation of our genetic resources and associated traditional knowledge and the issuance of erroneous patents.

104. Lastly, beyond the fact that the topic is discussed in other forums under other approaches, we believe that the WTO has an important role it should take on. To start, allowing the CBD Secretariat to provide further information on the subject and on how both instruments can be mutually reinforcing and supportive as well as updating the Secretariat's documents in order to progress with these discussions.

6.5 South Africa

105. I only reiterate my delegation's position on this item, which is unchanged. My delegation would also like to fully support and endorse the statements of the delegations that just spoke before me.

106. Finally, on the long outstanding item, that is the issue of the presentation on the Convention on Biological Diversity (the CBD), in our view, that would be very much consistent with the principles expressed in the last General Council in the submission WT/GC/W/871. In that regard we would hope that there is no objection to such presentation.

6.6 China

107. China would like to congratulate you for taking this very important post and we are looking forward to working together under your very wise coordination.

108. China has attached great importance to the TRIPS-CBD issue and has always been actively participating in discussions. China believes that in order to better protecting genetic resources and traditional knowledge, it is necessary to fulfill the obligations of prior informed consent and benefit sharing, while benefit sharing based on contractual agreements and traditional knowledge databases are far from enough to achieve effective protection. In the 2nd phase meeting of COP15 of the CBD, as presidency, China promoted the adoption of the "Kunming Montreal Global Biodiversity Framework", which is an ambitious and pragmatic framework, a milestone charting a new blueprint for global biodiversity governance. The framework will guide the international community working together to curb and reverse the loss of biodiversity, to promote the process of biodiversity restoration, and to jointly move towards the vision of harmonious coexistence with nature by 2050.

109. By listing it as one of the important goals, the framework will ensure the fair and just sharing of the benefits generated from the use of genetic resources, from digital sequence information of genetic resources and from traditional knowledge related to genetic resources. This reflected the great importance and common consensus attached by the international community to this issue. At present, we are witnessing a standstill at the discussion on this topic. We hope that the TRIPS Council could attach importance to the achievements and progress made in COP15 and we look forward to an early rejuvenation of this topic in the TRIPS Council.

110. Regarding the procedure issue, we support the suggestion for the TRIPS Council to invite the Convention on Biological Diversity (CBD) Secretariat to brief on the Nagoya Protocol and its progress. We hope the Secretariat could renew the three factual notes. In recent years, although The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has conducted a lot of discussions and negotiations on the protection of genetic resources and traditional knowledge, achieving certain results, however, China believes that WIPO IGC discussions and negotiations on the above-mentioned issues does not contradict with Members' discussion in the WTO.

6.7 Tanzania, on behalf of the African Group

111. First, I want to join other colleagues who have spoken before me to welcome you and to congratulate for your election to preside this important Council. I also want to assure you of the African Group's commitment to work with you in your endeavors during your tenure.

112. The position of the African Group on this particular agenda item has not changed and I think most of the delegations know, so I wanted just to reiterate that we continue to uphold our position. I wanted actually to insist our long-standing call that we would want the Secretariat of the Convention on Biological Diversity (CBD) to also be invited to our Council so that they can share their experience of the Nagoya Protocol implementation and their other experiences related to this particular agenda item.

6.8 Ecuador

113. As this is the first time we are taking the floor in this meeting, let me say how pleased we are to see you presiding over this Committee and extend our congratulations to you. We also wish to express our appreciation for the statements of the previous speakers.

114. My country's position on the three items on the agenda has not changed. Nevertheless, my delegation wishes to reaffirm its commitment to promoting balanced intellectual property regulation as a useful tool for promoting research and innovation.

115. We also consider it essential to have legal instruments that ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions, which promote appropriate conditions for access and use, and provide for disclosure of the source of origin, prior informed consent, access to and equitable benefit sharing.

116. We believe in the need to take into account the need to facilitate complementarity between intellectual property rules and standards and the international agreements and instruments relating to genetic resources, in particular the Convention on Biological Diversity.

6.9 United States of America

117. The United States does not support requests to ask the TRIPS Secretariat to update the three factual briefs, as we have explained in previous sessions and in bilateral meetings. We do not view this as a good use of the Secretariat's resources. Members remain able to freely access the minutes of past interventions and the subjects through the WTO website and we continue to be willing to discuss this bilaterally with interested Members.

118. Regarding the proposal to invite the Convention on Biological Diversity (CBD) Secretariat to brief the TRIPS Council, the United States is not in a position to support this proposal, as it is Nagoya Protocol parties that are responsible for implementing the obligations of the Nagoya Protocol. We believe that it is Members that should explain their domestic policies for implementing the proposal

rather than the CBD Secretariat. Over the years, there has been no shortage of outside events on the Nagoya Protocol that have included the CBD Secretariat that provide Members with opportunities to hear directly from Secretariat on issues that might be of interest to them.

119. As to the relationship between the TRIPS Agreement and the CBD, a number of delegations noted that they believe that there is a need to avoid erroneous patents that involve the use of genetic resources and related traditional knowledge. We agree that there is a need to avoid erroneous patents, but we disagree that a disclosure of origin would help improve the quality of patents. In the many years that this issue has been discussed, we note that many countries have imposed disclosure requirement upon applicants. If that disclosure requirement has, in fact, improved the quality of patents, then surely by now, there would be data to support this conclusion.

6.10 Japan

120. As Japan's position remains unchanged, we would like to comment briefly on these agenda items. Japan aligns itself with the statement made by the United States.

121. This delegation believes the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is the most appropriate forum for holding technical discussions on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Given that detailed discussions have been continuously held at WIPO IGC, we should avoid duplication thereof.

122. Lastly, Japan strongly condemns Russia's aggression against Ukraine and urges Russia once again to stop the aggression and withdraw its forces from the territory of Ukraine within its internationally recognized borders immediately.

6.11 Nigeria

123. I wish to recall our previous statements regarding agenda items 5 and 6.

124. We reiterate the importance for Members to engage in discussions with the aim to promote traceability of genetic resources, traditional knowledge and folklore. We consider it necessary to establish a requirement for a prior informed consent and benefit sharing systems in respect of any product manufactured through the use of genetic components or traditional knowledge and folklore. We believe the requirement of disclosure contained presently in the TRIPS Agreement remain inadequate. Hence the need to improve existing provisions by the consideration of past proposals in this respect. This will reduce the incidence of misappropriation. The improper acquisition of genetic resources and associated traditional knowledge without prior informed consent and on mutually agreed terms, in accordance with national laws of the country providing the genetic resource or associated traditional knowledge continue to be a significant concern for Nigeria. We believe that the WTO has an important role to play and that the discussions at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) can be complementary to the discussions at the TRIPS Council.

125. Finally, we urge the Secretariat to provide updates to the three factual notes. We stand ready to engage constructively on this matter.

6.12 South Africa

126. Just very briefly, we take the floor to express our disappointment that the United States was not able to join the consensus to invite the Convention on Biological Diversity (CBD). In our view that approach is inconsistent with the communication titled Improving Inclusiveness By Reviewing And Evaluating External Engagement (Document WT/GC/W/871), of which the United States was a co-sponsor at the last presentation in the last General Council and we would hope that this position expressed today could be reconsidered going forward.

6.13 Thailand

127. Thailand reaffirms its commitment to working with other Members to explore the possibility to discuss the relationship between the TRIPS Agreement and the Convention on Biological Diversity

(the CBD) under the principle of mutual supportiveness to promote the sustainable use of resources, as well as the possibility of amending the TRIPS Agreement, when appropriate, to contemplate a disclosure requirement of the origin of genetic resources in patent applications, prior informed consent and benefit sharing.

128. While welcoming the progress of the ongoing negotiations at WIPO, we believe the existence of such negotiations should not be understood to preclude discussions on these topics at the TRIPS Council, as we stand ready to constructively engage and build momentum on these important issues.

6.14 Korea, Republic of

129. Our position remains unchanged. I would like to reiterate that IP protection for biological inventions will ultimately contribute to improvement in welfare, particularly in agriculture and health sectors. Regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), we are of the view that the objective and jurisdiction of the two agreements are separate, therefore it is unnecessary to amend the TRIPS Agreement. Lastly, in order to avoid the duplication of discussion, we believe the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is the right forum to discuss this issue.

130. Regarding Ukraine's statement, we would like to echo previous speakers in supporting Ukraine and condemning the Russian Federation's illegal attacks.

6.15 Canada

131. Congratulations for your election to Chair this Council.

132. Canada's position is well-known, and we would refer to our previous interventions on agenda items 4, 5, and 6. With respect to procedural matters, as previously noted and without prejudice to our position on substantive matters, Canada could support a procedural briefing from the CBD Secretariat to the TRIPS Council. Canada could also support the compilation of the three factual notes on TRIPS and the CBD, and remains of the view that this would remain an information collating exercise.

133. There were several references this morning to disclosure in the present discussion, and on this Canada recalls, without prejudice, that last year, the WIPO General Assembly decided to convene next year a conference on an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources, which will very much be the forum for these discussions, including such that we should avoid duplication of these discussions and indeed these negotiations.

134. Canada joins other Members in strongly condemning Russia's unjustifiable invasion of Ukraine and calling for it to end.

6.16 Brazil

135. In relation to the relationship between trade and genetic resources and traditional knowledge associated with them, we gather here not merely to discuss trade in abstract terms but to recognize the profound interconnection between our economies and the invaluable wealth of genetic resources and traditional knowledge, which often find its roots in the stewardship of indigenous peoples and local communities. The impact of these resources on our daily lives is immeasurable, from the food we consumed to the medicinal remedies we rely on.

136. However, there is an essential aspect that we must bring to light. A study published in "Financing 2020" informs us that indigenous communities manage or hold tenure rights over a remarkable 25% of the world's land surface. Land which accommodates approximately 80% of our planet's biodiversity, are not mere statistics, but a testament to the crucial role of these communities in conserving and managing these invaluable resources. Our present conversation should pivot towards devising trade practices that are not only more sustainable but also imbued with fairness. It is our shared responsibility to ensure that the guardians of these priceless resources receive due

recognition and fair returns from their contribution. The Nagoya Protocol, for instance, serves as a beacon in this regard. It underscores the importance of prior informed consent in mutually agreed terms. Implementing these principles in practice translates into more inclusive decision-making processes and equitable sharing of benefits, by so doing we promote conservation, boost local economies and contribute to the fight against poverty.

137. On a similar note, let me bring up the essential role of disclosure requirements in patent applications. These requirements, already implemented by several countries ensure that any patent application is not just a quality patent, and that it involves a realm of knowledge that is related to genetic resources or traditional knowledge which must be disclosed. This practice fosters transparency, prevents biopiracy and ensures fair compensation for the use of these resources. In this vein, let us underline the significance of fostering capacity-building and technological transfer. By equipping these communities with the necessary skills and resources, we empower them to manage their resources and knowledge sustainably, thereby fortifying our collective future.

138. As we deliberate upon trade, let us bear in mind that we are not merely discussing commodities, but also we are acknowledging the fruits of our earth and the wisdom of generations, assets of immeasurable value that must be utilized sustainably and equitably for everyone's benefit.

7 NON-VIOLATION AND SITUATION COMPLAINTS

7.1 United States of America

139. The United States remains open to considering specific proposals for Members wishing to further examine the scope of modalities for complaints of these types. Unfortunately, the United States does not support requests to ask the TRIPS Secretariat to provide an overview of positions that are already well-known and documented, including in a summary note by the Secretariat in 2012, document number IP/C/W/349/Rev.2. We do not view that as a good use of the Secretariat's resources, Members remain able to freely access the documents and minutes of past interventions through the WTO website and, again, we continue to be willing to discuss this bilaterally with interested Members.

7.2 Bangladesh

140. The delegation of Bangladesh delivers this statement in national capacity.

141. As an interim arrangement, Bangladesh supported the extension of the moratorium until the 13th Ministerial Conference. Bangladesh is in favor of establishing a permanent moratorium on this issue. To avoid repetition, I refer to our delegation's previous statements on this issue. Bangladesh is ready to engage with Members on this issue.

7.3 Switzerland

142. On substance, Switzerland's position remains unchanged. We consider non-violation and situation complaints applicable also under the TRIPS Agreement, once the moratorium ends. We believe that no additional modalities are needed for NVCs in the TRIPS context.

143. Regarding the suggested overview, we note that such an overview was compiled in 2012 in document IP/C/W/349/Rev.2. It seems to us that the discussion did not evolve much since then. We therefore see no value added in another overview.

144. To conclude, Switzerland is ready to examine and to discuss scope and modalities of non-violation and situation complaints if other Members wish to propose such modalities.

7.4 Peru

145. Peru's position, reflected in document IP/C/W/385/Rev.1, which we co-sponsored, has not changed. In our view, the application of non-violation and situation complaints, that is, challenging measures that are otherwise consistent with WTO obligations, may, *inter alia*, upset the delicate balance of rights and obligations in the TRIPS Agreement, limit the use of the flexibilities outlined in the Agreement, and create legal uncertainty.

146. In sum, we have systemic concerns in connection with this item. However, we are not opposed to discussions and are ready to assess proposals on the scope and modalities that are presented. We also agree with the Chair's proposal that the Secretariat review the compilation document to facilitate our substantive discussions.

7.5 Canada

147. Canada's longstanding position on this issue remains unchanged, and notes that the availability of non-violation and situation complaints (NVSCs) claims under the TRIPS Agreement would create legal uncertainty for WTO Members.

148. Canada recognizes that Members worked constructively to arrive at a consensus-based decision on this matter at MC12, and encourages the TRIPS Council to continue to similarly engage in a constructive manner to identify consensus-based solutions to other important issues facing the WTO membership going forward.

7.6 United Kingdom

149. Firstly, the United Kingdom would like to thank you Chair for your effort to reinvigorate this agenda item.

150. Given the lack of substantive discussion on this longstanding issue since before the pandemic the TRIPS Council in October 2021 made the right decision to extend the NVSCs moratorium until MC13. The UK believes that it is important that the TRIPS Council turns its focus to NVSCs in the hope that Members can have a substantive discussion on the scope and modalities before MC13. We stand ready to proactively engage.

7.7 China

151. China reiterates its position on the issue that non-violation complaints and situation complaints are not applicable under the TRIPS Agreement. There have been insufficient cases of non-violation and situation complaints under GATT and the WTO that could serve as guidance on modalities and scope of such complaints. Given such circumstances, we believe that to apply NVSCs under the TRIPS Agreement would bring uncertainty to the application of the Agreement and break the balance of interests among Members under the Agreement. China would like to continue to take part in the discussion and work with other Members.

7.8 Colombia

152. From Colombia's perspective, the best approach to addressing non-violation and situation complaints is to extend the moratorium that has worked up until now. The other avenues are costly and very litigious and do not bode for a good outcome for MC13.

153. Furthermore, for Colombia and other countries, the IP moratorium has always been connected to the moratorium on e-commerce, such that ensuring the success of one encourages potential acceptance of the other, and vice versa. We therefore support maintaining the past practice, which has worked.

7.9 Korea, Republic of

154. Korea's position is unchanged. We would like to just reiterate our position on the application of NVSC to the TRIPS Agreement. While TRIPS does not directly regulate market access, the nature of NVSC is that of strengthening the rights to market access. Due to this nature, the application of NVSC to the TRIPS Agreement is relatively weak in justification. Besides, when there is already a great diversity in WTO Members' IP systems, in part due to the minimum standards nature of TRIPS, we are concerned that uncertainty will be increased if NVSCs are applied to the TRIPS Agreement.

155. However, we are ready to constructively engage in this discussion to reach consensus among Members.

7.10 Argentina

156. First of all, allow me to congratulate you for your appointment as Chair of this Council. With regard to this agenda item, the position of Argentina has not changed, and in that respect I would like to refer, as the delegation of Peru has done, to document IP/C/W/385/Rev.1 (of 27 May 2015), in which it is proposed that the TRIPS Council recommend to the Ministerial Conference that this kind of complaint provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 is not applicable for dispute settlement purposes with regard to the TRIPS Agreement.

7.11 Tanzania, on behalf of the African Group

157. Our long-standing position of the African Group is well-known in this particular agenda item and remains unchanged. The non-violation and situation complaints application is unpracticable to the TRIPS Agreement due to its nature. As we have consistently been calling that we make the moratorium a permanent thing. We remain, however, flexible to continue the discussion in any format proposed. However, its position will not change in that regard.

7.12 Indonesia

158. Indonesia's position remains unchanged in that we support the permanent moratorium of NVSC. As a developing Member, the absence of a moratorium will be concerning, particularly from a development perspective.

159. We view that there is a potential of misuse of the NVSC provision whereby a WTO Member can file a complaint to the Dispute Settlement Body even if the said measures do not technically violate the TRIPS Agreement. This provision can lead to higher degree of unpredictability and instability and will disadvantage developing Members and LDCs who traditionally have less bargaining power in international trade negotiations as well as resource and capacity constraints to be involved in a dispute.

160. Furthermore, with the current Appellate Body impasse, due to the continuing blockage to the appointment of new AB members, as mandated by Article 17.2 of the Dispute Settlement Understanding, the initiation of non-violation and situation complaints will create further substantial legal uncertainty around the question of the applicability of non-violation and situation complaints.

7.13 Nigeria

161. At the outset I would like to associate Nigeria with the statement made on behalf of the African Group by the delegation of Tanzania.

162. We wish to recall our previous statements under this agenda item. We take note of the MC12 Decision adopted on the 17 June 2022, instructing the Council to continue its examination of scope and modalities, for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article 23 of the GATT and to make recommendations to the 13th Ministerial Conference.

163. It is also agreed that, in the meantime, Members will not initiate such complaints under Article XXIII of GATT.

164. We remain open to working with other Members on this matter. However, we are of the view that the current moratorium should be made permanent because we believe that complaints should be made in the case of an actual violation.

7.14 Hong Kong, China

165. Hong Kong, China supports the TRIPS Council to continue its examination of the scope and modalities for non-violation and situation complaints cases as mandated in the TRIPS Agreement. We would be open to any new ideas on how to take forward this discussion, including the suggestion of having a factual overview of Members' views on the operation of non-violation complaints, based on existing materials and meeting records.

166. We have heard Members' reservations about such a factual compilation this morning, but I think it is a humble attempt to revive the substantive discussion. I wonder if we could at least perhaps re-attach the 2012 compilation to the Airgram or annotated agenda, or better still, update the 2012 compilation.

7.15 Thailand

167. Briefly, I just would like to reaffirm Thailand's position that non-violation and situation complaints should remain inapplicable to the TRIPS Agreement, while we remain committed, under your guidance, to engage with Members further on this issue in order to find a way forward and a permanent solution.

7.16 South Africa

168. South Africa's perspective on the issue of non-violation and situation complaints is well-known. We take the floor merely to reiterate that it is well-established that proponents of the application of NVCs under the TRIPS Agreement have not provided concrete examples of the kind of scenarios in which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations set out in the TRIPS Agreement.

169. Having said this Chair, we stand ready to discuss this matter further and we do welcome your suggestion on the factual compilation.

7.17 India

170. India's position on the issue of non-violation complaints under the TRIPS Agreement is well-known and remains unchanged. India is ready to engage in discussions and looks forward to working with like-minded Members in making non-violation complaints inapplicable to the TRIPS Agreement.

7.18 European Union

171. I would just like to restate the European Union position in that we are ready and open to hear and discuss any solutions for the future on this matter.

7.19 Moldova

172. We just wanted also to briefly mention our position, which also has not changed and we would also be in favor of continuation of the TRIPS-related moratorium.

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

8.1 South Africa

173. I have been instructed to briefly reiterate our remarks from the informal consultation on this issue. Article 71 states that the Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which may warrant modification or amendment of this Agreement.

174. Our delegation reiterates its view and places on record that it does not share the interpretation captured in the 25 May 2023 communication on the parameters of the review. There should be no attempt to confine the right of Members to make proposals based on developments, especially arising from the COVID-19 experience. In our view, the continued failure of the Membership to agree to a temporary waiver to ameliorate an unprecedented crisis makes it clear that a permanent solution is needed to address future pandemics. My delegation therefore reserves the right to put forward such proposals.

8.2 Argentina

175. Argentina is analyzing the proposal. In light of the mandate under Article 24 of the "Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics", which emphasizes the importance of analyzing the lessons learned and challenges experienced during the pandemic, it is our view that moving forward with this work may give rise to a substantive proposal that will enable us to fulfil the mandate under Article 71.1. The aforementioned Article states that reviews may be undertaken "in the light of any relevant new developments which might warrant modification or amendment" of the Agreement. This is in line with the Declaration on the WTO response to the pandemic and the MC12 Decision on the TRIPS Agreement, which bring to light the need for a response to global health emergencies, such as a pandemic.

8.3 Colombia

176. On this point, Colombia welcomes your proposal. The review mandated under Article 71.1 has not been completed, meaning that it is important to carry it out constructively. Your proposal to begin with specific topics, in dedicated sessions and with third-party involvement, seems like the right course to us and has our support. We can think of a few specific topics on implementation that we could discuss with you if we collectively decide to ultimately move forward in this direction. We hope that might be the Council's decision.

8.4 United Kingdom

177. The UK appreciates the efforts of the Chair and the Secretariat to invigorate discussions on the review of the implementation of the TRIPS Agreement as mandated by Article 71.1. We agree that this process should not intend to re-open the substance of the TRIPS Agreement and welcome the suggestion of considering through dedicated thematic sessions over a period of two years. This may provide an opportunity for Members to share their domestic experiences on a few well-defined areas and to engage in factual discussions. We also appreciate the proposed approach may be difficult for some Members, so we welcome their views and considerations. If this approach is agreed, we presume there will be an opportunity to agree which areas are pursued.

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

178. No statements were made under this agenda item.

10 TECHNICAL COOPERATION AND CAPACITY-BUILDING

10.1 WTO Secretariat

179. Since we have already been engaging in 90's nostalgia, I am going to take you back to the 1990s to reflect on how this reporting process came into being, and why, and in a sense, what we can get out of it today. The situation then, was as it is now, in that technical assistance relating to the TRIPS Agreement and implementation of the TRIPS Agreement is unusual in character because it involves engagement with an exceptionally wide range of counterparts and constituents. From the WTO point of view, in particular, it can be distinguished from some of the other areas of technical assistance, if you think of trade facilitation, or government procurement or the area of Sanitary and PhytoSanitary measures where there is a fairly specific set of issues to address, and most importantly in capital a very well-defined catchment area, if you like.

180. This is not the case with the TRIPS Agreement, which typically engages a wider range of domestic players, depending on the exact topic, and that makes coordination of TRIPS related Technical Assistance a distinct challenge. I believe, as I was in a delegation in the late 90s, the coordination of technical assistance was a consideration even then. This goes to both, those offering technical assistance, because it can come from a range of different programmes, and for the in-country partners for technical assistance because these range from customs departments to justice departments, to quite technical IP offices, to the departments dealing with health and environment, so the question of coordination is particularly challenging.

181. Further, and this is a practical observation from many years of this work, it is very rare to see a specific aid, or technical assistance programme, that is exclusively focused on TRIPS implementation as such, and indeed there are a number of instances where opportunities for co-operation are overlooked because the relevant programmes and the relevant needs on the face of it look as though they are in different categories altogether.

182. And yet, we know now from the fantastic reporting we are receiving from Members that there is a great deal of potential in a wider range of technical co-operation programmes, as you will see from the review we are about to put before you. A programme may bear the heading of, say, business readiness - this was a specific case I am thinking of – where a certain trademark office was in need of support for automation and improving its procedures, a very hands-on practical requirement, and there was real difficulty finding a technical co-operation partner. It turned out that separately there was a business-readiness technical assistance programme looking for counterparts to work with. The two had a completely congruent objectives and indeed ended up working together very fruitfully, but on the face of it there was no obvious correlation between the two. This is one example, and there are many of them, of why the process of information sharing and coordination in a practical sense does become very important. It is also a matter of effective use of resources in a climate in which we are looking at constraints of available resources, and necessity is the mother of invention, and that maybe fruitfully compels a more careful approach to making the best use of available resources.

183. Quite a number of the programmes that have been implemented to promote or assist with TRIPS implementation fall under quite a wide number of other categories, such as support for innovation or support for industry start-ups and SMEs. Obviously, the digital economy-related programmes and programmes supporting engagement with the online economy. Increasingly, sustainability has a TRIPS dimension, programmes on rural development, sustainable agriculture, health, environment and climate change. We are seeing all of these increasingly taking on a TRIPS component. All of this is to underscore why we would suggest that the process of promoting and improving coordination and sharing of information that was established by this Council 25 years ago is worthy of Members attention both in terms of making most effective use of available programmes and above all ensuring that developing countries and LDCs do get the priority resources and support that they are understandably looking for.

184. So, just to recall that this is an obligation in the TRIPS Agreement, the provision of technical assistance but it does presume a coordination-type process – a request and mutually-agreed terms and conditions as part of the process of identifying needs and responding to those needs. It also recalls what was clearly an early strong emphasis on the development of laws and regulations but also aspects of the prevention of the abuse of IP rights more structural and administrative infrastructure requirements as well. I hope I am not reading anything into this, but this is certainly how this provision has been played out. I might mention that this does refer to developed country Members as partners in technical co-operation, but of course a number of other partners have engaged in technical co-operation and that is clearly worthy of attention and something to learn from, for example South-South cooperation. But an important part has been the reports, the updates we have had from our international organization sister partners, and the reporting process has been expanded, at the request of the Council, to cover international organizations as well, and regional organizations.

185. One element of the coordination process that we would suggest has been underutilized, is the system of contact points for technical assistance that was established by a decision of this Council back in 1996. Since then, we in the Secretariat have maintained the list of contact points, which has been transformed from inaccessible documents to a provision on the e-TRIPS platform so that it is much easier to locate and track down the contact points. The practice for contact points has differed between Members. Some identify one individual or specific contact point for all areas of technical assistance, others have broken it down in different ways. Either according to subject matter, i.e. different contact points for copyright, or trademarks or patent law. Others have set aside a distinct contact point for enforcement, so it might be in the customs or the police department. Which means that there is quite a diversity of practice among Members in identifying their contact points. One thing we can say though, is that the contact point system has been tremendously underutilized – I had the honor myself of being a contact point for four years and was not contacted once. I think that is part of a broader trend, and this is perhaps one reason why the majority of contact points have not been updated for many years, in many cases for 15 years or even longer. We do know anecdotally that many of these contact points are completely out of date. People have moved on to

different jobs, so it is one of the areas in notifications and reporting generally where you can have a negative feedback loop. There is a sense of as it is out-of-date, no-one is using it, so we need not bother updating it. That then increases the incentives for ignoring it, whereas if it is kept up-to-date and there is more confidence that it is worth using, then there is a positive feedback loop being established. So we would certainly suggest that the challenges of coordination of technical assistance, the challenges of identifying the right partner in technical assistance has not become easier, arguably it has become even more complex, and so the role of the contact points, their potential contribution is, I would suggest, greater than ever. So it is certainly worth paying attention to making use of this possibility, because it is a solution that this Council came up with to a continuing challenge, and one that is in the interest on both sides of the bargain of mutually-agreed terms for technical assistance. This assists both sides in making the most of the resources available. That is the end of my advertisement.

186. The reporting material is another area where we have been gathering large quantities of information that are difficult to make use of. Ironically, the more diverse, the more inclusive, the more comprehensive the information, the harder it is to work with. And once again this was a measure that the Council itself established, again in 1996/1997, to promote exactly the coordination to line up available resources to address the needs of developing country Members. It was also based on the assumption that there would be a degree of conversation in the Council itself, based on that information. At that point, the Chair pointed out that this was a way, both of providing information, and also finding ways to match supply and demand in respect of technical assistance. So again, that critical coordination challenge that certainly remains the case today.

187. This was the background to the establishment of these reports, and the very range, the very complexity of these reports has made them ironically difficult to work with. So that is why we have been probing into the more recent reports, to get a sense of how we can draw out broader insights from them, in the hope that this may encourage and facilitate the use of these reports as a resource, as a practical tool, for coordinating the planning and delivery of technical assistance in priority areas. As you will see from this chart, from the very first days of this Council, there have been a number of reports submitted by Members about technical assistance programmes, reaching a high point, interestingly, in the early 2010s. This is in terms of specific reports received from individual Members, including collective reports, and you will see the comparisons we have made, and here I should acknowledge our colleagues Owen Henderson, who has ploughed through this material and produced these reports.

188. You will see the vast range of programmes - almost 600 distinct programmes were reported in 2016, and around 414 programmes last year. Apart from Owen and the translators, I am not convinced anyone else has read through all of these documents. They are long detailed documents, they are full of very interesting and worthwhile information, but making use of that information, using if for those practical reasons that the Council set up this programme in the first place, that remains a challenge. That said, also some caveats: We should not read too much into the drop in the sheer headcount of programmes. There is a great diversity across the different programmes reported upon, and so taking a simple headcount of the programmes is not a measure of the overall scale of impact and activity, but it is at least a starting point to understand the trends. Looking at reports from last year, we have from the point of view of Members, 414 distinct technical assistance programmes reported, and among international and regional organizations, some 411 programmes that were reported. Just to recall that at the time the reporting process was set up, while Article 67 does refer specifically to developed country Members, it was the decision of the Council at that stage also to extend this reporting, and to invite international organizations to contribute as well. That is why we have these combined figures.

189. If we look at the developments, and we will circulate this as a Room Document, we see an interesting spread across regions and within regions very roughly corresponding to the size and extend of the regions in particular. We do see interesting developments in these trends. In particular, there has been a marked increase in programmes working within Africa, Latin America and the Caribbean. We have not been able to break down in great detail what is behind that trend, but it is quite noticeable if you look at developments over time, as these charts certainly illustrate, but it is the kind of broader meta trends that can be discerned from these materials.

190. I think one of the very interesting aspects of this analysis are the different categories, or different forms of technical assistance that Members have reported. This not a taxonomy or a structure invented by the Secretariat, this an empirical observation as to the areas of technical

assistance that Members themselves have chosen to report on, and some of them quite rooted in the law of TRIPS and TRIPS implementation. This includes support for legislation and the development of domestic legal systems. Secondly, institutional support, the development of the various bodies and institutions that undertake administration of the IP system. And then more broadly, as I alluded to earlier, programmes that go beyond that and look at TRIPS implementation in a broader sense in supporting innovation and technology transfer as well as raising awareness of the IP system. there is also more specialized training, judicial training and the training relating to enforcement. And then again, as I mentioned earlier, what we can call Sustainable Development Goals (SDGs)-related or developed-related projects that look at the IP system and the implementation of TRIPS within the broader context of promoting transition to green technologies and of course dealing with public health issues and sustainable development goals more generally.

191. I did not want to single out anyone in particular, and this slide – page 15 – is really just to illustrate the point I made earlier. Firstly, there is a wide range of programmes that correspond to each of those six broad categories, but they can fall under quite different headings, or technical assistance programmes that you would not automatically assume related to IP and TRIPS implementation, but in practice do. This is an example of how making use of these reports can be very helpful in overcoming those coordination challenges, and can help find the appropriate partnerships between the provision of technical assistance and the priority needs of developing countries. Looking at the contrast between the reporting Members and the international and regional organizations, interestingly the international organizations have been more active on the administration aspects, the infrastructure aspects, and I would guess that WIPO's remarkable resources in that areas may be one explanation for that. But also in the area of IP awareness, much more activity on the international organization side than the reporting Members side. It is the opposite when it comes to enforcement and the training of the judiciary, and one can only speculate as to why that is the case. We also see a very significant chunk of work relating to development activities. You can break these down according to region, and it is interesting to look at overall trends. Likewise, when it comes to individual programmes, again we see the same kind of general trends between 2016 and 2022 among reporting Members. So here we see, for example, roughly the same focus on development related areas, we see interestingly an increase in programmes relating to legislative support, and yet a significant decrease when it comes to administrative infrastructure.

192. I hope this wets some appetite for the value of getting to grips with this data. I know how much hard work goes into compiling these reports, I certainly know how much work of the Secretariat goes into turning these reports into documents and building them into the e-TRIPS platform, and into translating the material. It is an enormous investment, generally, that Members are making in assembling this material and making it available, and the suggestion is that we can do more to dig into it and put it to service of Members to promote what I think everyone would hope for – the better use of available technical assistance resources, that are better matched to the immediate priorities of developing countries.

193. As far as Aid for Trade is concerned, it goes in two directions. Certainly, there are relevant programmes which the Secretariat puts together, which fall very generally under the Aid for Trade banner, but also programmes beyond our reach. There can be confusion about categories, or an assumption for example that Aid for Trade doesn't include dealing with IP in some way, whereas in practice it actually does. There remain coordination challenges, for example with the Enhanced Integrated Framework (EIF), with our colleagues in the International Trade Centre (ITC) as well, that is something that we are conscious of and need to work on further. It is a changing scene, for example there are programmes that touch on value-added for local agricultural products, so the Standards and Trade Development Facility (STDF) has a role in that area, the EIF, ITC and there is also a TRIPS dimension, so that is a good example of the kind of dimension we are seeking to practice in-house.

194. There are also COVID-related programmes and that is another example of coordination. Under our trilateral co-operation – which is a collaboration between WHO, WIPO and the WTO – the three Directors-General got together and instructed us to "ramp up" coordination in that area, and this has taken various forms, including policy support and drawing together information on policy responses at the practical level. For example, the Trilateral Gateway was established for Members seeking specific technical support in relation to COVID-19. That is a good example of where a coordinated approach is not merely desirable, but essential, because by definition there are overlapping fundamental health challenges, with an IP dimension, with a trade dimension from the

very beginning. Fortunately, that framework was already established at the time of the pandemic, but it had to be intensified and the three Directors-General set out a specific set of activities to intensify that at a technical-assistance-level response to COVID-19.

10.2 Bangladesh

195. The delegation of Bangladesh aligns with the statement that will be delivered by the LDC Group.

196. Under this agenda item, my delegation thanks developed country Members and IGOs for their support under TRIPS Article 67. My delegation also appreciates the Secretariat's plan for an informal workshop on the implementation of technical cooperation under TRIPS Article 67.

10.3 Djibouti, on behalf of the LDC Group

197. The LDC Group would like to thank Members who submitted the reports under Article 67 of the TRIPS Agreement on support and capacity-building for developing countries and particularly for LDCs. The programmes presented are of key importance for developing countries and for LDCs.

198. And we really do thank the WTO Secretariat for their management of the TRIPS platform on the management of data and information related to TRIPS. We encourage partners to continue their precious support to developing countries and in particular to the LDCs, as well as LDCs graduating from the category.

199. In conclusion, we note that the WTO Secretariat will be organizing an informal workshop on the implementation of Article 67 of the TRIPS Agreement. We welcome that effort, and we hope that that informal workshop will help prevent overlap between the implementation of Article 66.2 and Article 67 of the TRIPS Agreement.

10.4 WTO Secretariat

200. I just wanted to reassure Members that we would like to continue to engage with them, as we have already to consult with them on the format and the content of the workshop, because above all it is there to make their lives easier and programmes more productive. It is to encourage collaboration between Members on 11 and 12 October, but we have already had very fruitful informal discussions with Members and that will, of course, continue. So please do not hesitate to contact us if you would like to discuss it. We will be in touch in any event.

11 PARAGRAPH 8 OF THE MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022

11.1 South Africa

201. As the World Health Organization (WHO) declares an end to the public health emergency of international concern related to COVID-19, it is important to recognize that the pandemic is not over as a global health threat. In making the recommendation, the International Health Regulations Emergency Committee acknowledged that there remain uncertainties posed by the potential evolution of SARS-CoV-2. They advised that it is time to transition to long-term management of the COVID-19 pandemic. In this context, it is critical to continue addressing IP barriers related to COVID-19 diagnostics and therapeutics to address concentration and promote diversification of production of these key medical tools.

202. The World Intellectual Property Organization (WIPO) Patent Landscape Report of April 2023 highlights the significant IP barriers that still exist, which could hinder access to life-saving diagnostics and treatments, particularly in low- and middle-income countries (LMICs).

203. The report notes that although there has been a significant increase in the number of patent applications related to COVID-19 diagnostics and therapeutics, a majority of these applications come from a handful of high-income countries, with only a small proportion originating from LMICs. This concentration of IP ownership could limit access to these crucial tools in LMICs, where they are

needed most. In addition, the co-sponsors have extensively detailed IP barriers in numerous submissions such as IP/C/W/670, IP/C/W/671, IP/C/W/672, IP/C/W/673 and IP/C/W/674.

204. It has been argued that demand for COVID-19 therapeutics and diagnostics is low and that the extension is therefore not necessary; this notion is misleading. There is massive unmet global health need for COVID-19 therapeutics and diagnostics. Demand for COVID-19 therapeutics and diagnostics is artificially suppressed. The US-based civil society organization Public Citizen has identified four factors that explain the anemic demand for these necessary tools.

205. First, many patented tools are unaffordable for LMICs. The secrecy of supply agreements complicates country procurement decisions. Second, it is challenging for budget-constrained LMICs to compete with high-income countries to purchase products in initially limited and/or unreliable supply. Third, competing health priorities and strained resources limit the ability of governments to prioritize their country's COVID-19 response. Lastly, there are knowledge gaps regarding the available health technologies and the value of testing and therapeutics. In other words, supply challenges – high prices, opaque and delayed and unpredictable availability – constrain demand.[1]

206. In the case of South Africa, lack of affordability had a direct impact on suppressing the demand for tocilizumab. Despite an expert panel finding that the treatment reduced deaths, the recommendation was that the drug not be used because it was "not affordable at the current offered price".[2] At the cost of around USD 2,000 per patient, this life-saving therapy has been largely out of reach for African populations.[3]

207. Where Paxlovid is concerned, estimated health need in LMICs exceeds market demand by over 8 million courses.[4] It has also been estimated by the ACT-A Council Working Group on Diagnostics and Therapeutics that across ACT-A eligible LMICs, there will be an unconstrained need for 223 million antiviral treatments in 2023, compared to demand for 31 million treatment courses.[5] This would result in 192 million COVID-19 infections in LMICs that would benefit from antivirals, but will ultimately not have access.

208. IP barriers must be addressed in order to meet health need for therapeutics at affordable prices. For example, baricitinib – a potential alternative to tocilizumab – has been manufactured by generic manufacturers in India and Bangladesh at prices lower than USD 7, which is about 400 times cheaper than the price at which it is sold by the originator. This treatment is protected by patents in several countries including South Africa and Indonesia, thereby stifling the potential for widespread production and availability in LMICs.[6]

209. In the case of diagnostics, highly concentrated production backed by patent thickets have resulted in high prices.[7] For example, the estimated cost of production for the GeneXpert COVID-19 diagnostic test is just USD 3-5 per test, yet the price being charged is close to USD 15 in developing countries, over 3 times the estimated cost of production.[8]

210. There are over 400 treatment and antiviral candidates in clinical development.[9] Many of which could provide better clinical outcomes than existing treatments. It is critical that such treatments are widely available if we are to end the pandemic.

[1] See Public Citizen Prehearing Brief for Investigation No. 332-596: COVID-19 Diagnostics and Therapeutics and Flexibilities Under the TRIPS Agreement (Public Citizen) at page 10.
[2] https://mg.co.za/africa/2021-08-26-unvaccinated-untreated-africa-may-not-get-its-fair-share-of-covid-19-drugs/
[3] Ibid.
[4] Public Citizen at page 10.
[5] Report of the Access to COVID-19 Tools Accelerator Facilitation Council Working Group on Therapeutics and Diagnostics. "Unconstrained need is the total number of cases in LMICs in the next 12 months, regardless of a country's testing capacity, interest in the product, or capacity to roll it out".
[6] https://msfaccess.org/msf-responds-latest-who-recommendation-covid-19-therapeutic-baricitinib
[7] https://msfaccess.org/sites/default/files/2021-07/IP_IssueBrief_Local-diagnostics-local-health-needs_ENG_13.7.2021.pdf
[8] https://peoplesvaccine.org/wp-content/uploads/2022/11/A-fact-based-case-for-the-extension-of-the-TRIPS-COVID-19-decision.pdf.
[9] https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker.

211. As observed by Prof. Joseph Stiglitz, test and treat programmes in developing countries will be limited no matter how dire the need is, unless ample supplies of affordable diagnostics and treatments are readily available.[10]

212. Three factors indicate that the need for new medicines is increasing:

i. COVID-19 has become endemic so we need new medicines to deal with it.

ii. New variants are emerging and vaccine effectiveness require more booster doses and perhaps some vaccines are not that effective against the variants.

iii. We urgently need treatment for long COVID. Some studies show that 1 in 8 people develop symptoms of long COVID which can be incapacitating. Therefore the world needs medicines for prevention and treatment of long COVID.

213. Given the experience of PPE, vaccines, diagnostics and current medicines, LMICs cannot rely on the goodwill of corporations. The way to treat people is to ensure sustainable supply of new effective medicines by enabling local production.

214. Companies producing the two currently available antiviral medicines, and their mouthpieces behind national flags say that they have the capacity to supply LMICs, but in reality, little is available to people in those countries. Pfizer is allocating only 10 million courses of the antiviral Paxlovid for LMICs, including 4 million via UNICEF and 6 million via The Global Fund.[11] This is hardly sufficient for the millions of potential users in LMICs. Moreover, so far only a few thousand doses have reached those countries.

215. Finally, at the 8 June consultation and today, the idea of having a thematic workshop was mooted on the understanding that independent competent authorities such as the WHO would be a prominent role player in such a workshop. We would welcome the engagement.

11.2 China

216. China has always actively participated in the discussion on the issue of the TRIPS waiver and contributed to the successful conclusion of the Ministerial Decision on the TRIPS Agreement at MC12. We note that on 5 May 2023, the WHO announced that the COVID-19 pandemic no longer constitutes a Public Health Emergency of International Concern (PHEIC), which marked a significant outcome of the world's joint response to the pandemic. However, it must be noted that the announcement only means a transition in the level of management of COVID-19, from emergency mode to a level the same as other similar infectious diseases. COVID-19 still poses a threat to global health.

217. At present, we are witnessing a standstill in the discussion on this topic. China calls on Members to continue promoting consultations and make decisions in accordance with the MC12 mandate.

218. Noting the wide range of COVID-19 diagnostics and therapeutics and the complex status of the related intellectual property rights (IPRs), at the informal meeting held on 25 April 2023, China proposed to hold a thematic session on this issue, engaging representatives from governments, agencies, academic institutions, enterprises, and international organizations to share relevant information and experience. At the informal meeting held on 8 June 2023, many Members expressed support, which is highly appreciated. With the Chair's able leadership and the Secretariat's organization and Member's joint efforts, we hope that the thematic discussion could serve as a platform for thorough information exchanging and sharing, so as to contribute to follow-up consultations on this issue. China is willing to actively participate and offer due contribution including recommendation of capable panelists for this discussion.

[10] https://www.scientificamerican.com/article/the-international-community-must-prioritize-covid-treatment-and-test-access/\; https://asia.nikkei.com/Opinion/Delays-on-WTO-deal-for-COVID-treatments-are-costing-lives-in-Asia.

[11] https://www.reuters.com/world/pfizer-provide-10-mln-courses-covid-pill-developing-countries-the-global-fund-2022-03-02/.

11.3 Djibouti, on behalf of the LDC Group

219. With regards to paragraph 8 of the Ministerial Decision on the TRIPS waiver, the LDC Group aligns with the declaration made by South Africa just now on behalf of the co-sponsors of document IP/C/W/669/Rev.1. We are disappointed that Members have not been able to agree within the timeframe to arrive at the goal that was set for them by the Ministers on the extension of the TRIPS waiver for diagnostic and therapeutic products for COVID-19.

220. In December 2022, the TRIPS Council recommended that the General Council extend the deadline beyond 17 December 2022. We have pointed out that the deadline extension should not modify the Decision made during MC12 nor change its scope of application. It is regrettable that during the last General Council meeting in 2023, we could not take a decision in this regard.

221. We cannot turn a blind eye to the threat of further pandemics and the need for swift and affordable access to diagnostics and therapeutics. It is very urgent that we take the actions needed to prevent future tragedies, and to avoid human suffering, corporate bankruptcies, travel restrictions, and any other problems linked to health crises. It is always better to be safe than sorry. Prevention is preferable to last-minute efforts, which is why the MC12 Decision on the TRIPS waiver should be extended to diagnostic and therapeutic products as soon as possible. The LDC Group is concerned by the situation and remains in favour of continuing constructive dialogue on this very important subject.

11.4 Bangladesh

222. The delegation of Bangladesh aligns with the statement of the LDC Group and supports the statement of South Africa on behalf of the co-sponsors of document IP/C/W/669/Rev.1.

223. We must admit that the WTO could not play its role to address the COVID-19 pandemic in a timely manner - a future pandemic is still a threat. We must learn from our failures and the same mistakes and procrastination should not be repeated. Bangladesh sincerely hopes that without further delay, the MC12 decision on the TRIPS waiver will be extended to cover therapeutics and diagnostics.

224. To avoid repetition, I refer to my delegation's previous statement in the TRIPS Council. Bangladesh looks forward to working with Members on this important file.

11.5 Indonesia

225. At the outset, Indonesia would like to associate itself with the statement made by South Africa and other co-sponsors of document IP/C/W/669/Rev.1 proposal.

226. We would also like to refer to our previous statements on this agenda item, including to register our disappointment in our failure to agree on the extension of the decision to therapeutics and diagnostics at the mandated time.

227. The end of COVID-19 as a global health emergency is not the end of COVID-19 as a global health threat. COVID-19 is the most severe health crisis in a century and the world was not prepared. Almost 7 million deaths have been reported, but the total death toll may be higher – at least 20 million. It has also caused severe disruption to health systems, and severe economic, social and political upheaval. Developing countries and LDC Members took the biggest hit.

228. If we could learn one thing from the pandemic, the scientific discoveries of countermeasures that follow (including diagnostics, therapeutics and vaccines) have led to millions of lives saved. However, their availability, cost and uptake among targeted populations is mixed, with vast inequalities still present across the globe.

229. With that in mind, it is paramount that the WTO, particularly the TRIPS Council, during this standstill use this time to start to lay ground, including discussing the preparation for a mechanism that will allow us to swiftly respond to future pandemics without spending years negotiating, while people are dying. This discussion could become part of the thematic session that the Chair has suggested.

230. For that discussion to be fruitful, the WHO must be given a chance to provide updates on the pandemic treaty discussion to inform us on how the WTO can complement their work through this mechanism.

231. Indonesia stands ready to work with other Members constructively on this matter.

11.6 Nepal

232. I would like to congratulate you and extend to you my best wishes.

233. My delegation aligns with the statement delivered by Djibouti on behalf of the LDC Group and wishes to add a few points. It has been almost one year since MC12 where our Ministers in MC12 mandated to complete work within 6 months. But the discussion was inconclusive in the time given by the MC12.

234. We should not forget so fast how devastating the COVID-19 pandemic was, and how hard we've been suffering from the devastation. COVID-19 vaccines are a part of this, as only the vaccines can save the lives. Therefore, we have been warning Members to consider the extension of the TRIPS waiver to the production and supply of COVID-19 diagnostics and therapeutics. Finally, we call upon Members to engage constructively and demonstrate flexibility at the maximum possible level.

11.7 El Salvador

235. We would like to congratulate you on your appointment as Chair of this important Council and to thank you for the report and efforts made to promote discussions on this topic through a series of consultations with Members. We also appreciate the Secretariat's outstanding work to advance such discussions in order to ensure compliance with the decisions made by our ministers at MC12.

236. Although COVID-19 is no longer a global emergency, there continues to be a lack of global preparedness for future pandemics. Many countries have still not recovered from the negative impact of the recent pandemic, especially the most vulnerable ones. It is important for the WTO to help overcome these challenges and, at the same time, ensure compliance with the agreements previously reached at MC12.

237. We agree with Members that the fundamental goal is to achieve universal and equitable access to vaccines by temporarily simplifying the flexibilities provided by the TRIPS Agreement. Equitable access to diagnostics and therapeutics is critical for detecting and tackling new cases and variants, as noted by the World Health Organization (WHO).

238. For this reason, El Salvador is committed to an intellectual property system that promotes and encourages innovation. Moreover, with its overriding interest being to protect the life and health of its citizens, it supports the extension of the temporary exemption for the production and supply of COVID-19 diagnostics and therapeutics.

239. We deem it necessary to accelerate the work in this Organization to find a prompt solution, stepping up dialogue and cooperation between Members.

240. We reiterate the willingness of the delegation of El Salvador to continue working quickly and constructively to facilitate the production and supply of these essential life preserving products, setting an important precedent, as a temporary measure in a pandemic.

241. Lastly, we welcome the proposal to hold a workshop or thematic session on extending the waiver to the production and distribution of these products, drawing primarily on the WHO's experience during and after the health crisis, along with that of WIPO, and including various stakeholders, such as civil society and those responsible for distributing COVID-19 diagnostics and therapeutics.

11.8 Peru

242. We took the floor to support the proposal to resume substantive discussions in this Council in parallel with the internal consultations that some Members, including my country, continue to hold.

243. We reiterate that Peru must secure access to medical countermeasures, such as vaccines and medicines, without discrimination or privilege, given its difficult position as one of the countries hardest hit by the pandemic. We also understand the need to have evidence of whether our analysis of the causes and the measures to tackle them is correct and whether the analysis is sustainable over time.

244. In that respect, we support the organization of a workshop to promote exchanges with other international organizations and other relevant interested parties, ensuring as much diversity as possible, including in terms of geography, to draw on a multitude of experiences and knowledge.

11.9 Tanzania, on behalf of the African Group

245. We continue to express our disappointment, as we have done in the past, with this prolonged discussion on this particular agenda item. Tanzania had expected an expeditious process following the mandate given by the Ministers during MC12.

246. Also we want to welcome the idea you have raised about holding a thematic discussion, however, it is not our expectation that that process will delay or prolong further the extension of the Decision as mandated during MC12. We have expressed in the past our concern that following the pronouncement of coming to an end of the emergency of the pandemic, we somehow run the risk of paying little attention to this challenging problem. Considering the fact that new infections are being reported and that the news raised the existence of new serious variants. At this particular moment we think treatment of COVID-19 would have been even further better than even with the vaccine itself and considering that even vaccinated people can get infected and sick, therefore treatment should be the ultimate goal.

247. Therefore, our call as stipulated in paragraph 8 of the Decision of MC12 to extend a similar decision on the production of diagnostics and therapeutics is still an important and crucial decision that needs to be made in this Council. Also note that our previous position remains the same on this agenda item.

11.10 United States of America

248. Regarding the proposal for the thematic session, thank you for the suggestion. If organizations have information to share it would be helpful to receive the information in writing so we can make sure everyone in the decision chain receives the information. If there is a general agreement for a thematic session, we are open to discussing the topics, speakers and other logistics with Members and the WTO Secretariat.

249. As to provide information on the US ITC process. I will note that on 16 December 2022, the United States Trade Representative asked the US International Trade Commission to launch an investigation into COVID-19 diagnostics and therapeutics and to provide information on market dynamics to help inform the discussion around supply and demand, price points and the relationship between testing and treating, and production and access.

250. The ITC issued a notice in our federal register on 6 February 2023, which contains all of the relevant dates and deadlines for the hearings and submissions. All of the deadlines for public input have now passed but the ITC is still gathering input as they deem necessary.

251. With respect to the process thus far, the ITC held a public hearing on 29 and 30 March 2023. We saw testimony from 56 witnesses, 29 of which were remote. A transcript of the hearing was made publicly, as you noted a couple of weeks ago, and we thank the Secretariat for circulating the transcript to Members of this Council. My team tells me that 77 briefs, statements and written testimonies were filed before the hearing. These are publicly available on the ITC website. Also, 5 May was the deadline to submit post-hearing briefs, and it looks like well over 150 were filed. These are also publicly available on the ITC website. The ITC's report is due to USTR on 17 October 2023, and this report will be public. As we continue this process, we look forward to continuing to engage with WTO Members.

11.11 India

252. We echo the views of the co-sponsors of document IP/C/W/669/Rev.1 who spoke before me and we align ourselves with the statement made by South Africa on behalf of the co-sponsors. It is regrettable that we are unable to deliver on such a critical issue, despite a clear mandate from our Ministers at MC12. We wish to reiterate that the TRIPS Council should continue deliberating on the substantive aspects of this proposal, and in this regard we look forward to convening informal or formal meetings to take substantive discussions forward. The co-sponsors have remained actively engaged, and in fact have engaged in extensive bilaterals with several delegations and have discussed extensively and responded to the various issues raised by them, which was also duly reported to this Council.

253. Having said that we must avoid entering protracted and circular discussions and should engage with a view to arrive at an outcome, hopefully before MC13.

254. With respect to holding a thematic sessions and workshops with the participation of external stakeholders like the CSOs, academia, business representatives, etc. to inform the ongoing discussions, both on the paragraph 8 mandate as well as the response to pandemic work, it is important that this activity has a diverse representation, both geographically as well as in the diversity of voices and opinions with the presence of relevant organizations and representatives of civil society. In addition, Members' participation must be ensured in the drafting of the agenda, including the topics to be addressed, as well as in suggesting potential speakers. Further, we have to bear in mind that these workshops and thematic discussions do not in any way supplant the informal and formal meetings of the TRIPS Council that must be convened to discuss the mandated issue at hand.

255. Finally, we understand that this external engagement is limited to holding thematic sessions and workshops, while the deliberations and negotiations remain exclusively under the remit of Members. With this understanding we are ready to engage in these events.

11.12 Switzerland

256. Switzerland's view on a possible extension of the MC12 TRIPS Decision to COVID-19 therapeutics and diagnostics is well-known. Switzerland does not support an extension. We are convinced that an extension is unnecessary and would be counterproductive to our common goal of ensuring timely, affordable and equitable access and to pandemic preparedness.

257. Switzerland has engaged actively in the discussions. Together with Mexico we have submitted communication IP/C/W/693 with facts and data on *inter alia* supply-demand patterns, voluntary licences, pricing, etc. We are currently looking at Colombia's intervention, delivered last week in the informal TRIPS Council, in more detail. Switzerland is willing to engage further with the Colombian delegation.

258. Our intention with communication IP/C/W/693 was to contribute to an evidence-based discussion. The communication clearly demonstrates that we do not face a situation where we have an IP-induced lack of access to COVID-19 therapeutics and diagnostics or a lack of manufacturing capacity. Since this communication in November 2022, this view has been confirmed: the number of voluntary licence agreements has increased, while demand for COVID-19 therapeutics and diagnostics has decreased.

259. As agreed in the General Council, we can go along with further evidence-based discussions on this matter in the TRIPS Council.

11.13 European Union

260. The European Union has constructively engaged in the discussions on whether to extend the scope of the Decision to COVID-19 therapeutics and diagnostics, and we intend to continue this engagement.

261. The discussions are difficult and the situation is complex. Views vary, as we can also see in the present discussion. One important element that, in our view, adds to the complexity is the lack of a clear definition of these products, contrary to the situation of COVID-19 vaccines.

262. In addition there are multiple factors that affect their accessibility and affordability, such as available financing, licensing, procurement mechanisms or regulatory procedures, to name just a few. Following the discussions in the TRIPS Council in the last year and this one, it is clear that for a number of delegations open questions remain, especially as regards to the adequacy of the supply of COVID-19 therapeutics and diagnostics, the effect of mechanisms that are run by Medicines Patent Pool, UNICEF or the Global Fund on access to these products and, more generally, the assessment of various factors that contribute to the accessibility and affordability of COVID-19 therapeutics and diagnostics in low and medium-income countries.

263. The EU is committed to finding a way to advance discussions of the TRIPS Council by addressing questions that remain open, identifying concrete problems and the ways in which these problems can be addressed. We believe that a number of documents, communications that have been also referred to in today's session and submitted to this Council can help us in advancing these discussions. There was, for example, a helpful document proposed by Chinese Taipei with an approach on how to advance discussions, and also questions that have been posed in the document from Mexico and Switzerland.

264. In this context, we think that your proposal, Chair, to also have a thematic session is one of the ways to advance this discussion and we are ready to support you on this proposal and engage on the discussion of topics and speakers that would be relevant for this event. We will continue to constructively engage on this topic and more generally on this agenda item in future discussions.

11.14 Japan

265. Japan appreciates the efforts made by the Chair and the Secretariat to continuously provide us with opportunities to discuss this important matter.

266. In order to prepare for future pandemics, it is necessary to have mechanisms that provide strong incentives for the research and development of vaccines, diagnostics and therapeutics. From this perspective, intellectual property rights and the TRIPS Agreement play a crucial role in the research and development of vaccines, diagnostics and therapeutics.

267. With regard to paragraph 8 of the Ministerial Decision, Japan continues to believe that consideration and discussion about its extension for diagnostics and therapeutics should be based on facts and evidence regarding the multifaceted impact of IPRs and the TRIPS Agreement upon the production and supply thereof, within the context of COVID-19. In this regard, we understand that facts and evidence regarding various points of view from many stakeholders are included within the documents submitted and the ongoing investigation by USITC, and we appreciate these efforts.

268. Japan has shared various types of facts and evidence during past meetings for the purpose of holding a constructive discussion in order to reach a consensus-based decision among Members, and we are ready to continue contributing to this discussion in a constructive manner.

11.15 Thailand

269. On the issue of paragraph 8 of the Ministerial Decision, Thailand supports the continuation of fact and evidence-based discussions to bridge the gaps and reach consensus on this matter.

270. We believe that understanding what knowledge exists and determining the knowledge gap is essential for generating the necessary evidence in order to promote better understanding and allow evidence-informed policy decisions to be made and policy coherence to be achieved.

271. On the idea of having a one-day thematic session or workshop, we thank you Chair for your kind efforts and guidance. Thailand welcomes the opportunity to gather inputs, take stock of relevant developments and share experiences among Members and with outside stakeholders. We are flexible on the timing.

272. As for the substance, we think it might be useful to hear first-hand information on the experiences as well as challenges in utilizing and applying the existing flexibilities and other tools that are available in response to the pandemic, so we can deepen our understanding on the practicality of different tools and will be better equipped in preparing for the future. But we are also open to hearing suggestions from Members.

273. Thailand looks forward to participating and contributing to the session.

11.16 United Kingdom

274. The MC12 Decision on COVID-19 vaccines was brokered in a particular context of the pandemic and was clear in its scope and applicability. The landscape for COVID-19 vaccines is very different to that for therapeutics and diagnostics, both in terms of supply and demand dynamics, and the scope of products covered. At present, the United Kingdom has not formed a conclusion on an extension and we are still considering our position. The United Kingdom supports discussions, led by evidence and facts, as a necessary step to determine whether an extension is required, taking into account other factors, including unintended consequences that a broader scope may bring.

275. We welcomed the discussion papers circulated last year, by Mexico and Switzerland, and Chinese Taipei, as important contributions to the discussion. We understand that pertinent questions raised by these submissions are yet to be addressed. These relate to, among other things, identifying if any barriers to accessing COVID-19 therapeutics and diagnostics are caused by IP, how product scope could be defined, the current supply and demand dynamics for these products, as well as concerns over the broad scope of a possible extension.

276. Chinese Taipei's paper raised two fundamental questions: whether IP rights are the cause of insufficient accessibility, and whether an extension of the Decision will help? Their paper also notes the role of patents in incentivizing innovation and how weakening patent protection could adversely affect collective efforts to fight the pandemic.

277. The United Kingdom shares the view that more patent applications do not equal restricting access to products and instead are proof that the current IP framework provides confidence to innovators to develop new products. It is important to note that businesses of various sizes, including micro, small, and medium-sized enterprises (MSMEs), are involved in the development and manufacture of therapeutics and diagnostics. Patent protection is a way to help these businesses, particularly the MSMEs, attract investment. We would therefore be interested to better understand the concerns expressed by some Members that a growing number of patent applications should be interpreted as the patent system blocking access to therapeutics and diagnostics.

278. The paper also helpfully notes that a key factor to increasing production and enhancing access to therapeutics is closer industrial cooperation between originators and generic producers.

279. The number of voluntary licensing agreements in place for COVID-19 therapeutics is noted by Mexico and Switzerland in their submission. They say that, as of 11 October 2022, 138 bilateral or Medicines Patents Pool-based voluntary licensing agreements comprising some of the most highly demanded treatments have been signed all over the world. These agreements cover more than 127 countries. The United Kingdom recognizes the essential role of generic manufacturing and has reiterated that it should be enabled by voluntary licensing agreements which include technology and know-how transfer. It is positive to see these partnerships formed in the COVID-19 therapeutic space. We believe that discussions on how to promote technology transfer and voluntary partnerships can be fruitful, and the United Kingdom stands ready to engage constructively with Members on this topic.

280. We remain of the view that TRIPS strikes the right balance between incentivizing innovation and ensuring access through the flexibilities enshrined in the Doha Declaration. Therefore, decisions on TRIPS should be underpinned by evidence-based policymaking as businesses, of various sizes and all around the world, rely on certainty in the international intellectual property (IP) framework to seek effective protection for their inventions. Changes that could potentially weaken the ability of this framework to incentivize investment and innovation risks impacting our ability to tackle health emergencies both now and in the future.

281. Moving forward, we would welcome constructive sessions that bring valuable evidence to the conversation from a range of relevant stakeholders.

11.17 Brazil

282. Brazil's delegation supports the continued and focused dialogue on this agenda item. In this sense we gather here once again to test our collective commitment towards international cooperation and a balanced global IP system. The positive outcome of this continued and focused dialog will ensure that life-saving therapeutics and diagnostics which the most vulnerable and marginalized ones, with global effects in terms of widespread resiliency against COVID-19 and its variants. It will enable, moreover, WTO Members to adopt the necessary measures to protect public health and promote access to medicines for all – a well-established international principle that is vital in combating future global health crises, such as COVID-19. At the present time, as developing countries grapple with numerous challenges brought by the pandemic, the need for crucial therapeutics and diagnostics related to infectious diseases has never been more pressing.

283. The access to these tools, however, is just part of the solution. It is crucial that developing countries also have the scientific knowledge and technological capacity to address the challenges thrown up by the pandemic. This is where both discussions come into play, ensuring not only broader accessibility of vital therapeutics and diagnostics, but also facilitating transfer of knowledge and technology.

284. The dialogue we are advocating for today, therefore, is not only about equipping every country, especially those most in need, with the resources and the capability to fight against global health threats for the benefit of us all, but also about shaping an equitable and effective intellectual property regime that encourages innovation while also prioritizing public health and welfare. To conclude, this delegation remains constructively engaged in this debate and calls upon all esteemed delegations to stand in solidarity with the successful outcome of a robust and focused debate on this agenda item.

11.18 Korea, Republic of

285. One of the key issues in discussing paragraph 8 of the Ministerial Decision is whether intellectual property constitutes a barrier to the accessibility of COVID-19 therapeutics and diagnostics. As it is critical in striking a right balance between IP protection systems and the pandemic response, Members should work together to build a common understanding on this issue.

286. It has been repeatedly pointed out that therapeutics and diagnostics have broader scope and IP in comparison with vaccines. Such different features of these products should be addressed in our discussions on substance. We also need to look further into the various aspects of current supply and demand, logistics and distribution.

287. My delegation would like to reemphasize that ongoing fact and evidence-based discussions are of great importance and of great use to this end. They will also help us find an effective and balanced solution under fast-changing pandemic circumstances.

288. My delegation will continue to constructively engage in future discussions.

11.19 Cambodia

289. My delegation congratulates you for being elected as Chair for this Council.

290. My delegation aligns itself with South Africa and the LDC Group statements. We regret that agreement could not be reach on paragraph 8 of the Decision to extend the coverage to include therapeutics and diagnostics by the original deadline. The LDCs have been disproportionately impacted by the COVID-19 pandemic, which it is still ongoing and spreading. The extension of the TRIPS Decision would have provided to LDCs better access to all essential medical products in fighting against the current pandemic and improved readiness for the next pandemic.

291. My delegation supports your initiative on a thematic discussion and proposes to invite the WHO to take part.

11.20 Singapore

292. We agree with other Members that we should use the additional time in a meaningful manner by engaging in substantive discussions. It is important that we take a fact-based approach in our discussions. In this regard we are of the view that the papers tabled by Chinese Taipei, Mexico and Switzerland will be a good basis for us to take these discussions forward. We also remain open to discuss all papers on the table including those tabled by the proponents. Our discussions should examine a range of factors that affect access to, and distribution of, diagnostics and therapeutics, including demand and supply chain bottlenecks.

293. On the Chair's suggestion of a thematic session involving external stakeholders, Singapore is of the view that this could be useful in informing our substantive discussions. As my colleague from India mentioned earlier, it is important to ensure diversity in the stakeholders invited to the workshop or the thematic session, so that we can benefit from different perspectives. We will also be happy to engage further with you on the speakers and topics for this.

294. Lastly, I would like to reiterate that our discussions and any decision should preserve the incentives for innovation, which have enabled pharmaceutical companies to respond quickly to the COVID-19 pandemic and also do so for future pandemics. This was underscored by the recent WIPO Patent Landscape Report on COVID-19 Related Vaccines and Therapeutics 2023 which offered evidence that:

i. The rapid development and deployment of COVID-19 vaccines were the result of decades of vaccine technology R&D, supported by the intellectual property framework.

ii. There was extensive and successful collaboration between private and public sector organizations, underpinned by an IP framework of licensing and technology transfer agreements.

iii. The development of health technologies and solutions were primarily market-driven, and commercial interests had a direct impact on the flow of investments into related R&D.

295. Hence, we must uphold a robust IP ecosystem that promotes innovation and enable us to be prepared for future pandemics.

11.21 Hong Kong, China

296. Hong Kong, China joins others in welcoming the suggestion of holding an informal thematic session with participation from external stakeholders in late September or early October on the issue of paragraph 8 of the Ministerial Decision and more broadly on paragraph 24 of the Ministerial Declaration. We believe this would be a useful opportunity to revive the substantive discussion which should be based on relevant facts and evidence. We look forward to receiving the draft programme and speakers list in due course.

11.22 South Africa

297. It is important to address one theme that emerges from some submissions that we have heard now. We would like to indicate that from our perspective, voluntary licences are an important tool. Having said this, the COVID-19 pandemic has revealed that they are inadequate to deal with such health emergencies. As demonstrated, during a pandemic scaling up and diversifying production is key to a state's health security.

298. One of the factors that has limited the effectiveness of voluntary licences as a public health tool is that they contain geographic restrictions, resulting in market fragmentation and gaps in access, particularly for upper middle-income countries. When such countries are included, terms that limit scalability and effectiveness of the arrangements tend to be included.

299. I want to also give a practical example from my own jurisdiction: the MPP licence concluded with a South African-based pharmaceutical company dealing in particular with molnupiravir. The licence contained territorial restrictions which meant that neighbouring countries could not benefit.

In addition, this also had an adverse impact on economies of scale, of course. In addition, the terms exclude the South African private sector which accounts for approximately 80% of purchasing power in our country's health sector. The public sector, therefore, is ostensibly the only beneficiary of the licence. However, the public sector has declined to recommend molnupiravir due to contra-indications. The Health Ministry was not consulted on the conclusion of the licence.

300. This is a clear demonstration of the fact that voluntary licences are good, but they can certainly not be seen as a panacea when there is an urgent need.

12 INTELLECTUAL PROPERTY AND THE 1998 WORK PROGRAMME ON ELECTRONIC COMMERCE

12.1 South Africa

301. Document IP/C/W/698 is submitted in fulfilment of the mandate set out in the Work Programme on Electronic Commerce (WT/L/274). 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;
>
> - new technologies and access to technology."

302. The need to intensify these discussions was reconfirmed by Ministers at MC12. The WTO Ministerial Decision in this regard states that "We agree to reinvigorate the work under the Work Programme on Electronic Commerce, based on the mandate as set out in WT/L/274 and particularly in line with its development dimension".

303. In order to fulfil this mandate, the relationship between intellectual property and development and the various Sustainable Development Goals (SDGs) needs to be mainstreamed into the discussion of the TRIPS Council.

304. Reinvigoration of these discussions is timely. In the ever-evolving landscape of the digital era, e-commerce has emerged as a powerful catalyst for economic growth and global connectivity. As online platforms continue to reshape the way we do business, it is essential to recognize the intricate relationship between e-commerce and IP. The TRIPS Council is the relevant platform for this discussion.

305. The United Nations Conference on Trade and Development (UNCTAD) Digital Economy Report of 2021 provides crucial insights into the profound impact of e-commerce on global trade and development. It captures the transformative effect of digital technologies as follows: "Increasing digitalization of the economy and society is changing the ways people act and interact".

306. This far-reaching change has the potential to positively impact the lives of millions of people. However, without strategic interventions, there is a risk that the most advanced players in the digital sector will continue to grow more dominant while those at the lower end of the spectrum in terms of technological wherewithal, would remain locked -in as mere consumers rather than producers of digital products.

307. Take data collocation facilities for example. Data has become the lifeblood of the digital economy, enabling businesses to gain insights, improve decision-making, and enhance customer experiences. However, 80% are in developed countries, with the United States accounting for about 40%. Africa and Latin America together account for less than 5% of the world's colocation data centres. The Cloud market is also highly concentrated, with four out of the five providers based in the US. Equally, four online platforms dominate the intermediation market globally.

308. 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 Article 7 and 8 of the TRIPS Agreement. What role has the IP system played in the concentration of markets and is it sustainable?

309. Balancing the need for data access and innovation with the protection of IP rights is a complex challenge that requires careful examination. By fostering a deeper understanding of the relationship between e-commerce and intellectual property, Members can formulate policies and legal frameworks that strike the right balance. Such measures should aim to encourage innovation, promote fair competition, and protect the rights of creators and inventors.

310. Furthermore, exploring the connection between e-commerce and IP, including facilitating technology transfer and knowledge sharing among nations can be valuable in ensuring that developing countries, in particular, can leverage e-commerce to access global markets, participate in value chains, and tap into new business opportunities. Members need to identify the intellectual property issues arising from e-commerce, and discuss appropriate policy responses that address the development concerns, including in relation to the protection of these rights.

311. This paper seeks to stimulate earnest reflection on the relationship between IP and e-commerce with the view to enhancing Members' understanding of how this link can advance developmental aspirations. The questions posed in Section 4 of the paper are of a broad nature and seek to stimulate the said discussion.

312. Given that this discussion is mandated and in light of the extensive nature of issues that arise from the questions, my delegation proposes that this be made a standing agenda item.

12.2 China

313. China would like to thank South Africa for bringing this important issue to the table, we are glad to take this opportunity to exchange experience and good practices with Members on four of the nine questions listed in South Africa's proposal:

314. First, regarding Question 1 on the relations between exceptions and limitations and innovation and dissemination of technology. The Patent Law of the People's Republic of China provides for compulsory licensing systems as well as patent infringement exceptions such as patent rights exhaustion, rights of prior use, etc. These exceptions and limitations could help balancing patent holders' rights and public interests, as well as to promote the dissemination and utilization of technologies.

315. Regarding Question 3 as to how Members address anti-competitive conduct, and structure with respect to e-commerce including the abuse of intellectual property rights, the Patent Law of the People's Republic of China also stipulates conditions that constitute monopoly acts when applying for and exercising patent rights. Such monopoly acts would be handled in accordance with the Anti-Monopoly Law of China. Meanwhile, in order to eliminate or reduce the adverse impact of such behavior on competition, compulsory licensing may be carried out.

316. Regarding Question 4 as to the rapid expansion in artificial intelligence-related patent applications, how to improve access to such technology, in China, and in the rest of the world emerging technologies are rapidly developing, and the number of patent applications related to those technologies continues to grow rapidly. In this regard, China has adopted a series of measures for patent applicants. For example, in terms of clearer guidance on obtaining patent rights, we keep revisiting and continuously improving the examination standards related to the object, creativity, specification, and claim writing of AI applications. Then, in terms of efficiency on obtaining those patent rights, we provided multiple methods such as priority examination, centralized examination and a Patent Prosecution Highway. In terms of international information sharing, we participated in the discussion on the patent review standards of emerging technologies under multilateral cooperation frameworks, and studied the world's developing trends on overseas applications as well as a reference for domestic applications

317. Regarding Question 9 on the implications of new business models on IP systems such as streaming services, the rapid development of new industries such as AI, "Internet plus", big data, blockchain and metaverse is impacting on the patent objects, the review rules and many other

aspects of IP protection. China will continue to monitor the overall developing trend of new technologies and new business models, and to continuously optimize and improve relevant patent examination policies, examination models and rules, so as to support scientific and technological innovation.

12.3 Tanzania

318. Tanzania welcomed the submission made by the delegation of South Africa. Considering the exponential growth of the E-commerce and its technical applications with embedded IP protections, and also considering the monopolies behind the AI technologies, and the fact that our economies are in the transition into the digital economy, we see the importance of the Council's role. We need to intensify discussions on this particular agenda item. At least to have an honest discussion and see what are the challenges facing developing countries, and where leverage can be drawn for developing countries to benefit from the vast expanding technology of this particular area. Therefore, extending this agenda item to continue the discussion is important as called for by the delegation of South Africa.

319. It has come at a time where there is this need, a growing need from developing countries to also participate in this area, particularly to e-commerce. Therefore, we wanted to subscribe to the proposal made and we welcome the proposal while it is still in a preliminary stage of review. We will also engage our capital to look at it in details and perhaps see the possibility to join the delegation of South Africa in that particular matter.

12.4 Djibouti, on behalf of the LDC Group

320. The LDC Group would like to thank and congratulate South Africa for their communication in the document IP/C/W/698. This document raises significant questions about the reintegration of the Electronic Commerce Work Programme into the four bodies as designated in the 1998 Work Programme. In particular the issue of digital technologies and intellectual property is essential for LDCs. Article 7 and Article 66.2 of the TRIPS Agreement are important provisions for deepening relations in the field of electronic commerce. We hope that the TRIPS Council can continue discussions on the basis of the communication from South Africa which raises a number of issues in paragraph 16 of its submission. The LDC Group would be interested in the reactions of the WTO Members.

12.5 Indonesia

321. Indonesia would like to thank South Africa delegation for presenting this proposal. We will study this proposal further, but in general, our view is that with the growing importance of e-commerce, international trade rules on e-commerce must ensure the inclusivity and fairness of the global e-commerce ecosystem, including and not limited to the linkage between IPR protection and dissemination of new digital technology to developing country Members and LDCs.

322. On that note, Indonesia welcomes the idea that the TRIPS Council should establish the topic of IP and e-commerce as a standing agenda item to allow Members to raise issues for discussion in a regular manner in implementation of the 1998 Work Programme on e-commerce.

323. This will allow a substantive discussion based on the questions raised in the proposal by South Africa.

12.6 Australia

324. First allow me to congratulate you on your appointment and assure you of Australia's support as you pursue this important work and also the very important work in your informal role as karaoke leader for MC13!

325. We would like to thank South Africa for circulating this proposal which we are continuing to consider, and we hopefully come back with responses to the specific questions in the future.

326. Australia has been pleased to participate in the intensified discussions under the Work Programme on Electronic Commerce that have taken place since MC12. The Work Programme has

encouraged Members to focus more deeply on specific agreed issues and enabled positive, forward-looking discussions on the benefits to be gained from engagement with e-commerce.

327. Australia has also been pleased to see that most topics under the Work Programme have stimulated fulsome discussions, including on how we support developing and least-developed countries to more fully reap the benefits of electronic commerce, including through reduction of trade costs, improved productivity and increased ability to participate in export markets.

328. Australia does not generally see the benefit of introducing a standing agenda item on this topic in the TRIPS Council. There is of course nothing preventing a Member from requesting an *ad hoc* agenda item where they have a specific issue to discuss that relates to the nexus of intellectual property and e-commerce. We consider that such *ad hoc* agenda items, where they are based on specific proposals or communications are more conducive to ensuring Members are able to fully prepare for the particular issue to be discussed, when compared to a standing agenda item on such a broad topic as e-commerce. We therefore consider that *ad hoc* agenda items would lead to a more productive exchange of views.

12.7 India

329. India would like to thank South Africa for their document IP/C/W/698 and their presentation. We commend their efforts to bring this useful and relevant topic on the agenda of this Council.

330. Since the TRIPS Agreement came into force and twenty years since the landmark Doha Declaration was adopted science, technology, innovation, R&D, and the knowledge economy has evolved and come a long way. The first three objectives as mentioned in Article 7 of the TRIPS Agreement that is technological innovation, transfer and dissemination of technology, and the production and use of technological knowledge focus on technological development and the unfolding e-commerce revolution is one such development. IPRs have been designed to benefit society by providing incentives to introduce new inventions and creations. In introducing IPR protection, countries thus should frame the applicable rules so as to promote technological innovation and the transfer and dissemination of technology "in a manner conducive to social and economic welfare" as envisaged in Article 7. In addition, WTO Members are allowed to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development …", as laid down in the principles in Article 8 of the TRIPS Agreement.

331. Furthermore, the Preamble to the TRIPS Agreement, its Articles 7 and 8 alongside the Doha Ministerial Declaration and the Declaration on TRIPS and Public Health provide the foundation for a new legal and policy perspective on international IP regulation that is fully supportive and inclusive of social as well as economic development in Members. In addition, the MC12 Decision on the TRIPS Agreement adopted on 17 June 2022 becomes a landmark Decision in not so much, on how it delivered on ground, but in laying to rest ideological differences on the necessity of or utilisation of policy space, as it reinforces the freedom of Members to fully utilise the policy room within the TRIPS Agreement and that is a good starting point. As stated in the submission, therefore, the emerging issues owing to the overlap between IPRs, and competition policy, and e-commerce would need policy responses aligned with the principles and objectives as laid down in Article 7 and 8 of the TRIPS Agreement.

332. It is disappointing that technology transfer, at best, has been considered a subsidiary or an offshoot of the grant of intellectual property, which takes place, for instance, through the disclosure of patent information in the patent application process. It does not prescribe a general mandate for technology transfer for all countries at the international level. IP norm-setting through FTAs has further tipped the scales toward strengthening IP protection without reciprocal commitments on issues like technology transfer. While Free Trade Agreements (FTAs) and Bilateral Investment Treaties (BITs) have endorsed a TRIPS-plus framework for IP protection, the obligations relating to technology transfer as well as the new IP issues that are being brought to the fore by the evolving e-commerce ecosystem, have not exceeded Article 7 and Article 8 TRIPS' formulations. Given this structural mismatch in the current IP system, there is a need to re-conceptualize the relationship between IPRs and e-commerce including technology transfer from a developmental perspective, with technology development, diffusion, capacity-building and policy space as its fundamental elements.

333. I hope this paper will stimulate a discussion in this Council as it raises some pertinent questions on relevant issues and we would be happy to answer those and to engage with WTO Members to take forward these discussions. In this regard, we support the call for making this a standing agenda item in TRIPS Council meetings.

12.8 European Union

334. The EU would like to thank South Africa for their communication on "Intellectual Property and the 1998 Work Programme on Electronic Commerce". The EU is actively engaged in reinvigorating this Work Programme and we note that discussions are underway in dedicated sessions overseen by the General Council. These sessions include a broad array of aspects of e-commerce, including certain IP-related topics, as selected by the facilitator based on the proposals by Members, and this Work Programme is comprehensive, inclusive and the outcome of the discussions is highly informative. We therefore believe that in the best interest of the ongoing process, it would be preferable if Members could channel their substantive points via the dedicated framework. This will help maintain the needed focus and comprehensiveness of the process while avoiding duplication of discussions.

335. Members are, of course, always free to request an *ad hoc* agenda item in the TRIPS Council to discuss specific issues but given the ongoing process we do not see an added value in a standing agenda item on this matter.

12.9 United States of America

336. The United States thanks South Africa for its paper. Under the Work Programme on Electronic Commerce, the TRIPS Council is to examine protection and enforcement of copyright and related rights as well as trademarks and the new technologies and access to technology.

337. While there is renewed attention on the Work Programme, the TRIPS Council has never really stopped focusing on the issues identified by it. 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. Presentations by developing country Members and numerous international organizations and other bodies, such as the Working Group on Trade and Transfer of Technology, have emphasized both rules in 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 IP protection and enforcement designed to build the absorptive capacity of developing countries and LDCs.

338. 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, UNCTAD, and the OECD 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.

339. In light of this background, as called for by the Work Programme on e-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 enforcement relates to new technologies and access to technologies. The questions posed by South Africa run largely contrary to this mandate. To the extent that a discussion moves forward in the TRIPS Council, an appropriate place to start would be how the TRIPS Agreement applies to new technologies and how the protection and enforcement of IP rights can promote access to these new technologies. Because of the apparently significant disconnect between Members on the topic, we do not support adding the Work Programme on Electronic Commerce as a standing agenda item.

12.10 Switzerland

340. Switzerland thanks South Africa for their submission on "Intellectual Property and the 1998 Work Programme on Electronic Commerce". We note that certain IP-related topics have been taken onboard in the dedicated sessions of the Work Programme on Electronic Commerce. Being mindful not to duplicate discussions, we do call on Members to focus their exchanges under that framework

for discussing substantive issues. Recent sessions were highly instructive, and Switzerland appreciates the quality of the exchanges that took place.

341. Regarding the possibility of creating a standing item on the agenda of the TRIPS Council, Members are free to request an *ad hoc* agenda item to discuss any specific matter. We therefore see no value in such a standing item.

12.11 South Africa

342. South Africa thanked delegations for their consideration of its proposal. We naturally would like to express gratitude to delegations that reacted positively to the content and would also like to give a special thanks to the distinguished delegate from China that engaged substantially with the questions, and we would follow-up that discussion.

343. On the notion that discussing the e-commerce mandate in the TRIPS Council is a duplication, that is simply not in line with para. 4.1 and the mandate provided by the 1998 Work Programme. As a focal point for the African Group on e-commerce, I do participate extensively in all the dedicated discussions led by the facilitator and certainly do not see any reason that discussion in the TRIPS Council would in any way contradict or be a duplication particularly with the mandate of para. 4.1 in mind.

344. Having said that, we are committed to continuing to pursue the mandate set out in the 1998 Work Programme and will continue to play our part. We do thank delegations and look forward to further engagement.

13 IP AND INNOVATION: RESEARCH COLLABORATION ACROSS BORDERS

13.1 Chinese Taipei

345. We would like to congratulate you for being elected to chair this important Council. We wish you a wise guidance, and our delegation would like to contribute to constructive discussions.

346. According to the IMD World Competitiveness Yearbook 2022 released by the International Institute for Management Development (IMD) in Switzerland, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu ranked 7th in overall competitiveness out of 63 evaluated economies. We held the 1st position for total R&D personnel per capita and the 3rd position in terms of total expenditure on R&D as a percentage of GDP. With over 50% of our manufactured exports being high-tech products, we were ranked the 3rd in High-tech exports. The Global Innovation Index published by WIPO also highlighted our strength in innovation and research – in the global ranking of the top 100 S&T clusters with the highest concentration of inventors and scientific authors, the "Taipei-Hsinchu" cluster was ranked 26th position, demonstrating our significant strength in innovation and research, showcasing our robust capabilities in the field of research and development.

347. It is undeniable that innovation and R&D have a significant impact on economic growth and productivity. In recent years, the manufacturing industry has emerged as a primary driving force behind our economic growth. Particularly, the Information and Communication Technology (ICT) industry, which holds the highest share of our manufactured exports, has significantly enhanced industry value through innovative applications. In response to the restructuring of the global supply chain in the post-pandemic era, the government has adapted its approach and implemented the "Six Core Strategic Industries Promotion Plan" since 2020, building upon the previous foundation of the "5+2 Innovative Industries Plan." The above-mentioned industries include information and digital industries, cybersecurity industries, precision health industries, green and renewable energy industries, national defense and strategic industries, and strategic stockpile industries. The implementation of the Plan is spearheaded by 18 government agencies, including the Ministry of Economic Affairs.

348. Our cross-border collaboration in technology R&D involves a diverse range of partnerships between the public and private sectors. These partnerships include research teams composed of government-funded entities, academia, and industry players. The Ministry of Economic Affairs serves a pivotal role as a government agency, leading initiatives that promote international cooperation programmes. These programmes aim to attract international research expertise, establish beneficial

relationships with multinational corporations that will boost research investments in our land, and position us as an attractive partner for research, innovation, collaborative production, and value creation.

349. Taking our thriving ICT industry as an example, the government has taken concrete steps to support its growth, such as providing subsidies for collaborations between international industry giants and domestic supply chains, specifically in the areas of semiconductor equipment and materials, next-generation communications, and AI. Additionally, the government actively engages in international standardization efforts and technical cooperation to ensure alignment with global advancements in 5G technology. Strategic partnerships with leading international Electronic Design Automation (EDA) companies have also been established to encourage research and development investments in our land.

350. With the rapid advancement of digital tools and technology, we have achieved fruitful research collaborations with major global economies. An excellent instance of cooperation between us and Europe is a joint effort initiated by the Ministry of Economic Affairs. Acknowledging the EU's pioneering role in advanced technologies and their implementation in the communication industry and the synergies between our semiconductor and ICT supply chains, we have been actively engaged in the EU's "Horizon 2020" programme since 2016 under the "Targeted Opening Call" initiative. Our proposals were given due recognition and approval by the European Union (EU), paving the way for cooperative ventures with European firms in the research and development of 5G technology. To date, we have successfully completed two phases of cooperation, with a combined investment of EUR 18 million. The partnership between us and Europe provides valuable prospects for our domestic companies to expand their market presence and pursue new avenues of growth. Moving forward, we remain committed to deepening our collaboration with the EU, particularly in the fields of communication technology and more, within the framework of the new "Horizon Europe" programme.

351. The Ministry of Economic Affairs states that results yielded through R&D efforts, including their corresponding intellectual property rights, belong to the implementing unit, with exceptions made for cases related to national security, according to the Government Scientific and Technological Research and Development Results Ownership and Utilization Regulation. In instances of international cooperation, ownership of research and development results will be determined by the terms outlined in international cooperation contracts.

352. Collaboration on scientific research across borders is a mutually beneficial endeavor, and we recognize the importance of safeguarding intellectual property rights resulting from such collaborations. As technology and industry demands continue to evolve, we have taken proactive measures to enhance IPR protection, with the ultimate goal of creating an environment that appeals to multinational corporations for collaborative research and investment. We would greatly appreciate hearing from all Members about their international collaboration policies and experiences.

13.2 United States of America

353. Research collaboration occurs in a variety of ways across the globe and we look forward to an interesting discussion from all Members about the cooperative activities going on in their regions. In the United States, international engagement and partnerships are integral to US research and development. The US innovation environment relies on complex and diverse cross-sector collaborations and multi-stakeholder coalitions, and international relationships are critical to this mix of partnerships.[12]

354. While collaboration takes place between private and public institutions, for the purpose of the present discussion I will focus on some of the collaboration that occurs between the US government and other countries. The National Center for Science and Engineering Statistics reports that the United States collaborated with international partners on 40% of the US articles in 2020[13], with most articles in collaboration with China, the United Kingdom, Germany, and Canada.[14]

[12] https://www.ncbi.nlm.nih.gov/books/NBK572796/.
[13] https://ncses.nsf.gov/pubs/nsb20214/international-collaboration-and-citations.
[14] https://ncses.nsf.gov/pubs/nsb20214/international-collaboration-and-citations.

355. Scientific cooperation between the United States and other countries takes place using a variety of arrangements, from informal scientist-to-scientist collaborations to cooperation between research institutions to formal agreements between technical agencies.[15]

356. Bilateral, government-wide agreements, also referred to as Science and Technology agreements, seek to establish a framework to foster international science collaboration while protecting intellectual property, establishing benefit sharing, and preventing taxation of research equipment.[16] Agreements like this have been signed with over 40 nations[17], including China, Japan, Libya, Pakistan, India, Tunisia, Morocco, and Germany.[18]

357. These types of bilateral agreements are just a small sampling of the international research cooperation that occurs between the US and other countries. A wide variety of international research collaboration occurs between US government agencies via bilateral and multilateral projects. For example, the National Science Foundation (NSF) has conducted numerous bilateral and multilateral projects such as the International Biological Program (IBP) and Tropical Oceans-Global Atmosphere (TOGA) Program.

358. The NSF also participates in the International Gemini Observatory, which provides the astronomical communities in six participant countries with state-of-the-art astronomical facilities. In addition to financial support, each country also contributes significant scientific and technical resources. The other national research agencies that form the Gemini partnership include: *the Canadian National Research Council (NRC)*, the *Chilean Agencia Nacional de Investigación y Desarrollo (ANID)*, *the Brazilian Ministério da Ciência, Tecnologia e Inovação*, the *Argentinean Ministerio de Ciencia, Tecnología e Innovación*, and *the Korea Astronomy and Space Institute* (KASI).[19]

359. The US Department of Agriculture Office of International Research Engagement and Cooperation facilitates bilateral partnerships to work on agricultural issues that affect both partners, including South Korea, Israel, and Brazil. Multilateral partnerships through this office help address global agricultural issues, for example, the Global Research Alliance on Agricultural Greenhouse Gases or the Global African Swine Fever Research Alliance.[20]

360. As the discussion paper notes, it is important for collaborators to address intellectual property issues before engaging in collaboration. For example, the National Institutes of Health (NIH) will notify researchers of potentially commercially valuable products or processes as part of its project review.[21] NIH also offers a wealth of information on its website for both foreign organizations looking to secure NIH funding, or domestic researchers or institutions partnering with a foreign collaborator.[22]

361. In conclusion, the US National Science Foundation notes the importance of international research collaboration:

> "In today's world, NSF cannot achieve its goals in isolation…US scientists and engineers must be able to operate in teams composed not only of people from many disciplines, but also from different nations and cultural backgrounds. New ideas emerge from the intellectual interactions of people from diverse backgrounds everywhere and in every

[15] https://www.sciencediplomacy.org/article/2012/science-and-technology-agreements-tools-for-science-diplomacy.
[16] https://www.sciencediplomacy.org/article/2012/science-and-technology-agreements-tools-for-science-diplomacy.
[17] https://blogs.scientificamerican.com/guest-blog/how-international-cooperation-in-research-advances-both-science-and-diplomacy/.
[18] https://www.sciencediplomacy.org/article/2012/science-and-technology-agreements-tools-for-science-diplomacy.
[19] https://www.gemini.edu/.
[20] https://www.ars.usda.gov/office-of-international-research-engagement-and-cooperation/international-research-engagement-and-cooperation-partnerships/.
[21] Glover, Kira, Intellectual property rights and international collaboration: A US perspective. Current Science, Vol. 70, No. 12 (25 June 1996), pp. 1057-1059.
[22] https://nexus.od.nih.gov/all/2022/12/07/international-collaborations-advice-from-experts/.

country. Many scientific tools, both large facilities and large distributed and networked databases, will necessarily involve international partners."

362. International collaboration and effectively navigating IP and other issues involved will likely only increase in importance as we seek to address global challenges through research in science and engineering.

13.3 Australia

363. Australia is pleased to be a co-sponsor of the communication Intellectual Property and Innovation: Research Collaboration Across Borders, document IP/C/W/699, and would like to thank the US for its efforts in coordinating this communication.

364. We would like to provide some information on a specific cross-border research collaboration - the Australia-India Strategic Research Fund the "AISRF". Established in 2006, the Fund aims to support collaboration between Australian and Indian researchers in strategically focused, leading-edge scientific research and technology projects. Intellectual property is managed at the project level and agreed between project partners.

365. The Fund has supported 368 collaborative activities in a wide range of mutual priority areas such as agriculture, biomedical devices and implants, renewable energy, nanotechnologies and vaccines. The Fund has provided a pathway for researchers to establish links with counterparts and helped facilitate many successful research projects, including several documented large-scale projects which are of significant importance to Australia, India, and globally.

366. We consider the Australia-India Strategic Research Fund to be an example of the benefits of international research collaboration. We look forward to hearing other Members' experiences.

13.4 Singapore

367. I would like to thank the United States for preparing this paper which Singapore is pleased to co-sponsor.

368. For the past few decades, Singapore has made steady progress towards becoming an innovation-driven economy. Our national Research, Innovation, and Enterprise (RIE) 2020 and 2025 plans committed SGD 19 billion and SGD 25 billion respectively to grow our research and innovation ecosystem, and establish Singapore as a global innovation hub.

369. Today, Singapore is increasingly recognized as a global hub for innovation. In 2022, the Global Innovation Index ranked Singapore as the world's 7th most-innovative economy in the world.

370. Singapore also plays host to an increasing number of international collaborations. For example, through the Global Innovation Alliance (GIA), Singapore is well-connected to many other innovation nodes in the region and the world. Under the GIA, Co-Innovation programmes are run with partners in more than 35 countries.

371. A recent Singapore study with the World Intellectual Property Organization (WIPO) on innovation hotspots using patent data found that international collaboration in the field of research has been increasing. From 2001 to 2020, the number of co-invented patents involving cross-border collaborations rose about four-fold to around 3,000. Over the same period, the number of patents generated by foreign enterprises grew from 44.2% to 54.6% of all patents where at least one inventor is a Singapore resident, highlighting the steady rise of international collaborations in research and innovation.

372. This rise in international collaborations has helped to bolster Singapore's economy through foreign direct investments, a key economic driver given our small domestic market. MNCs such as Dyson, Procter & Gamble and Infineon Technologies, have all established R&D centres in Singapore.

373. In December 2022, American semiconductor equipment maker Applied Materials announced its "Singapore 2030" plan, which includes broadening its technology ecosystem partnership with and building a SGD 600 million plant in Singapore. This expansion is estimated to directly create around

1,000 new jobs in manufacturing and R&D, and will deepen Singapore's role as a critical node in the global semiconductor supply chain.

374. In addition, international collaboration projects, such as the UK-Singapore Collaborative R&D Call which subsides project costs for start-ups/SMEs, are another way the benefits of innovation can be brought to enterprises regardless of market size. One local company that benefited from this initiative is Aliena, a Singapore space-tech start-up that partnered with researchers from Imperial College London and UK-based aerospace firm, URA Thrusters. Aliena's new hollow cathode technology enables a more sustainable alternative to conventional satellite engines that run on fuel. This collaboration with international partners has allowed it to bring its technology to the market expeditiously, with its thrusters being used on SpaceX's rocket launch in January 2022.

375. The advent of emerging technologies, such as blockchain and generative artificial intelligence, will call for international communities to land on a common understanding of their benefits and impacts to unlock their full potential.

376. Singapore is committed to working with our partners, both locally and abroad, to catalyze Singapore's innovation and IP ecosystem for businesses, innovators, and creators.

13.5 Japan

377. First of all, the delegation of Japan would like to thank the delegation of the United States for introducing our concept paper.

378. As introduced in the concept paper, international research collaboration is a very useful tool for researchers and enterprises in areas such as efficiency and cost consideration—particularly for MSMEs, whose resources are often limited.

379. The Government of Japan has been actively supporting research collaboration across borders for entities including private enterprises and universities. For example, a national agency called the Japan Science and Technology Agency (JST) has launched a Strategic International Collaborative Research Program. As part of this initiative, JST cooperates with funding agencies in counterpart countries and regions to provide large-scale funding to researchers aimed at facilitating collaboration among researchers in a broad range of countries.

380. As stated in the concept paper, it is crucial to conduct negotiations prior to entering into such collaborations in order to determine how to approach the intellectual property generated through the joint research.

381. In order to help facilitate collaborative research activities, we would now like to introduce some of our related initiatives from an IP perspective.

382. Firstly, Japan has been continuously working on building better IP systems that serve as a global infrastructure to bolster collaborative research activities.

383. As mentioned in the concept paper, smooth collaborations among researchers and enterprises require an environment within which they can trust that their present or future intellectual property will be properly protected in the partner country or countries while engaging in joint research activities. In other words, effective collaborations can become hindered by IP systems that differ from country to country, or by insufficient protection or enforcement in a partner country.

384. In this regard, the Japan Patent Office has been cooperating with WIPO to assist emerging countries in developing legal systems and human resources by offering training courses to government staff and IP experts. In addition, Japan has been placing efforts on discussions and initiatives toward IP system harmonization within plurilateral and multilateral fora with the aim of harmonizing legal systems that differ from country to country. We believe that such initiatives will bring positive momentum to collaborative research activities.

385. Secondly, Japan has also been providing a wide variety of support for institutions and enterprises that engage in collaborative research initiatives in order to expand their business to foreign countries whose IP system differs from Japan's.

386. One of the initiatives led by the Japan Patent Office is the establishment of an International Business-Related IP Support Desk, which offers nationwide consultation and support for businesses. This IP Support Desk provides advice and suggestions regarding the acquisition and utilization of IP rights for Japanese companies that intend to expand overseas, and also provides support on collaborative research and contracts with foreign companies. In addition to private consultations, such support also includes seminars and e-learning lectures that offer tips on matters such as cross-border IP contracts and non-disclosure agreements.

387. Successful results to date include a Japanese company that consulted the IP Support Desk regarding its plans to expand its business into Southeast Asia, and ended up using the advice and suggestion to establish a joint venture together with a local enterprise, and then launch collaborative research together with a local university in order to better understand local customers' needs.

388. In conclusion, in order to engage in continuously smooth and efficient joint research, it is essential to have equal, fair and friendly cooperation among both companies and researchers. We would like to emphasize that the IP system can play a major role in achieving this, and we believe that the afore-mentioned initiatives can facilitate such future-oriented collaborations.

389. We sincerely hope that this presentation will be useful for other Members, and we look forward to listening to others share their experiences.

13.6 United Kingdom

390. The United Kingdom is pleased to co-sponsor this agenda item and would like to thank the other co-sponsors, in particular the United States, for bringing forward this paper on a topic important to global research, development, and innovation. We note with interest the informative statements provided by Members so far.

391. We live in an interconnected world, where the challenges we face are complex and cross-cutting both in discipline and territory. To create the free, secure, prosperous world we want to live in, we cannot act alone. It is essential that we work with international partners to support shared growth, address global challenges, and build momentum behind a digital and technological future.

392. The UK Innovation Strategy[23], published in July 2021, is our long-term plan to create innovation-led growth and in March 2023, we launched our Science and Technology Framework[24], setting out how our innovation and science policy will harness innovation to tackle some of our nation's most pressing challenges. Alongside this, our first International Technology Strategy[25] sets out the UK's approach for technology leadership on the global stage, defining four principles of being open, responsible, secure, and resilient. These principles will guide our international engagement, the partnerships we build and the actions we take to drive innovation to tackle some of the world's greatest challenges.

393. IP is integral to research, development, and innovation and an effective, robust IP framework supports effective international collaboration. The research, development and innovation landscape within the United Kingdom is highly diverse. We recognize that effective and appropriate international collaboration is vital to ensure that the extraordinary potential of UK research and innovation can be realized for social and economic benefit, to enrich and improve the lives of people in the United Kingdom and around the world. An IP system that is understood, accessed, and used effectively is fundamental in achieving these ambitions.

394. Working collaboratively with international partners can bring many benefits including diversity of thought, experience, and approach, and the sharing of knowledge and skills. In addition, access to wider resources, such as specialist equipment in key technology areas and at different stages of a research project, can help to reduce time and cost.

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[23] https://www.gov.uk/government/publications/uk-innovation-strategy-leading-the-future-by-creating-it.

[24] https://www.gov.uk/government/publications/uk-science-and-technology-framework.

[25] https://www.gov.uk/government/publications/uk-international-technology-strategy/the-uks-international-technology-strategy.

395. The United Kingdom is involved in a wide variety of international research collaborations between public institutions and private entities and across a mixture of both. Collaborations that go beyond traditional partners or models of engagement can support diversification and increase the resilience of supply chains.

396. The United Kingdom Intellectual Property Office supports UK research communities to maximize the positive impacts from the IP in their research both nationally and internationally. For example, we provide guidance on effective management of IP for senior leaders and technology transfer professionals across the business and research sectors. The UK government also provides guidance to research institutions to increase confidence in international collaborations and support informed decision making around potential risks linked to international research.

397. When a UK entity is thinking about collaborating overseas either with a university, research institute or business, it is vital they understand the UK and other in-country laws and regulations that apply. This includes the arrangements for existing IP and any IP arising from the collaboration, the importance of national security, who owns and commercializes IP arising from the collaboration, and how to manage the IP portfolio and share information. It is important to be aware of critical differences in national laws relating to IP, for example, how to take IP into and out of different territories. It is vital therefore collaborating parties have an IP strategy and actively manage the IP portfolio, IP rights, and any agreements.

398. To help companies and researchers collaborate, export, and invest overseas, the UK Intellectual Property Office has developed an International IP Service. This provides guides to the IP frameworks of different countries to help UK researchers and businesses make informed decisions about navigating the international IP environment, so that they can overcome common pitfalls and challenges. The International IP Service also provides guidance on how to apply for IP protection overseas either on a country-by-country basis or via international routes that allow for protection in multiple countries through a single application.

399. The UK also has a network of international IP attaches based overseas covering Southeast Asia, China, Latin America, North America, Gulf States, and India. This network of IP experts around the world are an invaluable resource providing guidance and support to entities seeking to collaborate in those markets. Our work, particularly with SMEs, means we understand how vital it is to protect IP assets before entering new overseas markets. We recognize that getting this information to researchers and businesses at the right time is important to their success.

400. An effective global IP system is fundamental in driving innovation and investment, supporting those who research, create, collaborate, and invent. We must ensure that the IP framework supports international collaboration and can embrace the challenges of the future, acting as a catalyst for creativity and innovation.

13.7 Hong Kong, China

401. I would like to first thank the United States for coordinating the paper which Hong Kong, China is pleased to co-sponsor. As the paper has rightly pointed out, scientific research benefits immensely from international cooperation, especially in sectors such as technology and life sciences. Such cooperation can take place in different forms and among different institutions, such as universities and research institutes.

402. For Hong Kong, China, our government released last December the Hong Kong Innovation and Technology Development Blueprint outlining a clear path and strategy as we press full steam ahead towards becoming an international innovation and technology hub. Indeed, Hong Kong, China has world-class capability in scientific research: we are home to five of the world's top-70 universities. We thrive on an international business environment, which is underpinned by the rule of law and a robust intellectual property rights protection system.

403. To develop Hong Kong, China into a hub for global research collaboration, we launched last year the "InnoHK research clusters" in the Hong Kong Science Park. This is a flagship project that pools together 33 top-notch universities and research institutes from 11 economies in setting up 28 research laboratories. These universities and research institutes include, for example, ETH Zurich, Guangzhou Institutes of Biomedicine and Health, Imperial College London, Institut Pasteur,

Karolinska Institutet, the University of Melbourne, Stanford University, Tohoku University, University of Waterloo.

404. So far, we have established two research clusters. The first cluster, Health@InnoHK, focuses on all types of healthcare-related technologies (including drug discovery, personalized medicine, molecular diagnostics). The second cluster, AIR@InnoHK, focuses on the development of artificial intelligence and robotics as applied in areas such as financial services, smart city and advanced manufacturing. Together, local and non-local researchers can come together to conduct impactful scientific researches.

405. The paper today has thus raised some pertinent issues in relation to such cross-border research collaboration. We very much look forward to hearing from other Members their experiences on this front.

13.8 Switzerland

406. Let me begin by thanking the United States for its submission IP/C/W/699. Switzerland is pleased to co-sponsor this communication as well as this item. We would also like to thank the Members, who have just shared their national experiences.

407. Aware of the global nature of modern research and competition, Switzerland is committed to international cooperation. Researchers benefit from global resources and expertise through access to international infrastructures, programmes, and services. This fosters the expansion of knowledge and the development of innovative solutions. Consequently, international collaboration is a key element in Swiss research policy.[26]

408. One of the prerequisites for successful international collaboration is the ability to manage the increased level of coordination. In addition, participants need a certain degree of cultural and scientific openness in order to get the most out of different backgrounds and approaches.

409. So how is Switzerland promoting international projects?

410. To foster collaboration, Switzerland is member in cooperation programmes. The programmes span a wide range of activities, from collaborations between small and medium-sized enterprises (SMEs) and market-oriented programmes, to programmes for fundamental research.[27]

411. Let me give you three examples of international collaboration in research:

- First: Switzerland is part of the programme Eurostars. This promotes cooperation of Swiss and international SMEs. More than 30 countries take part in this programme. It is aimed at innovative SMEs that develop products and services that are significantly different from existing ones.[28]

- Secondly: Joint Research Projects are collaboration between the Swiss National Science Foundation and funding agencies in various countries on four continents. These projects, lasting between three to four years, allow Swiss researchers to work alongside their counterparts in partner countries to explore specific research questions. Over the period from 2017 to 2020, more than 100 Joint Research Projects were funded, highlighting the commitment to international research collaboration.[29]

- Thirdly: The international research infrastructures, in the form of laboratories or observatories, provide tools that are fundamental for carrying out scientific activities in numerous fields.

[26] https://www.sbfi.admin.ch/dam/sbfi/de/dokumente/2018/07/bfi-int.pdf.download.pdf/bfi-int_d.pdf
[27] https://www.sbfi.admin.ch/sbfi/en/home/research-and-innovation/international-cooperation-r-and-i/cooperation-programmes.html
[28] https://www.innosuisse.ch/inno/de/home/forderung-fur-internationale-projekte.html
[29] https://www.sbfi.admin.ch/sbfi/en/home/research-and-innovation/international-cooperation-r-and-i/bilateral-programmes.html#1792883803

A notable example is CERN, the world's largest particle physics research laboratory, which is located on the border between Switzerland and France.[30]

- CERN provides state-of-the-art facilities for scientists to conduct fundamental physics research at the frontiers of knowledge to understand matter, the Universe and its evolution. With twenty-three Member States and contributions from other countries, CERN stands as a prime example of international collaboration that pushes the boundaries of science and technology for the benefit of all.
- CERN upholds the principles of open science and also acknowledges that IP allows them to claim credit for novel technologies and be recognized when products or services stemming from their contributions reach society at large.

412. How is the Swiss IP Office fostering research collaboration across borders? - The Swiss IP Office actively supports projects that improve the framework conditions for research and innovation. For instance, it collaborates closely with universities, technology transfer offices, and small and medium enterprises. These partnerships focus on crucial areas such as project management, training, and technical expertise. Through these collaborations, the Swiss IP Office aims to foster an environment that improves the framework conditions for research and innovation.

413. Moreover, the Swiss IP Office occasionally provides support for studies. For instance, as part of the SECO funded Swiss-Ghanaian Intellectual Property Project, the Swiss IP Office carried out a study exploring the economic contributions of the copyright and related rights-based industries in Ghana.

414. Researchers used to be students. Therefore, the Swiss IP Office is involved in IP lectures at various institutions. These lectures are mainly held at institutions with a large number of international students. For example, the Swiss IP Office participates in programmes at the summer school for students at the World Trade Institute and at other Swiss universities.

415. International collaboration in research presents significant benefits for society, researchers, and institutions involved. But to increase the incentive for international collaboration, it is important that the results of the research receive adequate IP protection. This will allow the parties to receive royalties or licence fees for their work or to increase their market share as a result of the research.

416. To conclude, allow me to mention the successful research collaboration between the Swiss Federal Institute of Technology of Zurich (ETH) and the Università degli Studi di Milano resulted in the recyclable anti corrosion coating for metals with self-healing properties. The costs caused by metal corrosion are estimated at up to 4% of global gross domestic product. Unfortunately, the products currently on the market cannot prevent corrosion if the coating is defective, and they are not recyclable. However, the coating developed by ETH and the Italian university can effectively protect the metal surfaces from corrosion, its self-healing and recyclable. This important invention was patented in 2022 and received the ETH Spark Award[31] in 2023.[32]

13.9 Canada

417. Canada would like to thank the United States for drafting the communication for this item, and all Members that have provided insightful views so far today on the topic of research collaboration across borders.

418. As several delegations have already noted today, international collaborative partnerships are an essential catalyst for science and technological innovation. These collaborations can often accelerate the pace of scientific and research discovery, and result in improved commercialization. Leveraging international collaboration in research and development (or R&D) can also be particularly important for the ability of small and medium-sized enterprises (or SMEs) to compete and succeed in the global marketplace. Given the relative resource constraints faced by SMEs, R&D collaboration with businesses or research institutions in other jurisdictions can facilitate the sharing of know-how and expertise, as well as opportunities to license IP and exporting to other markets. This

[30] https://knowledgetransfer.web.cern.ch/activities-services/intellectual-property-management and https://www.wipo.int/wipo_magazine/en/2010/06/article_0003.html

[31] https://ethz.ch/en/industry/researchers/ip/sparkaward/2023.html.

[32] More information can be found on this links: Link 1, Link 2, Link 3.

collaboration often relies on transparent and predictable IP frameworks. Balanced and clear IP frameworks can help ensure that all parties involved in a collaborative partnership understand and can readily navigate the rules around how to use existing IP, as well as how to address the ownership of IP developed in the course of research.

419. In facilitating international research collaboration efforts, the Canadian Intellectual Property Office (or CIPO) provides a range of IP frameworks and innovation programmes that assist researchers, including SMEs, to build and maintain collaborations across borders. These include online guidance for businesses on licensing or assigning IP rights to third party collaborators; business intelligence on how to use IP data to learn about innovation in a particular field; and financing resources for IP. Furthermore, Canada's ongoing work to align with international IP standards and filing systems helps maintain an enabling environment for research collaboration, for instance, by harmonizing IP filing procedures available to businesses collaborating in networks across jurisdictions.

420. More generally, Canada has developed frameworks for international collaboration and partnerships with established and emerging innovation networks around the world. This includes the negotiation of Science and Technology (or S&T) agreements with a number of international partners, including in the Asia-Pacific, Europe, Latin America and the Caribbean. These S&T agreements serve as guidelines for Canadians to effectively partner and work with partner countries to increase international science and technology capacity. A related initiative, the Canadian Technology Accelerator (or CTA) provides high-growth, market-ready Canadian companies support to access global markets and entrepreneurship services within the information and communications technologies, life sciences, and clean technology sectors. Managed by the Canada's Trade Commissioner Service, the CTA provides support for Canadian technology SMEs to access global market opportunities in 12 global technology hubs worldwide, including in North America, Europe, and the Asia-Pacific.

421. Another related programmes available to Canadian innovators is CanExport Innovation. This programmes provides support to Canadian SMEs, academic institutions, and non-governmental research centres who are seeking to commercialize technology by pursuing collaborative international R&D opportunities through partnerships with key players in foreign markets. Delivered by the Trade Commissioner Service in partnership with the National Research Council, CanExport Innovation provides financial support for a wide range of export marketing activities, including in respect of IP protection and certification expenses in foreign markets.

422. Similarly, the Canadian International Innovation Program (or CIIP), managed by the Trade Commissioner Service and Canada's National Research Council, is a bilateral funding programme that fosters collaborative R&D projects for the commercialization of R&D between researchers in Canada and international partners in Brazil, China, India, and Korea, and Israel. CIIP funds a range of projects, such as initiatives to adapt already commercialized products to reach new markets, as well technology co-development projects to create new products, services, or processes with an uncertain path to commercialization.

423. Canada is also an associate country of EUREKA, an international network for market-driven industrial R&D. EUREKA includes over 45 economies from Europe, Israel, and Korea, and serves as an international network to coordinate national funding sources between international project partners, to accelerate innovation in new technologies, products and services for commercialization. Since joining EUREKA in 2012, Canada's associate membership has provided Canadian innovators, most of which are SMEs, with the opportunity to pursue projects with international partners with a combined value of over USD 401 million). As well, as part of this programme, participants retain complete IP ownership and negotiate IP arrangements amongst themselves on a project-by-project basis.

424. Finally, Canada would like to briefly note the recent establishment of a blueprint for the new Canada Innovation Corporation (or CIC). The CIC will help Canadian businesses across all sectors and regions to innovate, commercialize, grow, and create good jobs in a changing global economy. Using best practices established by similar agencies around the world, the CIC will be an outcome-driven organization that will work with the private sector to provide targeted support to new and established Canadian firms by delivering funding and advisory services. This will include support to Canadian businesses in developing and protecting their IP. This will include referring refer clients to a portfolio of recently created programmes, including the Innovation Asset Collective, IP Assist,

Elevate IP, and Explore IP, to ensure that more Canadian businesses have access to resources that will support the development and commercialization of IP.

425. Canada would be pleased to provide updates on any of these initiatives in future discussions under this item, and would also be glad to discuss in more detail with any interested Member. Again, we thank those Members that have shared their experiences on this topic today, and look forward to further discussion on this and related topics.

13.10 European Union

426. The European Union delegation is pleased to co-sponsor this agenda item.

427. The European Union would like first to thank the United States delegation for its lead in the drafting of the document submitted today to the TRIPS Council and we also thank the United States more generally for their involvement in the coordination of the Group.

428. The paper that we present today to the TRIPS Council together with the FOII members shows that international research project teams combine the experience and know-how of the individual national cultures so that the greatest possible benefit can be derived from this cooperation.

429. The cooperation between researchers and scientists beyond the frontiers is of a great importance for the innovation and the scientific progress in the world. According to the research community itself the cross-cultural cooperation in matter of research and development fosters creativity so that unconventional solutions and innovations can arise.

430. Efficient intellectual assets management and protection are key to accelerate the uptake of innovative solutions and to develop new technologies, products, and services to address the most pressing societal challenges such as ensuring fair green and digital transitions.

431. The establishment of an environment where intellectual assets protection and management practices are clearly implemented, defined and communicated is a decisive step to facilitate their valorization in the R&I ecosystem.

432. The European Union fosters close and intense relationship of the research centres, public and private, of the European Union member States with their counterparts all around the world. In this respect, the European Union has developed several initiatives and instruments in favour of the "research collaborations across borders". I am going to evoke briefly 3 of them which illustrate perfectly the importance of the cooperation between researchers and will give a flavour of the variety of actions the EU develops in this area.

433. First and foremost, the European Union has adopted Code of practice on the management of intellectual assets for knowledge valorisation in March 2023. The objective of this Code is to increase the use of research results, accelerate the uptake of innovative technologies and offer practical guidance for all R&I ecosystem actors in the management of their intellectual assets.

434. In line with the Guiding principles for knowledge valorisation adopted just before, in 2022, the Code of practice goes beyond IPRs as such and offers guidance for the management of other types of intellectual assets - including any result or products generated by research and innovation activities such as publications, data and know-how - to maximize value creation opportunities.

435. The Code provides guidance in view to make the management of intellectual assets in joint and international research activities more efficient.

436. Notably, the Code :

i. Clarifies ownership of intellectual assets as early as possible in the context of international collaborative agreements and in predominantly publicly funded projects.

ii. Establishes clear collaboration conditions. The Code offers guidance to establish fruitful research and innovation collaborations, for instance with respect to licensing or

transfer of results, spin off creation, background results and non-disclosure agreements.

437. Specific guidance concerns international collaborations, for instance with respect to foreseeing the role of facilitators (experts in different socio-cultural settings) to assist partners with different backgrounds and raising awareness on different IP regimes in third countries.

438. In support to the Code, the European Commission is currently running an 18-month awareness raising campaign on knowledge valorisation that will last until the end of 2024. Through national and stakeholder events the campaign aims, *inter alia*, to foster the uptake of the Code and foster efficient management of intellectual assets.

439. The objective of the campaign is to make this publication widely spread, notably on the Knowledge Valorisation Platform, to raise awareness on the Code of practice and to foster its uptake by the broadest possible range of R&I actors, in the European Union and beyond.

440. This Knowledge Valorisation Platform is hosted by the European Commission. The Platform is a digital exchange space that aims to foster international collaboration as it connects actors across Europe and beyond, promotes sharing of knowledge, experiences and best practices and boosts cross-border dialogue and cooperation with the aim to improve the broad uptake of research results in society and economy.

441. The European Commission has initiated a Multilateral Dialogue on Values and Principles for Research and Innovation in July 2022. The objective of this dialogue is to have an open discussion between European Union member States and foreign partner countries to develop a common understanding as a reliable basis for international R&I cooperation.

442. In this framework, the European Commission organises a workshop on knowledge valorisation and intellectual assets management in the context of the multilateral dialogue on principles and values in international R&I cooperation (foreseen in Autumn 2023).

443. This fifth workshop of the series focuses on Knowledge Valorisation and Intellectual Assets Management and aims to compare international practices on how to motivate R&I actors to fully utilise intellectual assets and intangible assets for the benefit of the society.

13.11 Indonesia

444. At the outset, Indonesia thanks the proponents for the submission of document IP/C/W/699 and would like to further provide our preliminary view and question on this proposal.

445. While we share the idea that scientific research will benefit from international cooperation and collaboration, not less through intellectual cross-fertilization, but we should still be mindful on the interaction between "intent" and "impact".

446. Our primary concern on this proposal is that it does not really elaborate on how it will address the underlying asymmetry of such international collaboration, particularly in cases where it involves partnership between researchers from developed and developing country Members, in research that mainly funded by those with more resources, financial and otherwise.

447. There is an emerging body of research on "decolonizing research partnership" out there that merit further consideration in shaping an equal collaboration, among others, with regard to: agenda setting; input in designing the project and outcome; transparency; and visibility and dissemination of knowledge.

448. Furthermore, developing countries are the main providers of genetic resources and traditional knowledge. Conversely, most intellectual property rights (IPRs), such as on medicines are concentrated in developed countries. In this regard, how international collaboration could address the issue that those who have provided the most significant input in the form of genetic resources and associated knowledge (i.e., indigenous people and local communities) from being excluded by IPR and/or to be benefited from the research?

449. With all that being said, as a developing country Member, Indonesia is supportive to a sustainable, mutually beneficial working relationship that, aside from advancing science, must address inequity and shine light to the researchers from the developing countries and LDCs, develop capacity with a long-term perspective (such as: through transfer of technology and know-how), and preserve the dignity of the local people by ensuring equal sharing of benefits of research that will truly uplift their status.

13.12 Djibouti, on behalf of the LCD Group

450. The LDC Group would like to thank the co-sponsors of the communication IP/C/W/699 on scientific technological collaboration at the international level. We listened carefully to the statements made and thank them. The various communications do include a number of important factors which merit further consideration, and we would like to better understand the concept of research cooperation and collaboration, taking into account the fact that there are many types of research partnerships with various requirements in terms of interaction, communication and reciprocity. This is true in particular for cooperation between rich and poor countries. The issues raised in the communication are relevant and will be useful in furthering future discussions. We are still working on answers to the various questions, and we hope that the exchanges will continue and will come up with productive results.

13.13 World Intellectual Property Organization

451. Allow me first to congratulate you and to wish you every success.

452. The World Intellectual Property Organization (WIPO) would like to thank the co-sponsors for preparing document IP/C/W/699 and for bringing to the attention of this Council the role of intellectual property in research collaboration across borders.

453. WIPO has identified the increasing importance of collaboration in enabling innovation to flourish. Our 2019 World Intellectual Property Report on "The Geography of Innovation: Local Hotspots, Global Networks" looked at this in detail. Analysis of relevant data including patent information highlights that research collaboration is widespread and these innovation links are increasingly cross-border in nature.

454. Effective management of intellectual property is one element that can ensure cross-border collaborations and deliver concrete results with real-world impact. While success also relies on conditions beyond the IP framework including active intermediaries, sustainable financing and human capital, IP is a crucial component to be considered in cross-border collaboration. A balanced IP system with well-established conditions allows for efficient use of the IP system to promote innovation. WIPO stands ready to provide the technical assistance that can support the identification of IP assets and the appropriate management of the associated IP rights. In particular, WIPO provides relevant support including through:

a. Regional and country projects such as our work with the Baltic States to create a Technology Transfer Office Network and the associated Cooperation Agreement and foster academic collaboration among the three countries and provide an input to their economies. We are also helping to develop a similar network in Africa and to support the adoption of common principles for IP valuation in ASEAN countries.

b. The WIPO Technology and Innovation Support Center (TISC) programme to develop national, regional and virtual networks and the promotion through these networks of an exchange of knowledge and technologies.

c. Public-private partnership programmes to facilitate access to knowledge. The Access to Research for Development and Innovation (ARDI) programme, provides access to scientific and technical journals and the Access to Specialized Patent Information (ASPI) programme, allows access to commercial patent databases comprising more sophisticated search and analysis tools for retrieving and assessing relevant technology.

455. The WIPO Arbitration and Mediation Center also plays an essential role in the collaboration ecosystem by providing dispute resolution advice and case administration services to help parties

resolve disputes arising in the area of research and development (R&D). Around 15% of the WIPO Center's cases relate to R&D and technology transfer with most of these cases being international in scope. The Arbitration and Mediation Center website provides a number of relevant case examples.

456. The WIPO Center collaborates with relevant stakeholders and organizations in the development of Model R&D Agreements including WIPO Mediation and WIPO Expedited Arbitration clauses, and regularly administers cases submitted under such clauses.

457. Also, as part of the WIPO COVID-19 Response Package, the WIPO Center has launched in 2022 new ADR options to facilitate contract negotiation and dispute management in long-term life sciences licensing agreements and R&D collaborations.

458. Further information on these initiatives can be found on the WIPO website. We remain available to support Members in the management of IP in cross-border research.

14 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

14.1 WTO Secretariat

459. 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.

460. Since our last report during the TRIPS Council Meeting in March, the Trade Policy Reviews of El Salvador, the Organization of East Caribbean States, Liberia and the European Union. During these reviews, delegations engaged in the discussions and sought further details on:

- The domestic implementation of the TRIPS Agreement;
- Institutional arrangements for the administration and enforcement of intellectual property;
- Copyright and related rights regimes;
- Trademark regime;
- Protection of geographical indications;
- Patent regime;
- Enforcement, online and at the border; and
- Measures taken in response to the COVID-19 pandemic.

461. The Secretariat has prepared the IP chapters for the Director-General's Trade Monitoring Reports covering the G20 and the WTO membership. The period covered by these reports is from mid-October 2022 to mid-May 2023. The reports will be circulated in July and discussed at a special meeting of the Trade Policy Review Body.

462. We would like to thank delegations that submitted information for the trade monitoring exercise. The WTO Secretariat works closely with all delegations to collect complete, up-to-date and accurate information on their trade and trade-related measures. An important step is the Secretariat's verification exercise, which provides Members with the opportunity to confirm relevant information collected from non-official sources.

15 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

15.1 Indonesia

463. Indonesia would like to reiterate our support to the request made by the South Centre and the Secretariat of the Convention on Biological Diversity to be accorded observer status at the TRIPS Council. The granting of observer status could also in the form of *ad hoc* participation for selected meetings in the TRIPS Council.

464. We believe that a closer cooperation and liaison between the WTO and both organizations will enrich and mutually support each other's work accordingly. And as stated during the previous day by the delegation of South Africa, it will support the idea of inclusiveness suggested by some Members in the last General Council meeting.

15.2 Colombia

465. In Colombia's opinion, the participation of external actors is valuable as one of the pillars of the Organization's reform. The participation of such observers in the Council for TRIPS should be revitalized. From our perspective, the presence of external actors achieves two objectives simultaneously - it encourages further exchange on ideas and data, and it helps enhance the Organization's legitimacy.

466. For these reasons, we should unblock this agenda item and admit observers who have been on the waiting list for a long time, as well as opening it to new interested parties.

15.3 United States of America

467. The United States cannot join the Members seeking to include the South Centre or the Convention on Biological Diversity (the CBD) as observers either on a permanent or *ad hoc* basis. The United States values the contributions by Members, and we are satisfied with the current set of *ad hoc* and permanent observers. We do not see a gap that needs filling by adding new observers at this time.

15.4 China

468. China would like to reiterate our position on this issue. TRIPS CBD is an important issue in the TRIPS Council. Inviting the Convention on Biological Diversity Secretariat (CBD) as an observer to the TRIPS Council will update the CBD Secretariat on the discussion and development in the Council, and correspondingly have the WTO Members better understanding the principles, requirements and the work of the CBD. We believe the mutual support and the deep communication to the CBD Secretariat and the WTO will contribute to our discussion at our Council. Again, with regard to the South Centre, its role in serving the progress and the development of developing Members have been widely recognized and it has carried out extensive research in the fields of intellectual property technology transfer and knowledge accessibility which has enhanced the developing Members' understanding and application of the TRIPS Agreement. Therefore, we would like to reiterate our support for granting the CBD Secretariat and the South Centre observer status at least on an *ad hoc* basis.

16 OTHER BUSINESS

469. No statements were made under this agenda item.