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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 6 JULY 2022

Chair: H.E Ambassador Lansana Gberie (Sierra Leone)

Addendum

The present document contains the statements made during the Council for TRIPS meeting held on 6 July 2022.

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AT THE MEETING OF COUNCIL FOR TRIPS 6 JULY 2022*

* 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 2022:

Under Article 63.2

2. Brazil has notified two amendments to its Copyright Act that relate to the collective management of copyright, and to the mentioning of voice actors in the credits of audio-visual works.

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

4. Montenegro has notified amendments to its Law on copyright and related rights, to its Patents Law, and to its Law on the protection of Trade Secrets.

5. Croatia has notified a consolidated version of its Copyright and Related Rights Act.

6. Ukraine has notified amendments to its law on collective management of copyright and related rights to ensure collection of rights revenues by collective management organizations.

7. Guatemala has notified amendments to its Regulations under the Law on Copyright and Related Rights to include the definitions derived from the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled.

8. Bahrain has notified a law concerning the protection of New Plant Varieties.

9. The Republic of Moldova has notified a law on the protection of geographical indications, appellations of origin and traditional specialities, a government decision amending Regulations on the filing and examination of patent applications and the issuance of patents, further laws amending and supplementing certain legislative acts.

10. Trinidad and Tobago has notified the Trade Mark Regulations, and Regulations relating to the Border Enforcement Measures on Trade Marks from 2020.

Under Article 69

11. Cote d'Ivoire has notified a contact point for IP enforcement under Article 69.

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

1.2 Brazil

13. Thank you, Chair, for giving me the opportunity to introduce Brazil's notifications IP/N/1/BRA/8 and IP/N/1/BRA/9. Both notifications refer to amendments to Brazil's main copyright law (Law N°9,610 of 19 February 1998).

14. The notification IP/N/1/BRA/8 refers to the Law 12,091 of 11 November 2009. The legal text amends Article 81 of Brazil's main copyright law to include the name of voice actors in the credits of audiovisual works, so that the producer must mention their names in every copy of such works.

15. The notification IP/N/1/BRA/9 refers to the Law 12,853 of 14 August 2013. The legal text amends several articles of Brazil's main copyright law in aspects related to the collective management of copyright and other measures.

1.3 European Union

16. I would like to say a few words about the Croatian notification in document IP/N/1/HRV/47. The new Croatian Copyright Law has been revised and adjusted to the technological development and digital environment. The Act sets down rules for digital and cross border uses of copyright protected

works and subject matter, adapts exceptions and limitations to copyright and related rights and provides for measures to facilitate certain licensing practices and wider access to content. Thus, the Act transposes provisions from EU Directives 790/2019 and 789/2019.

17. Apart from the compliance with this EU-level reform, further additions and improvements are made in the following areas: copyright protected work created in the course of employment, creation of copyright protected work on commission, creation and use of copyright protected work in specific areas, wider regulation of press publishers' right, more specific rules for rights that are managed in a collective manner and clarification of rules applicable to adapted works.

1.4 Bahrain, Kingdom of

18. The Kingdom of Bahrain would like to introduce its notification contained in document IP/N/1/BHR/5. The Kingdom of Bahrain, in its efforts to establish the legal ground to join the International Union for the Protection of New Varieties of Plants, issued Law N°31/2021 for the protection of new variety of plants. This law comes in line with most of the treaty articles and guidelines. The legal text provides the general framework, leaving other specific practices and applications to the technical regulations at ministerial orders that are in the process of being issued to implement Law 31 of the year 2021. Once the legal framework is entirely completed, the Government of the Kingdom of Bahrain will take necessary actions to join the Union. In general, the Law provides four elements related to national treatment, conditions of protection duration, exceptions in mandatory licensing, plant growing rights, species names or verification of rights and precautionary measures and penalties.

1.5 Republic of Moldova

19. I would like to thank the WTO Secretariat for circulating the recently updated notifications as well as for assisting us in drafting these notifications under Article 63.2 of the TRIPS Agreement. This update contains all IP and TRIPS relevant changes in the Moldovan legislation between 2018 and 2022. For the sake of brevity, I will not present the notified modifications in a comprehensive manner. However, short descriptions are available on the notified document, however, we would like to point out two notifications which deserve attention.

20. The first one is related to document IP/N/1/MDA/12. This relates to the Government decision 406 from 2017 which operates modifications to the Regulations on the procedure of filing and examination of patent applications and grants of the patents approved by the Government Decision N° 528 and this brings the regulations in line with the latest amendments to Law N°.50 from 2008. The amendments refer mainly to the rules applied within the procedure of examination and validation of European patent applications. There are also improvements to the general rules of filing and examination of patent applications, including the opposition and appeal procedures.

21. Another notification which deserves our attention is document IP/N/1/MDA/13. These amendments are mainly related to the modifications of the courts' competencies. Previously the litigations had to be challenged within the court from the capitol of Moldova in Chisinau. However due to the recent modifications these litigations can be challenged in any court from Moldova's districts. The rest of the notifications represent the consolidated laws on GIs and patents.

22. In conclusion, 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 Fernandez for their much-appreciated assistance in the process of up-dating our notification through the e- TRIPS Submission System. While this required some adjustments from our delegation in the approach of submitting a TRIPS notification, we find it very valuable. Indeed, it is very efficient and easy to use, and we would like to thank once again the Secretariat for their assistance provided.

1.6 Trinidad and Tobago

23. The delegation of Trinidad and Tobago would like to introduce these two notifications which represent some of the enabling regulations of the new trademark legislation in effect in Trinidad and Tobago.

24. The Trademarks Act N° 8 of 2015 and concomitant Regulations were proclaimed by Her Excellency, the President of the Republic of Trinidad and Tobago on 25 June 2020. This proclamation comes after Trinidad and Tobago's accession to the Singapore Treaty on the Law of Trademarks which brings harmonization of administrative trademark registration procedures, especially in the field of communication technologies. The Act and its Regulations, which are wholly in line with the Singapore Treaty, establish the Electronic Online System (EOS) for the Trinidad and Tobago Intellectual Property Office in the Office of the Attorney General and Ministry of Legal Affairs (TTIPO).

25. Prior to this, Trinidad and Tobago operated its TRIPS-compliant trademark system under the Trademark Act, Chap. 82:81, which itself was based on 1955 legislation that was progressively amended to comply with the TRIPS Agreement, to incorporate subsequent amendments and to give effect to various trademark treaties and conventions.

26. A decision was made to start with a clean slate and repeal and replace the Trademark Act, Chap. 82:81 with newer legislation that would incorporate the Singapore Treaty on the Law of Trademarks. This would usher in electronic filing and also allow non-traditional marks for sounds, scents, texture and taste. It would also allow accession to the Madrid Agreement Concerning the International Registration of Marks. This was a more effective approach than trying to amend older legislation in this instance.

27. The Trademarks Regulations, 2020, enable the provisions of the Act. The Trademarks (Border Enforcement Measures) Regulations, 2020, specifically provide guidance to enhance the trademark enforcement initiatives of the Customs and Excise Division in keeping with the new types of marks that can now be registered.

28. Subsequent regulations regarding international trademarks arising under the Madrid Protocol will be introduced at a later session.

29. These form part of a number of amendments being considered to other pieces of IP legislation to support the burgeoning IP ecosystem in Trinidad and Tobago.

1.7 Japan

30. This delegation is pleased to inform the Council that Japan recently amended its Patent Act, Design Act, and Trademark Act. The amendments have been notified to this Council in accordance with Article 63.2. The reference numbers are documents IP/N/1/JPN/62, IP/N/1/JPN/63 and IP/N/1/JPN/64. Taking this opportunity, we would like to briefly explain some major points about the amendments.

31. The revised Patent Act introduced a new system which allows courts to broadly call for opinions from third parties in litigation involving patent right infringement. The revised Design Act and the revised Trademark Act, as part of the efforts for addressing an increasing number of imported counterfeit products for private use, recognize the sending of counterfeit products to Japan via postal mail and other means by overseas businesses as infringement of trademark or design rights, at the time when those products enter the territory of Japan.

32. The revision also includes other amendments, such as review of the structures of patent and other fees, and relaxation of the conditions on which right holders are allowed to restore their patent and other rights which have been forfeited due to the expiration of the time frame for required procedures.

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

1.8 Montenegro

34. Montenegro welcomes the opportunity to briefly present the key points of the legislation that entered into force on 8 January 2022, which is the subject of notifications under Article 63.2 of the TRIPS Agreement. As already indicated by the Secretariat, these are the Law on Amendments to the Law on Copyright and Related Rights, the Law on Amendments to the Law on Patents and the Law on the Protection of Trade Secret.

35. The first notification under document IP/N/1/MNE/8 relates to the Law on Amendments to the Law on Copyright and Related Rights, which regulates in detail the issue of collective management of copyright and related rights as to the authors and other holders of related rights, as well as obligations and powers of organizations for collective management of copyrights and users of those rights. The Law further prescribes the obligations of the collective management organizations in relation to the distribution of amounts due to rightsholders and management fees and other deductions from the rights revenue, as well as in the procedure for issuing authorization for the use of the copyrighted works.

36. The most important novelties introduced by the Law relate to the significantly increased transparency of the work of collective management organizations, a more detailed procedure for supervising the work of collective management organizations by the competent authority, increased inspection supervision over unauthorized use of copyrighted works and protection matter, as well as stricter misdemeanour policy. In addition, the tariff determination procedure is improved.

37. As for the notification under document IP/N/1/MNE/9, it refers to the Law on Amendments to the Law on Patents, which has followed Montenegro's recent ratification of European Patent Convention. The amendments to the Law prescribe provisions for the effective implementation of the European Patent Convention in the national legislative framework. Specifically, these are provisions related to the impact of European patent applications and European patents in Montenegro, filing of a European patent application, conversion of a European patent application into a national patent application, revocation of the European patent and protection against infringement.

38. It is also prescribed that, as of the entry into force of the European Patent Convention in Montenegro, the European Patent Office will be the Receiving Office for the International Applications filed in accordance with the Patent Cooperation Treaty, instead of the Montenegrin National Office or the International Bureau of the WIPO. And the third notification under document IP/N/1/MNE/10 refers to the Law on Protection of Trade Secret.

39. This Law regulates the civil protection of trade secrets against their unlawful acquisition, use and disclosure. It also prescribes a definition of trade secret, as well as when the acquisition, use or disclosure of a trade secret shall be considered lawful or unlawful. It further prescribes provisional measures that the competent court may order against the alleged infringer, as well as measures resulting from a decision on the merits of the case.

1.9 Ukraine

40. Ukraine would like to present its notification and to inform the WTO Members about the adoption of the law amending national legislation governing collective management system.

41. The Law aims at ensuring the collection of royalty by collective management organizations (hereinafter – CMOs) with respect to public performance and broadcasting of musical non-dramatic works under extended collective management. The law entered into force on the 13 of February 2022.

42. It provides for the possibility of voluntary collective management in these areas by registered CMOs within their catalogue until the tariffs are agreed upon by new accredited organizations according to the procedure of negotiations with the relevant users' associations. The law provides for the formation of a new personal composition of accreditation committee, sets timelines for it and for a selection process of new accredited CMOs in the mentioned areas.

43. Given this opportunity, we would also like to inform you that on the 1 of April 2022 Ukraine adopted the Law n° 2174-IX with the purpose of protecting intellectual property interests of stakeholders during the martial law regime, imposed due to the military aggression of the Russian Federation against Ukraine.

44. This law entered into force on the 13 of April 2022 and its provisions are aimed at maintaining the validity, use period and enforcement of intellectual property rights during and after the state of war. To fulfil our transparency obligation, we submitted appropriate notification to the e-TRIPS

Submission System yesterday so that you will have an opportunity to familiarize yourself with the text of the Law.

45. To conclude, we would like to reassure the WTO Members that Ukraine is doing its best to ensure efficient protection and enforcement of intellectual property rights, despite the brutal war launched by the Russian Federation.

1.10 Guatemala

46. Pursuant to the provisions of the TRIPS Agreement, we would like to inform you that, in April, we notified Government Decision No. 52-2022 through the e-TRIPS system. This Decision contains the amendments to the Regulations implementing the Law on Copyright and Related Rights (Government Decision No. 233-2003). This notification can be found in document IP/N/1/GTM/2.

47. The amendments to the Regulations implementing the Law on Copyright and Related Rights are the product of the ratification of the Marrakesh Treaty to facilitate access to publish works for persons who are blind, visually impaired or otherwise print-disabled. Government Decision No. 52-2022 incorporates, for supplementary purposes, the definitions established in the Marrakesh Treaty into the Regulations implementing the Law on Copyright and Related Rights, in addition to all the provisions on the duties and powers of entities authorized under the Treaty to manage and use works and to ensure the enforcement of the rights attached to them.

48. We wish to conclude by thanking the Secretariat for the support provided on the use of the e- TRIPS system and appreciate its ease and efficiency.

2 REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

49. No statements were made under this agenda item.

3 IP MEASURES IN THE CONTEXT OF COVID-19

3.1 South Africa

50. South Africa would like to reiterate its support for this item to remain on the agenda of the TRIPS Council and thanks the Secretariat for its ongoing work to update the membership of relevant measures. The overall theme that emerged from the experiences shared has been the inadequacy of existing flexibilities to deal with the pandemic.

51. The WTO Ministerial Decision on the TRIPS Agreement offers a supplementary policy option that Members can use to facilitate access to COVID-19 vaccines. Going forward, it will be important to add the experiences of Members in implementing the Ministerial Decision. This will enable the accumulation of best practice that Members can draw from.

52. We would once again like to appreciate the Secretariat working paper entitled "*Innovation and the Patenting Activities of COVID-19 Vaccines in WTO Members – Analytical Review of Medicines Patent Pool COVID-19 Vaccines Landscape (VAXPAL)*". We look forward to the presentation that will take place on Friday, 8 July 2022. Officials from our national IP office, the Companies and Intellectual Property Commission (CIPC) will participate. We believe that presentations of this sort as well as the World Intellectual Property Organization's (WIPO) presentation on the Patent Landscape Report which took place earlier this year, can assist Members to better understand the patent landscape related to COVID-19 health products and take appropriate, evidence-based measures.

3.2 China

53. China would like to thank Members for sharing their measures responding to the pandemic. The open and transparent sharing of such measures would help Members learn from each other and better respond to the pandemic. In previous meetings, China has notified relevant measures, among which is the green channel for patent applications related to prevention and treatment of COVID- 19. We would like to share some updated information on this measure. As of June 2022, there have been 2600 patent applications granted priority review through the green channel, which have

successfully facilitated the industrialization of relevant patents related to the prevention, diagnostics and therapeutics of COVID-19.

3.3 Sri Lanka

54. Sri Lanka welcomes the Ministerial Declaration on the WTO response to the COVID-19 pandemic and preparedness for future pandemics contained in document WT/MIN(22)/31, adopted on 17 June 2022, which provides a mandate for WTO Members to frame effective solutions in case of future pandemics to address an array of challenges, including intellectual property measures in the context of COVID-19 pandemic, in an expeditious manner, as such new solutions may go beyond the existing flexibilities provided for in the present Agreement.

55. Sri Lanka believes that this Ministerial Declaration re-affirms the need for a solution on IP that would address the difficulties faced by developing countries in accessing TRIPS flexibilities and relevant provisions contained therein, so that they could be applied automatically during future pandemics, health emergencies and other crises.

3.4 Pakistan

56. Pakistan would like to thank the Secretariat for the compilation of the IP measures in the context of COVID-19. The fact that many Members have resorted to various measures highlights the need for effective solutions to IP-related challenges in the context of COVID-19, but also in the context of our preparedness for future pandemics. What is also noteworthy from such compilations is the obvious inadequacy of the existing flexibilities within the TRIPS Agreement to cater for health emergencies of the type we have witnessed during the ongoing pandemic, and that lasting solutions need to be found.

57. In this regard, we also take this opportunity to welcome both outcomes from MC12 in the TRIPS Decision and the Pandemic response document. In both these documents, Ministers have clearly highlighted the need for addressing IP related challenges for ramping up production and providing equitable access to all COVID-19 products including therapeutics and diagnostics, for the current and future pandemics.

58. We aim to and look forward to continue our constructive work to fulfil the ministerial mandates in this regard, and also support this item to remain on the agenda to allow us to be guided by the measures taken by Members.

3.5 United States of America

59. The previous interventions of the United States of America on the item concerning IP measures in the Context of 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.

60. In past meetings, the United States highlighted the US Patent and Trademark Office COVID-19 pilot program which prioritizes 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.

61. As of 21 June 2022, 961 applications have requested prioritized examination status in the USPTO's COVID-19 Prioritized Examination Pilot Program, 623 of which have thus far been granted. The pilot program was originally set to expire after the USPTO accepted 500 applications into the program, but this application limit has been removed. The pilot will include all qualifying patent applications received by midnight eastern time on 30 June 2022.

62. 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. The winners will be announced for this program by fall 2022. The United States Copyright Office also made adjustments in response to the pandemic. To assist creators affected by the pandemic, the Copyright Office temporarily adjusted statutory deadlines for copyright owners under the 2020 Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). The CARES Act authorized the Register of

Copyrights to temporarily adjust statutory deadlines for copyright owners and other affected parties if she determined that a national emergency declared by the president was generally disrupting the normal operation of the copyright system.

63. Several adjustments were made. For example, adjustments allowed affected copyright owners to receive additional time to register a work in order to be eligible for certain remedies in infringement actions, provided additional time for submitting documentation for certain statutory licenses and termination notices, and authorized 'secure tests', which are handled under special registration rules, to include tests normally administered at specified centres but temporarily administered remotely.

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

64. Around 80% of the world's population uses traditional medicines such as herbal medicines, yoga, acupuncture etc. Traditional medicine has been an integral resource for health for centuries in communities around the world and it is still a mainstay for some with inequities in access to conventional medicine. The sociocultural practice and biodiversity heritages of traditional medicine are invaluable resources to evolve inclusive, diverse sustainable development. Studies estimate the world herbal trade to stand around USD 120 billion and is expected to reach USD seven trillion by 2050. Over 40% of pharmaceutical formulations are based on natural products and originating from traditional medicine. The contribution of traditional medicine to health systems is yet to be completely realised. 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. These facts and developments attest to the importance of the linkage between TRIPS Agreement and Convention on Biodiversity (CBD).

65. As an ancient civilisation India has preserved a rich body of traditional knowledge associated with biological resources. This traditional knowledge is both coded, as in the texts of Indian systems of medicine such as Ayurveda, Unani and Siddha; and non-coded, which exists in the oral undocumented traditions. The difficulties faced by countries like India, therefore, lies in the misappropriation of this knowledge. Thus, India reiterates the long-standing demand of an international enforceable regime to contain misappropriation. Patents should not be granted for existing traditional knowledge and associated genetic resources. Further where traditional knowledge and associated genetic resources form the basis of scientific development, it is important to have disclosure of source or origin of the resource/knowledge along with disclosure that the access was on mutually agreed terms. This will also strengthen and add to the Members' commitment to transparency, since transparency obligations cannot merely be limited to notification obligations.

66. Article 16.5 of the Convention on Biological Diversity clearly recognizes "that patents and other intellectual property rights may have an influence on the implementation of this Convention". It mandates that the parties "shall cooperate in this regard, subject to national legislation and international law, in order to ensure that such rights are supportive of and do not run counter to its objectives". 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. However, the TRIPS Agreement continues to ignore numerous IPR-related obligations in the CBD which are of interest to the developing countries.

67. Despite several submissions like the disclosure proposal (document IP/C/W/474) submitted in 2006, document TN/C/W/52 submitted in June 2008 with the support of 109 Members followed by the last submission on this issue document TN/C/W/59 in April 2011, which is a draft decision to enhance mutual supportiveness between the TRIPS Agreement and the CBD proposed by a vast majority of WTO membership, it is regrettable that for the past many years we have not made any

progress. Some Members have argued that TRIPS Council is not an appropriate forum for these discussions. Developing countries argued in the late eighties that TRIPS did not belong to GATT as WIPO existed as a functional organization to deal with IP issues, the developed countries refused to accept that argument at that time. Now, when we seek that the TRIPS Agreement be amended to address the concerns of biopiracy, we are being shown the door to WIPO, where the IGC process has not been able to make much headway since years. Given the enforceability of the TRIPS Agreement and the fact that much of the misappropriation is a consequence of trade, there is a need and mandate to build the linkage between the TRIPS Agreement and the CBD under the aegis of this Council.

68. Therefore, considering the mandate from the Doha Ministerial Declaration and the 2030 Sustainable Development Goals, 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 our responsibility to take these discussions forward towards an outcome. India is of the view that a formal briefing by the CBD Secretariat on the latest developments of the Nagoya Protocol will be useful for Members. We also support updating the three factual briefs by the Secretariat on these issues. India remains committed to continue our efforts in building momentum on these important issues.

6.2 Tanzania on behalf of the African Group

69. I would like to start by congratulating you Chair for your leadership, Dr Ngozi Okonjo-Iweala, Director-General of the WTO and the entire membership for the adoption of a Ministerial Decision on TRIPS during the MC12.

70. Reverting to agenda items 4, 5, and 6, the African Group has a long-standing position which is well known to the Council of which I will not go through. I will direct myself only issue of the CBD Secretariat.

71. The African Group has been urging Members to allow the CBD Secretariat to be invited to share their experience in the TRIPS Council. Our call is in line with Article V of the Marrakesh Agreement which directs WTO Members to effectively cooperate with other international organizations on matters related to the WTO. The African Group has been mindful of the critical importance for WTO bodies to cooperate with other relevant international organizations and we have exercised due restraint from objecting such arrangements in the past in other bodies. Therefore, we would like to once again urge other Members to exercise a similar approach on the CBD Secretariat to be invited and share their experience in this body.

6.3 Bangladesh

72. On agenda items 4, 5 and 6, 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.

6.4 Brazil

73. Brazil's positions regarding the three agenda items under consideration are well documented and remain unchanged to date. We remain convinced of the need to amend the TRIPS Agreement so to provide for a mandatory disclosure requirement of the origin of genetic resources and associated traditional knowledge in patent applications.

74. Brazil's position on this issue is without prejudice to any outcome on negotiations that are underway at WIPO's Intergovernmental Committee on IP, Genetic Resources, Traditional Knowledge and Folklore (IGC).

6.5 South Africa

75. We will also be brief. We align ourselves with the intervention made by Tanzania on behalf of the African Group and fully support those made by the other distinguish delegations that have just been made. We would like to recall our previous statements on these items. As indicated previously,

in this discussion we often lose the relative importance of the individual components making up the 'Triplets'. The Doha Ministerial Declaration made a clear instruction, and we remain fully convinced that biopiracy remains a pervasive problem and the absence of a multilateral solution, as applicable under the TRIPS Agreement, national disclosure requirements will remain inadequate. Discussions in this forum and those under the auspices of the WIPO IGC are complimentary and not mutually exclusive. In line with our previous statements, we reiterate the call for the CBD Secretariat to brief the TRIPS Council. Finally, we wish to raise once more the issue of the update of the three technical notes.

6.6 Indonesia

76. We would like to recall previous information provided on agenda items 4, 5, and 6 of which our position remains unchanged. In this regard, our delegation stresses the importance of the negotiation on the relationship between the TRIPS Agreement and the CBD as well as the need to protect traditional knowledge and folklore.

77. Indonesia also believes that it is paramount for the Council to give adequate attention to address this issue, including through the update of the long overdue Secretariat summary note and inviting the CBD Secretariat to brief the Council on the Nagoya Protocol and its update. Indonesia stands ready to engage constructively with Members on these matters.

6.7 Sri Lanka

78. These three issues are currently being discussed in detail at WIPO Intergovernmental Committee (IGC) meetings as well. The Sri Lanka delegation would like support to keep these issues on the agenda considering the substantial importance of these three issues for developing countries, and we support the continuation of discussion of these important issues.

79. Furthermore, a disclosure requirement proposal contains in document TN/C/W/59, which has been submitted by number of developing countries in 2011 is the latest standing proposal and therefore it should be reflected in the state of play on the annotated agenda as this proposal incorporates elements from the Convention on Biological Diversity and the Nagoya Protocol.

6.8 Egypt

80. I would like to associate my delegation with the statements made by previous speakers especially the statement made by Tanzania on behalf of the African Group. Our position on the issue under consideration is well-known, and it does not need to be re-stated. However, we wish on this occasion to express our concern over the impasse that characterizes the triplets. The review of the provisions of Article 27.3(b) has been a long-standing item on the agenda of this Council, however, still without any substantial progress. Based on the standards of morality and ethics we cannot support patentability of life forms for trade and trade-related gain, and these should not be subject to patent protection. The same thing it is important to maintain the flexibility on the forms of a *sui generis* regime developed for the protection of plant varieties based on individual country systems and requirements. This will contribute towards improving food security situations of indigenous people by ensuring that their inventions are protected and access to seeds is guaranteed.

81. The protection of biological resources, traditional knowledge and folklore is an important development issue for Egypt. We consider that protection of biological resources, traditional knowledge and folklore is critical for the implementation of the TRIPS Agreement. Biodiversity is a core issue and an important source of livelihood for the majority of populations living in most of our countries. We still maintain our position that disclosure in the patent application of country of origin of the genetic resource and the associated traditional knowledge used in the invention is the only effective way to move forward to ensure proper sharing of benefits arriving from their utilisation.

82. We support the call for inserting a mandatory requirement in the TRIPS Agreement for a patent applicant to provide information concerning prior informed consent and fair and equitable access and benefit-sharing. The TRIPS Agreement should not overlook the sovereign rights of nations over their biological resources, nor should it deprive those nations of enjoying their economic advantages.

6.9 Peru

83. Peru wishes to reiterate its support for the idea that TRIPS should work in concert with the CBD to share advances made with the Nagoya Protocol and to inform the Members with the view *inter alia* to being able to apply these instruments in such a way that they are mutually supportive of each other. Also, Peru appreciates the updates by the Secretariat and being able to count on information made available by Members in these discussions. Lastly, we agree that the work being done in WIPO IGC should help facilitate discussion in this forum.

6.10 United States of America

84. I will be brief as our positions are well known and recall our previous statements. Regarding genetic resources, traditional knowledge and folklore we continue to believe that WIPO serves as the best forum to address these issues. With respect to the various requests made today, the United States is not in a position to support these requests but remains open to discussions including bilaterally with delegations in between and at the margins of TRIPS Council meetings.

6.11 Canada

85. 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.

6.12 China

86. We align ourselves with other developing Members that made statements before. Our position remains the same. Briefly, we supported to invite the CBD Secretariat to brief on the Nagoya Protocol and its progress. We hope the Secretariat could renew the three factual notes.

6.13 Japan

87. Japan's position remains unchanged. Regarding the proposal to introduce the disclosure requirement in the IP system, there is concern that the introduction of such a requirement would discourage industries from conducting research and development activities on biological materials.

88. The delegation of Japan believes the WIPO IGC is the most appropriate forum for holding technical discussions on genetic resources, traditional knowledge and folklore from IP aspects. We remain willing to contribute to evidence-based discussions on these issues in a constructive and effective manner.

6.14 Chile

89. Our country's position is well known by the Membership. However, we nevertheless wish to reiterate the importance of the flexibilities contained in the TRIPS Agreement as elements of further development. In this context we think that the flexibilities contemplated in the Agreement enable each Member with its intellectual property system and in the light of its ethical criteria and public health notions should be taken on board. Consequently, for Chile it is important that these flexibilities be preserved, and that each Member should be able to reconsider its intellectual property model in the light of social, cultural and economic changes particular to it. In connection to the relation between the CBD and the TRIPS Agreement, our delegation, like others, considers that the TRIPS Agreement and the CBD are complementary instruments. Consequently, we believe that there is no need to create amendments to the Agreement to establish consistency between the two agreements. Finally, we should like to support the proposal that the CBD Secretariat make informal presentation in this Council. We believe that a factual presentation can enlighten Members on the subject and feed into a dialogue.

7 NON-VIOLATION AND SITUATION COMPLAINTS

7.1 Tanzania, on behalf of the African Group

90. The African Group does not have new ideas on this, but I would like also to make known the long-standing position of the Group. First let me begin by welcoming Ministers' adoption of the Decision on Non-Violation and Situation complaints as agreed by the General Council on 10 December 2021. The African Group has seen that due to the nature of the TRIPS Agreement it will be difficult to recommend to Ministers the scope and modalities of application of subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 in WTO Dispute Settlement Mechanism. It is also in our understanding that the expiry of moratorium will not trigger an automatic application. Nevertheless, the African Group remains committed to work with other Members in the direction of continuing with the examination of 'scope and modalities' should they envisage the feasibility to do so.

7.2 India

91. We welcome the Decision arrived at MC12 contained in document WT/MIN(22)/26 to extend the moratorium on NVSCs until MC13. India's position on the issue of non-violation complaints under the TRIPS Agreement remains unchanged. India looks forward to working with like-minded Members in making non-violation complaints inapplicable to TRIPS.

7.3 Bangladesh

92. Bangladesh is in favour of establishing a permanent moratorium on this issue. As an interim arrangement, Bangladesh welcomes the MC12 endorsement of the General Council decision for an extension of the NVSC moratorium until the 13th Ministerial Conference. Bangladesh is also ready to constructively engage on this issue further.

7.4 Brazil

93. As we initiate a new cycle of consultations on the issue of non-violation and situation complaints applied to the TRIPS Agreement, my delegation would like to reiterate its openness to assessing proposals on the scope and modalities of NVSCs, as mandated by Article 64 of the TRIPS Agreement. We are ready to assess any contributions Members might have that could lead to an agreed and permanent solution on this file.

7.5 Indonesia

94. Indonesia welcomes the adoption of the Ministerial Decision in June 2022 to extend the moratorium until the upcoming MC13 in December 2023. While Indonesia's position remains unchanged, we would like to reiterate our concerns on the negative impacts that non-violation complaints in TRIPS can have on the regulatory policy space of Members and on TRIPS flexibilities. With that being said, we should intensify discussions on this issue and come up with a way forward and a solution for this long-delayed issue. Rest assured, Indonesia is committed to engage constructively in the discussion of this matter.

7.6 Sri Lanka

95. Sri Lanka welcomes the Ministerial Decision adopted on 17 June 2022 contained in document WT/MIN(22)/26, in which Members agreed to extend the moratorium stipulated under Article 64.2 of the TRIPS Agreement, and that Members would refrain from bringing any unintended violations of provisions, including in using compulsory licenses of the TRIPS agreement, by a Member, to the WTO dispute settlement system. Accordingly, Sri Lanka welcomes the extension of the moratorium and the decision to instruct the Council to continue its examination of scope and modalities, and to make appropriate recommendations to the 13th Ministerial Conference.

7.7 Argentina

96. We welcome the Ministerial Decision adopted last June as part of the Ministerial Conference which allows the TRIPS Council to continue reviewing this issue. Nevertheless, Argentina's position

has not changed. We are co-sponsor of document IP/C/W/385 and we therefore request that our prior statements also be reflected in the minutes.[1]

7.8 Chile

97. Chile again welcomes the Ministerial Decision to extend the existing moratorium for this type of matters. Indeed, this extension reflects the fact that this topic has not generated consensus in the past revealing the need to continue dialogue and seek consensus-based responses on this matter bearing in mind all potential repercussions, including the link between the moratorium and other issues in this house. Chile, like other delegations, believes that this type of complaint should not apply at multilateral level within the TRIPS Agreement bearing in mind the lack of legal certainty that it generates for users and creators of an innovation ecosystem.

7.9 China

98. China welcomes the Ministerial Decision on the extension of the NVSCs moratorium to the 13th Ministerial Conference. Our position on this issue remains the same. We would like to see Members come to agree that NVSCs are not applicable under the TRIPS Agreement. There have been insufficient cases of non- violation and situation complaints under GATT and the WTO to 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 this discussion.

7.10 South Africa

99. We align with the statement made by Tanzania on behalf of the African Group. South Africa takes the floor only to indicate that our position on this matter remains unchanged. We will submit our full statement for the minutes.

100. South Africa subsequently submitted the following statement: It is a matter of course that proponents of the application of NVCs under the TRIPS Agreement have not provided concrete examples of the kind of scenarios under which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations set out in the Agreement. As suggested previously, in order to advance discussions on this matter, delegations could be invited to identify areas or elements of agreement which could be collated by the Secretariat. This can build on previous discussions on what NVCs should not be applicable to. This would narrow the issues to those areas in which we still need to engage to ensure focussed discussions going forward.

101. Finally Chair, South Africa would like to reiterate its view that the traditional linkage between the moratorium on NVCs and the e-commerce moratorium cannot hold. The linkage is artificial and no longer sustainable.

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

102. No statements were made under this agenda item.

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

103. No statements were made under this agenda item.

[1] Argentina's previous statements under this agenda item are contained in the minutes of the TRIPS Council meetings. Its statements since 2019 are contained in documents IP/C/M/103/Add.1; IP/C/M/100/Add.1; IP/C/M/96/Add.1; IP/C/M/95/Add.1; IP/C/M/93/Add.1 and IP/C/M/91/Add.1.

10 TECHNICAL COOPERATION AND CAPACITY-BUILDING

10.1 Bangladesh

104. The delegation of Bangladesh thanks the Secretariat for the updates and welcomes the reports under TRIPS Article 67 from the Developed Country Members on capacity building support to the developing countries and particularly the LDCs. These reports provide information on a wide range of programs and activities customized for the beneficiary Members. My delegation also thanks the Secretariat for managing the e-TRIPS system.

105. Bangladesh sincerely thanks the developed country Members and IGOs for their help and would like to request them to continue their valuable support for the developing countries and particularly the LDCs and the graduating LDCs.

10.2 Republic of Moldova

106. I would like again to thank the Secretariat for the e-training provided to our delegation on e- TRIPS session and we consider this type of session very useful, especially for our capital-based officials and therefore we encourage more Members to apply for such sessions.

10.3 World Intellectual Property Organization

107. The World Intellectual Property Organization continues to support Members to leverage intellectual property as an enabler of the creativity, innovation and entrepreneurship needed to address global challenges. WIPO remains committed to working now and in the future to enable an effective global response to the COVID-19 pandemic and to facilitate sustainable post COVID-19 recovery efforts.

108. Technical co-operation and capacity-building are key components of the WIPO COVID-19 response package, approved in October 2021, and designed to leverage WIPO's strengths in support of the global community's response to COVID-19. The WIPO COVID-19 response package includes a commitment for WIPO to strengthen its cooperation with the World Health Organization (WHO) and the World Trade Organization (WTO) as part of the trilateral cooperation to address the individual needs of Members in this regard.

109. Since 2009, the Trilateral Cooperation has enabled the WHO, WIPO and the WTO to step up practical coordination on issues relating to public health, intellectual property and trade. This trilateral cooperation is intended to enhance the empirical and factual information basis for policy makers in order to support them in addressing public health in relation to intellectual property and trade. On 15 June 2021, the Directors General of WHO, WIPO and WTO met to map out further collaboration to assist Members' responses to the COVID-19 pandemic. The Directors General were conscious of the pressing global challenges at the intersection of public health, intellectual property and trade and they agreed on a number of actions in support of the members of the three organizations.

110. As part of their actions, the Directors General agreed to establish the WHO-WIPO-WTO COVID- 19 Technical Assistance Platform. The new joint Platform for tripartite technical assistance was launched in April 2022. The Platform provides a one-stop shop for members of the three organizations and for WTO accession candidates. It offers the full range of expertise on access, intellectual property and trade matters provided by WHO, WIPO and WTO in a coordinated and systematic manner.

111. The Trilateral Technical Assistance Platform is an additional pathway to requesting technical assistance within the framework of the trilateral cooperation. The Platform offers easy-to-find and use information about the technical assistance that can be obtained individually and together from WHO, WIPO and WTO with regards to COVID-19 response. In order to improve outreach, the three organizations have agreed to establish the new platform with a new trilateral domain: https://www.who-wipo-wto-trilateral.org/. The platform focuses on COVID-19 related technical assistance and maps out related information in WHO, WIPO and WTO which is accessible through the platform. Such information includes direct links to the Trilateral Study Promoting Access to Medical Technologies and Innovation as well as the updated COVID-19 extract on an integrated

health, trade and IP approach to respond to the COVID-19 pandemic. Both publications are available in the six United Nations languages through the platform.

112. In addition, the platform provides direct links to pertinent information about the full range of options for technical assistance provided for by WHO, WIPO and WTO. A contact form can be used to send any queries regarding how to request trilateral technical assistance – this is available online at the gateway. The contact form encourages the user to submit structured and detailed information and guides the user as to which information is useful for the respective secretariats to expedite the inquiries.

113. Translations of the Trilateral Technical Assistance Platform into Arabic, Chinese, French, Russian and Spanish are currently in the final stage of preparation and will be upload shortly. At this stage, the Trilateral Technical Assistance Platform focuses on COVID-19 related technical assistance. We see potential for this platform to develop further into a comprehensive trilateral information resource that can support the global policy discussion in the fields of health, intellectual property and trade in a holistic manner in order to make the potential of the trilateral cooperation work for all members of WHO, WIPO, WTO and WTO accession candidates.

114. WIPO reaffirms its commitment to combining the three organizations' services together to offer Members comprehensive support in addressing the pandemic and beyond. We invite you to make active use of the platform and to share with us any feedback about this new feature of the trilateral cooperation.

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

11.1 South Africa on behalf of the co-sponsors of IP/C/W/669/Rev.1

115. On 15 June 2021, the Directors General of the World Health Organization, World Intellectual Property Organization and the World Trade Organization issued a joint statement in which they underscored their "commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies". The three DGs underlined that this commitment is anchored in the understanding that this is an urgent moral imperative in need of immediate practical action.

116. We have learnt from the experiences of this pandemic that it is critical to scale up production and access to not only vaccines, but other tools, including therapeutics and diagnostics to prevent the spread of COVID-19 and to treat the disease and prevent deaths. These resources have been in acute shortage in many countries leading to very limited accessibility. The scope of products is also reflective of the national COVID-19 response strategies of many countries that acknowledge that the prevention, treatment and containment of COVID-19 involves a range of health products and technologies. Vaccines are necessary but not sufficient to respond to the pandemic. No country adopts only one intervention in this and any pandemic. Vaccinations, test and treat strategies and their related health products and technologies are urgently needed alongside other interventions.

117. In relation to therapeutics, WHO's consultations on COVID-19 therapeutics reveal that "[d]espite the great success of COVID-19 vaccine development, therapeutics are still urgently required" and that a range of therapeutics will be required including "drug combinations targeting specific aspects of infection, as well as suites of treatments targeting different disease processes (such as antivirals, immunomodulators and anti-coagulants)".[2] The European Union COVID-19 therapeutic strategy also states that "vaccines will not eliminate the disease overnight and therapeutics will still be needed for patients in hospitals and at home, including people suffering from 'long COVID'. For these reasons, therapeutics will continue to play a significant role and complement the EU strategy for vaccines." Notably, several therapeutics have been approved, registered and have received national emergency use authorization or qualified for the WHO emergency use listing.

[2] P. 5 https://cdn.who.int/media/docs/default-source/blue-print/06_therapeutics_full-achievements-report.pdf?sfvrsn=d6cdb802_3&download=truereport.pdf?sfvrsn=d6cdb802_3&download=true. See also pp. 12 and 13.

118. Since the currently available vaccines are not able to prevent infections, therapeutics play an important role in our effort to contain and treat COVID-19. In document IP/C/W/670, the co- sponsors have presented a preliminary patent landscape providing a non-exhaustive snapshot of the patent filing and granting status of five selected therapeutics candidates for COVID-19. In document IP/C/W/672 as well as in document IP/C/W/673 the co-sponsors have highlighted IP-related challenges in the area of therapeutics and how restrictive voluntary licensing practices continue to pose supply challenges to countries. The WIPO patent landscape report has subsequently shed further light.

119. In relation to diagnostics, pillar 5 of WHO's Strategic Preparedness and Response Plan for COVID-19 considers testing to be the cornerstone of the management of the COVID-19 pandemic. Testing is critical to detect cases and investigate clusters of cases so that public health actions can be rapidly taken to isolate those infected, quarantine contacts and break chains of transmission. Testing allows for new COVID-19 variants to be identified to begin to build vaccines and therapeutics that can prevent or treat infection. Major gaps in testing are still putting lives at risk and threatening progress to end the pandemic. There is therefore a need to scale up testing and ensure immediate, equitable access to diagnostic tools in every country across the world. The co-sponsors have provided examples highlighting IP challenges in previous TRIPS Council meetings (see paragraphs 42-46 of document IP/C/W/672 as well as paragraph 65 of document IP/C/W/673).

120. We commend Dr Ngozi Okonjo-Iweala, Director-General of the WTO, for the work undertaken towards the Ministerial Decision on the TRIPS waiver. Work conducted within the Secretariat such as the "Working Paper on Patent Related Actions Taken in WTO Members in Response to the COVID- 19 Pandemic" as well as the "Working Paper on Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members: Analytical Review of VaxPaL", both provide rich information that Members may use in developing appropriate measures within their jurisdictions. Paragraph 8 of that Decision contains a clear Ministerial mandate for Members to decide on extension of the Decision to therapeutics and diagnostics within 6 months – that is, by 17 December 2022.

121. The co-sponsors have prepared a room document that sets out why it is important to expeditiously fulfil the paragraph 8 mandate. The room document also proposes a time frame for the consideration of the membership, aimed at assisting us to timeously fulfil the mandate set by Members at MC12. The time frame is indicative, and it has just been brought to my attention that 22 July is the last day of the WIPO General Assembly. Obviously this would have an impact on the ability of some delegation to participate, so this is indicative and we are happy for Members to reflect and provide a time frame that would be workable.

122. As stated by Dr Ghebreysus, Director-General of the WHO, "Vaccines alone will not end the pandemic". "Many countries need diagnostics, lifesaving therapeutics – including oxygen and support for vaccine rollout." The WTO membership has urgent work to do in order to emulate the commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies demonstrated by the trilateral DGs. Extension of the WTO Ministerial Decision on the TRIPS Agreement to cover therapeutics and diagnostics will be a significant step in the right direction.

123. We have heard some mention voluntary licenses as an alternative to full use of TRIPS flexibilities and extension of the Ministerial Decision on the TRIPS Agreement. Here I would state that our delegation appreciates the value of voluntary licenses. However, due to various limitations, voluntary licenses cannot be considered as the only means that Members should have at their disposal if we are to diversify production on an adequate scale. Some of the limitations involved with licensing include: lack of transparency, geographical limitations, and exclusivity.

124. South Africa is a co-sponsor of the Solidarity Call to Action and the WHO COVID-19 Technology Access Pool (C-TAP) together with 41 other countries. At the early stages of the pandemic, the Call to Action made three requests of holders of knowledge, intellectual property or data to existing or new therapeutics, diagnostics and vaccines, including. Namely, that they:

a. Voluntarily license such rights on a non-exclusive and global basis to the Unitaid-established and supported Medicines Patent Pool and/or through other public health research and development mechanisms, consortia or initiatives that facilitate global and transparent access; and/or voluntary non-enforcement of intellectual property rights,

as appropriate, during the COVID-19 pandemic, to facilitate the wide-scale production, distribution, sale and use of such health technologies throughout the world;

b. Facilitate equitable, affordable and timely access to their products for all countries; and

c. Share voluntarily the relevant knowledge, intellectual property and data to enable wide-scale and worldwide production, distribution and use of such technologies and necessary raw materials through mechanisms such as the Technology Access Partnership (TAP) hosted by the UN Technology Bank or the Open COVID Pledge Initiative[3].

125. These requests were largely unheeded, which has contributed to the concentration of production in a few locations and inequitable access to COVID-19 tools. The co-sponsors have consistently argued that business as usual approaches are ill-suited to situations of extreme urgency such as pandemics. We have also called for vigilance given the ever-present threat of new variants and sub-variants. The emergence of the highly transmissible BA.4 and BA.5 Omicron sub-variants as well as the BA.2.12.1 sub-variant, which was first detected in the United States of America in December 2021, have resulted in spikes in the number of infections in different regions. The impact of these spikes is yet to be determined but there are some initial indications that the risk to global health presented by the latest sub-variants is potentially greater than that of original BA.2. The ability to identify and treat these variants and sub-variants as well as those which continue to emerge will depend on the deconcentrated availability of therapeutics and diagnostics. Extension of the WTO Ministerial Decision to cover these crucial COVID-19 tools is urgent and will be a key facilitator in this regard.

11.2 Uruguay

126. Our country has a direct interest in matters relating to the equity and affordability of, and easy access to, goods and services developed on the basis of patents and other intellectual property tools in order to combat COVID-19. Uruguay, as a net importer of medical technology, welcomes document RD/IP/49, which was circulated today.

127. We stand ready to hold discussions with the proponents of the document on the inclusion of aspects relating to COVID-19 diagnostics and treatments in the Ministerial Decision adopted in June, with a view to securing an outcome prior to 17 December 2022. However, given the urgent nature of the matter, we understand that the flexibilities provided under the TRIPS Agreement and voluntary licensing must be used as a matter of priority to meet Members' needs.

11.3 Pakistan

128. Pakistan wishes to align itself with and echo the statement delivered by South Africa on behalf of the co-sponsors of the original TRIPS waiver decision. Pakistan would like to appreciate Dr Ngozi Okonjo-Iweala, Director-General of the WTO, and her efforts to achieve a Decision for the Membership on the TRIPS waiver. The Decision, even though not as ambitious as what the co-sponsors would have liked, does underscore to the world at large the importance of a solution to the intellectual property-related challenges faced by many developing countries in their fight against the COVID-19 pandemic.

129. The Decision, therefore, very aptly instructs Members in Paragraph 8 to decide on the extension of the Decision to therapeutics and diagnostics within six months, i.e. by 17 December 2022. Indeed, the solution to the overwhelming challenges faced by developing countries in their ongoing fight against COVID-19 is very limited if it remains confined to vaccines and does not address therapeutics and diagnostics. More specifically, while the pandemic is now entering a late stage, new variants will continue to develop and newer manifestations of the disease will come to surface, for instance long-term side effects, and repetitive infections with their own complications. In this phase, the need for going beyond vaccination and timely access to diagnostics and therapeutics has become crucial.

130. This aspect has been duly recognized by the Directors General of the World Health Organization, World Intellectual Property Organization and the World Trade Organization in their

[3] https://www.who.int/initiatives/covid-19-technology-access-pool/solidarity-call-to-action.

joint statement underscoring a "commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies". The need for therapeutics and diagnostics in our efforts to detect, treat and contain the spread of COVID-19; and the various challenges in the IP system to achieve that aim, particularly challenges in achieving success through voluntary licensing mechanisms, has also been deliberated in great detail by the co-sponsors of the waiver in documents IP/C/W/670, IP/C/W/672 and IP/C/W/673.

131. In terms of the work done by international organizations, WIPO's patent landscape report has explained these aspects in good detail alongside the WHO's strategic preparedness and response plan for COVID-19, which underscores diagnostics, particularly testing, as a key ingredient of a wholesome COVID-19 management strategy.

132. This continuing need for a waiver for therapeutics and diagnostics is not new. It was pushed further during the negotiations on the waiver to allow more focus on vaccines at the time. This does not diminish the crucial importance of extending the waiver to diagnostics and therapeutics, which is even more necessary now. It is not just a technical or economic argument. It is an urgent moral responsibility that we as the membership owe to the world to demonstrate that we are actually interested in fighting the pandemic and saving human lives across the globe, that those lives in developing countries also matter, and that the waiver on vaccines is not mere window dressing.

133. With this urgent need in mind, Pakistan fully supports the room document that has been circulated today on behalf of the co-sponsors. It clearly delineates a time frame for fulfilling our Ministerial mandate in a timely and effective manner. We urge Members to seriously consider this timeline ahead of us and work positively, constructively and meaningfully to deliver this decision within the stipulated time.

11.4 Maldives

134. The Maldives warmly welcomes the adoption of the TRIPS waiver at MC12, as it is a crucial step towards a comprehensive WTO response to the ongoing pandemic. The agreement will greatly enable vaccination rates across the world. In the spirit of this progress, we request the Council to begin the work of extending the waiver agreement to cover much-needed therapeutics and diagnostics.

135. Diagnostics are crucial to manage the virus as people can be tested quickly and efficiently to limit the spread. Without widespread access to affordable diagnostics, managing the spread of the virus is significantly more difficult. Expanding local production of diagnostics to a broader range of geographical locations is a necessary step to overcoming the challenge of accessibility.

136. Currently, according to the World Intellectual Property Organization, therapeutics outnumber vaccine patent filings. In this regard a therapeutic provision is necessary to provide care quickly and effectively to people of low- and middle-income countries. There are many factors such as break-through cases and new strains not covered by existing vaccines which could lead to hospitalization. In these instances, timely access to proper therapeutics is critical. Similarly, as new therapeutics are developed it is important that they are made available promptly, in sufficient quantities and at affordable prices to meet global demand.

137. Without an agreement on these elements of the waiver, Members that lack proper access to diagnostics and therapeutics will continue to be disproportionately affected with the challenges of the pandemic. Excellencies and colleagues, we have an opportunity to seize the current momentum to strengthen the waiver and enable all Members to comprehensively respond and manage the COVID-19 pandemic. The Maldives remains committed to the work of this Council and looks forward to further collaboration.

11.5 Ukraine

138. Ukraine welcomes the adoption of the Ministerial Decision on the TRIPS Agreement and believes that it will lead to achieving the common goal of ensuring universal access to vaccines needed to fight the COVID-19 pandemic. With respect to provisions of paragraph 8 of the mentioned Decision, we would like to reiterate that the availability of affordable COVID-19 diagnostics and therapeutics is a matter of great importance for Ukraine. Ukraine will follow discussions on this

matter in the TRIPS Council and we are ready to engage constructively in order to find an acceptable solution in the WTO.

11.6 Egypt

139. Egypt aligns itself with the statement delivered by South Africa of behalf of the co-sponsors of the original waiver proposal. At the outset, let me assure you that we are looking forward to engaging constructively with other Members to implement all the outcomes of MC12, including the Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022. In this regard and pertaining to paragraph 8 of the referred Ministerial Decision, there is global recognition that controlling COVID- 19 requires a comprehensive approach beyond vaccines. There is no dispute that therapeutics and diagnostics are central to effectively responding to the COVID-19 pandemic and to socio-economic recovery.

140. On 29 June, Dr Tedros, Director-General of the World Health Organization, announced that the pandemic is not over yet. To date the WHO has recommended a number of therapeutics, but many of them are either unavailable and/or unaffordable in many developing countries.

141. The extension of the Decision has its rational base, among other things. First of all it is not only vaccines that are needed now. Supply and production of diagnostics and therapeutics have become more important. Existing patents on diagnostics and therapeutics increase the cost of treatment making it difficult to create modern mechanisms through which to deliver medicines at visible and affordable cost, especially in low-income developing countries. The use of compulsory licenses as per Article 31 of TRIPS to override the patent barrier and a waiver of the Article 31(f) condition could facilitate equitable access. With respect to testing, WHO recognizes it to be the cornerstone for the management of the COVID-19 pandemic. Testing is critical to detect cases, to identify new variants and the rate of infection, but disparity in testing is huge. In May 2022, Dr Tedros, Director-General of the WHO, highlighted the importance of timely access to affordable diagnostics tools in developing and least developed countries.

142. Against this background we underscore that a holistic approach is required to ensure an effective response to COVID-19, and we stress the importance of the TRIPS Council to take urgent steps, within the timeline proposed in room document RD/IP/49, to facilitate access for diagnostics and therapeutics, through extending the Ministerial Decision to cover the production and supply of COVID-19 diagnostics and therapeutics.

11.7 Tanzania on behalf of the African Group

143. The African Group welcomes the Ministerial Decision reached during MC12 and welcomes the document presented by the delegation of South Africa on behalf of the group of co-sponsors. It can be recalled that during MC12 the African Group consistently insisted on the importance of adopting a comprehensive Decision which comprises vaccines, therapeutics and diagnostics as a holistic approach to address the COVID-19 pandemic. It is also well-reflected in the co-sponsors' document that access to testing tools and life-saving drugs is limited and unaffordable.

144. It is evident that COVID-19 therapeutics such as Paxlovid are in short supply. In most developing countries and least developed countries, particularly in Africa, COVID-19 therapeutics are either unavailable or unaffordable. This situation calls for a swift extension of TRIPS flexibilities to cover COVID-19 therapeutics as a means of scaling up and diversifying their production to facilitate equitable and affordable access.

145. Regarding diagnostics, the World Health Organization continues to insist to Members that COVID-19 testing is an appropriate strategic measure to address the pandemic. Testing is critical to detect cases, new variants and to better understand the extent of infection in a certain population and leads to taking an informed and timely measure to tackle it. Nevertheless, the rate of testing in developing countries and in LDCs – particularly in Africa – remains alarming low due to shortages and unaffordable supplies of kits and testing chemicals. Testing in LDCs is almost negligible in proportion to their population, and it is merely done when a patient is severely sick – a situation which increases the risk of rapid and extensive viral spread. This situation calls for an extension of TRIPS flexibilities to cover COVID-19 diagnostics as a means of scaling up and diversifying their production to facilitate equitable and affordable access of diagnostics as well.

146. In conclusion, the African Group concurs with the timelines proposed in the co-sponsors' room document: that discussion should commence before the summer break and be continued immediately after the break, with a view to concluding the discussions on extending TRIPS flexibilities to cover the production and supply of COVID-19 diagnostics and therapeutics, at least by November or early December 2022.

11.8 Bangladesh

147. Bangladesh welcomes the temporary TRIPS waiver Decision by our Ministers at MC12 to support production and affordable and timely supply of COVID-19 vaccines with a future opportunity to extend the Decision to therapeutics and diagnostics. My delegation thanks the TRIPS Council Chair, Dr Ngozi Okonjo-Iweala, Director-General of the World Trade Organization, Ms Annabel González, Deputy Director-General of the WTO, and every delegation for a collective effort for a final outcome on the temporary TRIPS waiver Decision. This is a much-delayed Decision after the outbreak of the COVID-19 pandemic; however, it is expected that the Decision will be helpful for scaling up COVID-19 vaccine production. Without further delay, we must begin discussion now to extend the Decision to therapeutics and diagnostics as instructed by the Ministers. The social and economic effects of COVID-19 have been and continue to be disastrous, especially for developing countries and LDCs. My delegation strongly appeals to Members to consider the room document RD/IP/49 circulated today and agree on a positive decision as soon as possible in the next six months. Bangladesh thanks the delegation of South Africa and other delegations on behalf of the proponents, for bringing this room document.

148. It is evident that there is an urgent need to expand manufacturing globally and to diversify the supply of vaccines, therapeutics and other medical products to effectively fight the pandemic. Therapeutic options for COVID-19 primarily fall into two categories: monoclonal antibodies (administered by infusion) and oral antivirals (administered as tablets). But most of the products, even those recommended by the World Health Organization, are either unavailable or unaffordable to many developing countries. Intellectual property monopolies, especially patents, remain a major barrier to scaling up production and to facilitating equitable access in developing countries. Due to limited manufacturers, there are significant supply constraints for the therapeutics recommended by WHO and for potentially new therapeutics.

149. Likewise, testing is critical to detect cases, to identify new variants and to better understand the scale of infection. It also allows for rapid action to be taken and to break the chain of transmission. Testing allows for new COVID-19 variants to be identified to begin and develop vaccines and therapeutics that can prevent or treat infection. Testing in developing countries and especially in least developed countries remains low.

150. The MC12 Decision on a TRIPS waiver for COVID-19 vaccines is just half-way progress. Extending the TRIPS Waiver Decision to cover the production and supply of COVID-19 therapeutics and diagnostics will immensely help middle- and low-income developing countries and LDCs. The issues of therapeutics and diagnostics were also emphasized by Ministers in their Declaration on the WTO Response to the Pandemic. Bangladesh hopes that WTO Members will not fail to deliver a fuller and strengthened TRIPS Waiver Decision including therapeutics and diagnostics to address the most pressing need of humanity today. My delegation stands ready for further work in this regard.

11.9 Indonesia

151. At the outset, Indonesia would like to align itself with the statement made by South Africa on behalf of the co-sponsors. On this agenda item, our delegation would like to thank Dr Ngozi Okonjo- Iweala, Director-General of the World Trade Organization and yourself for showing able leadership to steer us towards the adoption of the Ministerial Decision on the TRIPS Agreement during the MC12 meeting last June. I would also like to congratulate the Members for the cooperation and flexibilities shown that allowed us to come up with a much-needed result in addressing the ongoing COVID-19 pandemic.

152. While reported cases and deaths from COVID-19 have now declined 90% from their peaks in January, we should not be misguided and think that we are at the end of the pandemic. In fact, transmission is increasing in many countries, while new and more dangerous variants are emerging. Furthermore, bear in mind that 40% of the world population remains unvaccinated, and new variants

also pose health risks to those who have already been vaccinated. Vaccines are only part of the solution. As we look forward to a world free from the pandemic, our work is far from over and we should seize the momentum to build a more resilient global health system, not only for today's purpose, but also for tomorrow's challenges.

153. In fact, one of our priorities, as the current chair of the G20, is to encourage the strengthening of global health resilience and help make the global health system more inclusive, equitable, and responsive to crises. To that end, one of our deliverables is ensuring access to emergency medical countermeasures. In this regard, therapeutics and diagnostics are inseparable parts of the countermeasures devised in the World Health Organization's four-pillar strategy, which also includes vaccine and health protocols, and has been proven to be effective in the prevention, containment, and treatment of COVID-19 and subsequent pandemics.

154. Learning from the lesson of this current pandemic, global health resilience is only as strong as the weakest link. Therefore, we should ensure equitable access to countermeasures through the extension on therapeutics and diagnostics no later than six months after its adoption. With that in mind, Indonesia would also like to extend our full support to document RD/IP/49, submitted by South Africa, India, Pakistan, Indonesia, Egypt and Tanzania on behalf of the co-sponsors, that highlights the urgency of holistic countermeasures to the pandemic, as well as guides our work on the key remaining issues on therapeutics and diagnostics. Indonesia, as always, stands ready to engage constructively on this issue.

11.10 Argentina

155. Argentina welcomes the Ministerial Conference Decision on the TRIPS Agreement and aligns itself with the statement made by the distinguished representative of South Africa on behalf of the co-proponents. My delegation supports this initiative to set up a time frame for meetings to ensure compliance with the multilateral mandate in paragraph 8 of the Decision and to expand the waiver to diagnostics and therapeutics for combatting COVID-19. Indeed, we need to expand access to help in an equitable, universal way to bring an end to this pandemic and save lives all across this planet. That is why Argentina co-sponsored the document which was circulated today and encourages delegations to take a positive view on this proposal, which allows discussions within the established time frame.

11.11 Sri Lanka

156. According to paragraph 8 of the Ministerial Decision on the TRIPS Agreement, document WT/MIN(22)/30), which was adopted on 17 June 2022, a negotiation process should lead Members to arrive at a decision by 17 December 2022 on whether or not to extend it to therapeutics and diagnostics. We would like to emphasize that the world is experiencing an evolution of the COVID-19 pandemic such that antibodies triggered by vaccination are less effective at blocking new Omicron variants and even vaccinated and boosted people are vulnerable to multiple Omicron infections.

157. On the other hand, therapeutic options for COVID-19 recommended by the World Health Organization are either unavailable or unaffordable for developing countries. Intellectual property monopolies, especially patents, remain a major barrier to scaling up production and to facilitating equitable access. Supply constraints are expected to continue for most of 2022, even for products where voluntary licenses exist.

158. These licenses also exclude supply to many developing countries. There are significant supply constraints due to limited manufacturers for the therapeutics recommended by WHO and for potentially new therapeutics. Diagnostics are critical for effective use of therapeutics. Testing allows for new COVID-19 variants to be identified to begin to build vaccines and therapeutics that can prevent or treat infection. Testing in developing countries and especially in LDCs remains absurdly low.

159. In this regard, the Sri Lankan delegation would like to reiterate that the TRIPS Decision will not provide any credible solution to COVID-19 if the scope does not immediately extend to therapeutics and diagnostics. Equitable and affordable access remains a massive challenge for therapeutics and diagnostics, and we should not delay addressing these aspects.

160. Therefore, considering the ongoing challenges and experiences shared by many countries with regard to the COVID-19 pandemic, the Sri Lankan delegation would like to re-emphasize that this TRIPS Decision needs to be advanced favourably on the extension process to cover the production and supply of COVID-19 diagnostics and therapeutics and to ensure the negotiation process shall commence as quickly as possible with a view of fulfilling this Ministerial mandate. Furthermore, Sri Lanka welcomes the latest proposal contained in document RD/IP/49 submitted today by South Africa, India, Pakistan, Indonesia, Egypt and Tanzania, and we would like to continue constructive discussion with Members in this regard.

11.12 China

161. With joint efforts by all Members, MC12 adopted the important Ministerial Decision on the TRIPS waiver of COVID-19 vaccines, which represents WTO's contribution to the global fight against the pandemic and will help address the accessibility and affordability of COVID-19 vaccines in developing Members.

162. Regarding paragraph 8 of the Decision, which is about the extension to diagnostic and therapeutic products, we appreciate the recent room document tabled by the co-sponsors. China shares the view that the extension of the policy tools provided in the Ministerial Decision to therapeutics and diagnostics will help developing Members to address intellectual property barriers to the expansion and diversification of production. China stands ready to continue our active participation in the follow-up consultations of the TRIPS Council along the schedule proposed by the co-sponsors towards the objective of achieving a decision within six months.

11.13 India

163. We acknowledge the Decision reached at MC12 contained in document WT/MIN(22)/30. While the delayed outcome falls short of the expectations and demands of the co-sponsors of the document IP/C/W/669 waiver proposal, it does, however, indicate that the World Trade Organization Membership can go beyond their hard positions and can respond in extraordinary and unprecedented situations. This indeed provides a glimmer of hope for the world at large and for us at the WTO: another opportunity for the Organization to further consolidate and build upon the mandate as provided in paragraph 8 of the Ministerial Decision, and to decide to extend the scope to COVID-19 therapeutics and diagnostics.

164. We have had over the past several months extensive discussions and consultations on the need for a waiver covering therapeutics and diagnostics as well. As highlighted earlier by the distinguished delegate from South Africa, these are well-documented and publicly available. Let me reemphasize again that therapeutics and diagnostics are integral components that constitute a comprehensive prevent, test and treat strategy to combat the pandemic. Globally it is well-recognized that testing and treatment are essential aspects of controlling and managing COVID-19. They are recommended by the World Health Organization, as well as form part of national strategies for controlling COVID-19.

165. As we have seen, the spectrum of medical therapies to treat COVID-19 is growing as well as rapidly evolving. It includes antivirals, monoclonal antibodies, immunomodulators and antithrombotic therapies. Despite the progress in COVID-19 vaccine development, therapeutics are still urgently required as people continue to fall sick despite vaccinations and require treatment to recover. Furthermore, WHO's Strategic Preparedness and Response Plan for COVID-19 considers testing to be the cornerstone of the management of the COVID-19 pandemic. Testing is critical to detect cases, to identify new variants and to better understand the scale of infection. It also allows for rapid action to be taken and to break the chain of transmission. Testing allows for new COVID-19 variants to be identified to begin to build vaccines and therapeutics that can prevent or treat infection. In May 2022, WHO alerted the world that in the absence of testing "we are essentially blind to how the virus is mutating. We do not know what is coming next". Therefore, while the uncertainty continues to linger on regarding mutations, new variations and the efficacy of existing doses, therapeutics and diagnostics, along with vaccines, will continue to be critical for protecting public health.

166. We must not yet rejoice and pat our backs for achieving the outcome at MC12 and putting this behind us. In fact, as mandated we still have another crucial decision to make on therapeutics and

diagnostics, which will further enhance production and ensure access and affordability to COVID-19 therapeutics and diagnostics. To this end, Chair, the co-sponsors of the waiver proposal have circulated room document RD/IP/49 highlighting the urgent need to extend the Decision to therapeutics and diagnostics, as well as proposing an indicative timeline that will help the Membership in scheduling and prioritizing our work in the TRIPS Council to fulfil and realize the mandate in paragraph 8.

11.14 Russian Federation

167. Mr Chairman let me express gratitude to you for your leadership and openness during the tough negotiation at MC12. The Russian Federation welcomes the Decision of the Ministerial Conference on the TRIPS Agreement. This outcome has become an important indication of Members' ability to achieve tangible results through compromise despite the long-standing deadlock. It shows us as well the great value of the TRIPS Agreement and its flexibilities. We expect that the implementation of the Decision will help eligible Members to combat COVID-19 more effectively. My delegation believes that the Decision will have greater benefits if it goes together with the initiative for the voluntary transfer of technology and constant quality control. The implementation of the measures also should bring special attention to the issue of counterfeiting. In our opinion, counterfeit vaccines can pose serious threats to the healthcare system in the time of a pandemic. The Russian Federation supports future negotiations to expand the coverage to diagnostics and therapeutics. Treating the disease is just as important as preventing it. We thank the proponents for room document RD/IP/49 for the initiative. We will study it carefully.

11.15 Hong Kong, China

168. I would like to thank the co-sponsors of the unofficial room document which is very timely. Just some initial thoughts. First, the proposed schedule of meetings looks sensible – in particular the fact that no meeting is intended for August. It also makes sense that this Council reports to the General Council on the progress made from time to time.

169. Indeed, time frame aside, we are more concerned about the process. In particular, we are concerned as to whether the discussion will be confined to a selected group of Members, or whether it will be open to the full Membership. As we have said before, the discussion process should be transparent and open for participation by the full WTO Membership – and my delegation stands ready to participate constructively in the relevant discussions.

11.16 Chile

170. Our delegation takes this opportunity to celebrate the agreement achieved during MC12 in improving the distribution and production of COVID-19 vaccines worldwide. Related to this point, it is important, as my colleague from Hong Kong, China pointed out, that our discussions between now and 17 December are inclusive and transparent. As for the procedure, we deem it of utmost importance that all delegations have the opportunity to submit their proposals and to be heard during the discussion, ensuring a constructive debate that achieves consensus. It is also key that delegations not lose sight of the sense of urgency and adopt a pragmatic, evidence-based approach when it comes to exchanging their views on the matter, considering the particular needs and challenges of developing countries in facing the pandemic. Finally, I would like to reiterate Chile's commitment towards the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, which aims to identify effective solutions in the event of new pandemics. As we have pointed out in previous sessions, we are convinced that a holistic response will be the best response to this and future pandemics. Our delegation shall engage constructively in discussions under this agenda item.

11.17 Bolivia, Plurinational State of

171. We thank South Africa for submitting the document on behalf of the co-sponsors. We believe that it is of vital importance to comply with the mandate of the Decision adopted last June and make progress toward therapeutics and diagnostics, and toward affordable and equitable solutions. Otherwise any other decision will continue to fall short. It will be very positive for the Organization to reach an outcome and avoid repeating mistakes of the past, which will not allow us to respond rapidly as required. Time continues to pass, and COVID-19 continues to affect our economies and

take lives. We continue to foster a patent system that prioritizes life for all people on the planet and we reiterate our willingness to engage constructively on the matter.

11.18 Australia

172. Australia welcomes the consensus agreement at MC12 for a TRIPS outcome for COVID- 19 vaccines. We thank Members on all sides, we thank you Chair, and we thank the Secretariat for their constructive engagement in achieving this outcome. We look forward to engaging in the discussion on extending the scope of that outcome to therapeutics and diagnostics in the coming months. We urge all Members to approach these further discussions in the same spirit of compromise that enabled us to secure the MC12 outcome. We would like to thank the co-sponsors for their document RD/IP/49, circulated earlier today, which we are still reviewing.

11.19 Brazil

173. Brazil has been an active participant of the discussions that led to the Ministerial Decision on the TRIPS Agreement on 17 June 2022. It is our belief that we have reached with that Decision a balanced outcome that preserves the integrity of the TRIPS Agreement, while improving and streamlining procedures and requirements associated with the use of the special compulsory licensing system under the TRIPS Agreement.

174. We believe a similar path could be taken to extend the Decision to therapeutics and diagnostics. We are ready to assess Members' proposals under paragraph 8 of the Ministerial Decision and will engage constructively towards a decision on the agreed time frame.

11.20 United Kingdom

175. The United Kingdom would like to thank you, Chair, and the Secretariat for navigating the TRIPS Council through a complex negotiating process during MC12. While the process for reaching the consensus-based TRIPS Decision was by no means perfect, and lessons could be learned, your leadership and guidance was valuable in helping us reach an outcome and will no doubt be required moving forward. We also extend our gratitude to all Members for their cooperation and patience throughout the process.

176. The United Kingdom has listened carefully and understood concerns raised by developing countries, particularly those regarding use of the compulsory licensing system. Bearing such feedback in mind, the United Kingdom engaged constructively in discussions on how compulsory licensing could help developing countries to achieve their public health policy objective of accessing COVID-19 vaccines. After a series of intense negotiations, we understand the aim of this Decision is to make it easier for eligible Members, who choose to do so, to make exports of life-saving COVID- 19 vaccines more streamlined, while preserving incentives to invest in innovation embedded in intellectual property rights.

177. The United Kingdom will engage constructively and in good faith, being guided by evidence and noting the distinction between vaccines, therapeutics, and diagnostics. We welcome all Members' views and the opportunity to engage bilaterally on the matter. We are pleased to see the IP framework has been put in use by licensing partnerships for COVID-19 treatments underway, including via the Medicines Patent Pool.

178. We also thank delegations for the unofficial room document RD/IP/49 circulated today. This text will certainly form part of our analysis of the matter. Given the complexities of therapeutics and diagnostics, we will use the time available, and we call on others to do the same, to gather and analyse evidence and engage bilaterally during the summer months, so that we are able to deliver on the mandate via multilateral evidence-based discussions to take place after the summer. We see the TRIPS Council with you, Chair, at the helm as the right forum to hold these discussions.

11.21 Singapore

179. I would like to echo previous colleagues in commending the Chair, Secretariat, and all Members for delivering an outcome on the TRIPS Waiver Decision at MC12. This bears testament to the ability of all Members to exercise flexibility. As we are now faced with the next step on the extension of the

Decision to diagnostics and therapeutics, Singapore hopes that Members will continue to engage in a constructive spirit to reach a solution on this issue.

180. We would also like to thank the proponents for their room document RD/IP/49 on the extension of the TRIPS Decision to cover diagnostics and therapeutics. While we will require some time to consider the proposal carefully, Singapore remains committed to working constructively with Members on this issue in an open, transparent, and inclusive manner.

11.22 Norway

181. Norway welcomes the Ministerial Decision reached at MC12. We are encouraged by Members' ability to achieve consensus on this important topic. The waiver ensures a balanced approach between, on the one hand, ensuring that intellectual property rights do not constitute a barrier to solving the current or future health crises, and on the other hand, preserving the incentives for innovation. We thank you Chair, the Secretariat and all others that helped ensure this important result.

182. Our work on the waiver is, however, not finished. We are currently consulting with Oslo on paragraph 8 of the Ministerial Decision on the TRIPS Agreement. Six months is not a lot of time, and the clock is ticking. On process, we need to ensure that further negotiations are conducted in a manner which is open, transparent, and inclusive. In this respect we thank the proponents of the unofficial room document distributed today and will thoroughly consider the proposals contained therein.

11.23 Canada

183. Canada was pleased to see the international community come together to find a multilateral solution on this important issue at MC12. Canada has always supported a consensus-based solution on the TRIPS waiver, and positively notes the ability of the WTO Membership to reach consensus in recent weeks.

184. Canada has long recognized and promoted the importance of balance in intellectual property frameworks that provide incentives for innovation while ensuring that WTO Members can continue to pursue important public policy objectives, like public health. Canada also recognizes that the global management of COVID-19 is informed by a broad range of factors, including supply chain barriers and considerations related to the distribution and delivery of medical interventions. In this regard, Canada continues to support a broad range of near-term solutions to enhance immunization and access to COVID-19 medical interventions and diagnostics, including those measures contemplated under the WTO response to the pandemic, such as measures to address supply chain constraints and export restrictions, as well as ongoing support for the Access to COVID-19 Tools Accelerator and its vaccines, diagnostics, and therapeutics pillars.

185. Canada also looks forward to further discussions regarding eligible Members' experiences in vaccine production in the months ahead, and on the role of IP in this complex process. We also encourage the sharing of any Member experiences in respect of access to, and distribution of, COVID-19 therapeutics and diagnostics, including with respect to any challenges experienced in relation to, or arising from, the TRIPS Agreement. Canada remains of the view that ongoing discussions will continue to be aided by an evidence-based exchange on Members' experiences in responding to the COVID-19 pandemic, with a view to ensuring that Members can again identify consensus-based solutions to global challenges.

11.24 Japan

186. The delegation of Japan believes that the intellectual property system has played and will continue to play a crucial role in providing incentives for developing COVID-19 vaccines, diagnostics and therapeutics, as well as facilitating voluntary partnerships across the private, public, and academic sectors. While it is unclear how the discussion related to paragraph 8 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022 (document WT/MIN(22)/30) will be conducted, we believe that such discussion should be conducted in an evidence-based manner. We are ready to continue such discussion constructively with Members.

11.25 Korea, Republic of

187. Korea appreciates the Ministerial Decision at MC12, which is a meaningful and compromise outcome for the WTO response to the pandemic. My delegation believes the upcoming discussion on paragraph 8 of this Decision will be another path to finding the right balance between the two important values of the intellectual property system and a response to the pandemic.

188. As the consultation with stakeholders is ongoing, Korea needs more time to prepare for future discussions. Meanwhile, at this point, my delegation would like to express our preliminary view on the structure of upcoming discussions. Stakeholder Members should be able to participate at the upcoming discussions, which should be held in an evidence-based and more open and inclusive manner, especially given the broader scope of therapeutics and diagnostics and the bigger group of stakeholder Members in comparison to COVID-19 vaccines.

189. Regarding document RD/IP/49, which was circulated before today's meeting, my delegation will review it carefully. Korea looks forward to working with Members and engaging constructively in the upcoming discussions.

11.26 European Union

190. The European Union welcomes the outcome achieved during the WTO Ministerial Conference in June on a number of clarifications and a waiver of certain obligations of the TRIPS Agreement to allow eligible WTO Members to authorize a company to manufacture and export COVID-19 vaccines in a fast and simplified manner without the consent of the patent owner.

191. The solution backs and clarifies the flexibilities that exist in the TRIPS Agreement. It simplifies the process to export vaccines and their ingredients to other developing countries, which should help overcome difficulties related to the domestic implementation of the TRIPS Agreement flexibilities and support developing countries in scaling up their production capacity and supplying vaccines to other developing countries.

192. The outcome and the discussions that we have had over the last year should also lead to all WTO Members equipping themselves with agile and efficient legislative frameworks that fully use all the flexibilities that already exist in the TRIPS Agreement. Clearly one of the key lessons learned from this exercise is that currently this not the case and that there is an important margin for improvement. The agreed outcome maintains the protection of intellectual property, a key element for developing countries not only to benefit from the innovation that the system sustains but also to have the environment that incentivizes the needed investments in the pharmaceutical sector.

193. The European Union is ready to engage constructively in the discussions on the extension of the mechanism agreed by the WTO Ministerial Conference to therapeutics and diagnostics. We are currently analysing the situation on the market as regards these products in order to prepare consultations with our Member States. In that regard, we would like to thank the co-sponsors of document IP/C/W/669/Rev.1 for the room document, which we will analyse in detail.

194. We also welcome the Declaration on the WTO Response to the Pandemic and Preparedness for Future Pandemics and want to emphasize the need for comprehensive action when it comes to addressing pandemics, including a commitment to transparency, timely and comprehensive information sharing, and restraint in imposing export restrictions.

11.27 Malaysia

195. At the outset allow me to thank Dr Ngozi Okonjo-Iweala, Director-General of the World Trade Organization, and Ms. Annabel González, Deputy Director-General of the WTO, and you, Chair, for your leadership in delivering the first Ministerial Decision on the TRIPS Agreement. This is indeed a strong testament that with pragmatism and flexibility we could deliver an outcome. We remain cognizant of the role of intellectual property rights in research and development. Nevertheless the COVID-19 experience tells us that life-threatening pandemic situations warrant interventions. We continue to support Dr Ngozi Okonjo-Iweala, Director-General of the WTO and you, Chair, in future inclusive WTO responses to future pandemics.

11.28 United States of America

196. The United States is committed to continuing to lead responding to the global COVID-19 pandemic. We have committed to donate over 1.2 billion vaccine doses to date. We have already delivered more than 560 million doses to over 115 countries. The United States has also contributed more than USD 19 billion in help and humanitarian assistance to help combat COVID-19 issues and to help ensure communities around the world have the resources that they need. Over the year the United States, as part of its comprehensive effort to end the pandemic, worked constructively with other WTO Members to facilitate discussions and bridge differences that led to an outcome on intellectual property that achieved consensus across 164 Members of the WTO.

197. Through difficult and protracted discussions, and with the support of the WTO Secretariat and the TRIPS Council Chair, Members were able to bridge differences and achieve a concrete and meaningful outcome to get more safe and effective COVID-19 vaccines to those who need them most. This Decision shows that we can work together to make the WTO more relevant to the needs of regular people. We have started our domestic consultations on whether to extend this Decision to cover the production and supply of COVID-19 diagnostics and therapeutics and look forward to continuing to engage with all Members on this topic. On the process going forward, we recognise the urgency of the situation. At the same time, Members need to have enough time to conduct their domestic consultations.

11.29 New Zealand

198. New Zealand strongly welcomes the Decision made by Ministers on the TRIPS waiver. WTO Members worked hard to find a balanced outcome that reflects wide divergences in position. We thank all Members who demonstrated considerable flexibility, up until the last moments of the Conference, to ensure we were successful in reaching a conclusion. Let me also thank you, Chair, for your efforts in guiding us toward the outcome and to the Secretariat team for their assistance in reaching the outcome. We heard both before MC12 and again today an interest to extend the Decision to COVID-19 diagnostics and therapeutics.

199. We look forward to active engagement over the next 6 months in fulfilment of our Ministers' Decision. As we progress our engagement, we would ask that Members, possibly aided by the Secretariat, share their practical experiences of implementing the existing Decision to inform our decision-making here. We are still considering the room document circulated today.

11.30 Nicaragua

200. The delegation of Nicaragua wishes to welcome the proponents' document RD/IP/49. We think that the proposed schedule in this document is reasonable and is in line with the elements in the Decision adopted in the Ministerial Conference, if this schedule works for the World Trade Organization. Furthermore, we would like to participate in discussions aiming to extend this Decision to diagnostics and therapeutics, which will allow us to combat the COVID-19 pandemic.

11.31 Thailand

201. Thailand wishes to join the previous speakers in thanking you and the Secretariat in guiding us though MC12 and achieving consensus. With respect to discussions on paragraph 8 of the Ministerial Decision we support that discussions be held in a transparent and inclusive manner. In this regard, we like to thank South Africa and the co-sponsors for the room document RD/IP/49. We remain committed and look forward to working and engaging constructively with all Members in the coming months.

11.32 Switzerland

202. Accepting paragraph 8 of the Ministerial Decision of 17 June was a significant concession by our delegation, made in an effort to find a consensus on the Decision on the TRIPS Agreement and the broader MC12 package. Switzerland is ready to engage constructively in the discussion on paragraph 8 of the Ministerial Decision on the TRIPS Agreement.

203. The work on COVID-19 vaccines entailed highly complex and technical questions. This will be even more so the case when looking at this from the angle of therapeutics and diagnostics. One reason for this is that, contrary to COVID-19 vaccines, which are single use goods, vaccines and therapeutics can serve multiple treatment purposes beyond and outside of the COVID-19 pandemic.[4]

204. My delegation is currently examining these and other factors internally in order to usefully prepare for this discussion. Internal procedures as well as consultations with stakeholders are under way in order for our delegation to be in a position to participate usefully in the Council discussion. It will have to be evidence- and fact-based. It is essential that we have a good understanding of the situation on the ground. This is all the more important considering that the scope of products covered by the paragraph 8 mandate is potentially very large. In relation to fact-based approaches, my delegation would like to thank the WTO Secretariat for organizing this Friday an Information Session on Innovation and Patenting Activities of COVID-19 Vaccines in WTO Members.

205. The Council's discussion under paragraph 8 of the MC12 Decision on the TRIPS Agreement should be Member-driven, open, transparent and inclusive. To allow for a useful discussion, Members need to be given sufficient time and due advance notice to prepare accordingly for meetings.

206. Let me recall that engaging in this discussion is without prejudice to its outcome, and to delegations' substantive positions. It is also recalled that IPRs and TRIPS have played an instrumental role for the quick development of the new COVID-19 vaccines. intellectual property rights and TRIPS worked as enablers for the hundreds of partnerships formed to scale up the manufacturing of the new vaccines to answer global demand. This applies similarly to the development and manufacturing of new COVID-19 therapeutics and diagnostics. Also, no convincing evidence has been submitted that would demonstrate that IP has indeed worked as a barrier to access to COVID-19 vaccines.

207. This said, my delegation is ready, under your guidance, Chair, to constructively engage and look at the facts and evidence Members will present. We thank the proponents for their room document RD/IP/49, made available to Members today. As a first preliminary reaction on the schedule of meetings proposed in the room document, let me repeat that consultations and the analysis of the complex technical points involved are currently under way. In order to usefully participate in the discussion, we need the necessary time to do this work. The room document seems also to assume a reporting obligation of the TRIPS Council to the General Council for the discussions under this agenda item. As an initial reaction, we note that paragraph 8 provides a time frame for discussion to decide whether or not to extend the MC12 Decision on the TRIPS Agreement to therapeutics and diagnostics. The Ministerial mandate does not foresee a mandate to submit any intermediate report to the General Council on the TRIPS Council discussions, and for this reason we see no need for the TRIPS Council to report to the July General Council meeting.

11.33 Panama

208. I like to thank you and Ms Annabel González, Deputy Director-General of the World Trade Organization, and the Secretariat and especially the Members for the Ministerial Decision. My delegation thinks that it would be important to extend the scope to therapeutics and diagnostics. Like other delegations we welcome the document submitted by South Africa, India and the other co-sponsors. We will look at it carefully so that we can start this discussion as soon as possible and, in this way, comply with the mandate as established in the Decision. It is very important that we are able to respect the mandate. Before concluding, I would like also to reiterate the importance that these discussions be transparent and inclusive. As has been mentioned – I do not know how many times today – it is important for all interested Members to be heard.

11.34 Mexico

209. We would like to echo the words of thanks and congratulations to the Secretariat and to you for the Ministerial Decision. We would like to thank the co-sponsors for the document, and we are ready to comply with what it is mandated under paragraph 8. As has been mentioned repeatedly during the negotiations of the Ministerial Decision, Mexico believes that therapeutics and diagnostics have a different nature from vaccines, and they require different treatment and further discussion.

[4] (According to Airfinity (a scientific analytics company), there are, for example, 111 COVID-19 treatments being used in 94 other infectious diseases).

We welcome the proposal for the coming meetings and for the moment Mexico continues to consult with the appropriate authorities.

11.35 Peru

210. Peru welcomes the joint efforts deployed in the context of the Ministerial Conference to achieve an agreement on clarification and extension of certain provisions of the TRIPS Agreement to combat COVID-19. We are sure that we have a positive and real impact on how populations are going to access vaccines no matter where they are. The flexibility within that framework to achieve that Decision shows that we can achieve consensus in the next few months on this new mandate included in paragraph 8. And here we should clarify that the negotiations that take place in that framework should be open, transparent and inclusive, as other have said. Furthermore, we would like to welcome the submission of document RD/IP/49 today, which we will look over carefully together with the other available documents in order to be able to hold substantive discussions that will be useful in the short time that we have.

12 INTELLECTUAL PROPERTY AND INNOVATION: IP LICENSING OPPORTUNITIES

12.1 United States of America

211. The United States of America is pleased to co-sponsor this agenda item as part of a three-part series this year on intellectual property and financing. This agenda item hopes to foster discussion amongst TRIPS Council Members on the variety of opportunities that organizations have in licensing their IP.

212. Because IP licensing opportunities include a vast array of experiences across both the public and private sector, I will only touch on a few initiatives here and look forward to discussion from other Members about their initiatives. Starting with "Patents 4 Partnerships" is an initiative of the United States Patent and Trademark Office (USPTO) that brings together those who have technologies and want to make them available for licensing and those who have an interest in and the ability to commercialize the technologies.

213. For those who want to make their inventions available for licensing, the IP Marketplace Platform provides a centralized and easily accessible place to list US patents and patent application publications. It offers to potential licensees a database of available technologies that permits searches using a variety of parameters.

214. The IP Marketplace Platform provides a voluntary listing of patents and patent application publications indicated as "available for licensing" on external public websites or in the USPTO Official Gazette Notices. It also offers a link to sources that include the licensing information. The initial release of the IP Marketplace Platform focuses on listing technologies related to the prevention, diagnosis, and treatment of COVID-19.

215. Another USPTO initiative is the annual Women's Entrepreneurship Symposium. Sponsored by the Office of Innovation Outreach (OIO) and held each year during Women's History Month, the symposium raises awareness of a variety of pathways to advance the role of women in IP, including best practices and successful habits for today's fast-moving business climate. The most recent instalment included a discussion featuring innovative women executives who turned ideas into commercial success stories. The OIO supports the mission of the USPTO by providing relevant IP, innovation and invention resources to independent inventors, small businesses, entrepreneurs, and underrepresented or underserved populations by creating annual programming to help everyone better understand, secure, and utilize IP.

216. Each year, hundreds of new inventions are made at the National Institutes of Health (NIH) and the Centre for Disease Control (CDC) laboratories. NIH Institutes or Centres (ICs) transfer NIH and CDC inventions through licenses to the private sector for further research and development and eventual commercialization. To achieve the goals under the Federal Technology Transfer Act and related legislation, the Food and Drug Administration, or FDA, seeks commercial partners interested in developing and marketing technologies that FDA scientists have created. Collaborative research and development work with commercial entities generally occurs under cooperative research and development agreements.

217. In the field of trademarks, brand licensing activities can enhance the reach of the brand without the expenses of advertising and promotion. Benefits of these partnerships include increased brand awareness, increased goodwill and long-term value of the brand, broadened retail presence/cross- promotional opportunities, and increased touch points with existing customers and potential new consumers.

218. Licensing can also be used to support a variety of existing programs for an organization. For example, at the United States Marine Corps (USMC), the Trademark Licensing Office registers trademarks related to the military branch – logos, slogans, designs, etc., and licenses the use of those trademarks to commercial companies who produce USMC branded merchandise. The Trademark Licensing Office polices for unauthorized use of its marks and provides educational information worldwide to protect and enhance the USMC brand in the commercial marketplace.

219. The United States Marine Corps (USMC) retains control over its logos and marks, thus ensuring the quality and consistency of all licensed merchandise. The trademark licensing program creates a cooperative and positive working relationship with the manufacturers and retailers who work with the USMC. Copyright licensing can help artists and musicians reach a broader audience and fan base with their work. A variety of private entities enable artists to license their images for use on commercial products. Companies that sell housewares, clothing, decor, and other items to retailers need beautiful art to put on their merchandise, and many source their art from freelance artists.

220. Likewise, musicians rely on licensing to broaden their fan base through services like Spotify and Apple music, and also rely on royalties generated by such licensing as a form of payment. Some forms of licensing, such as sync licensing, which pairs recordings and musical works with audio-visual works, can help reach a broader audience. Because copyright is a bundle of rights, copyright- based MSMEs are becoming very innovative in how they leverage their bundles of rights as collateral.

221. In one example, a company provides a digital marketplace for artists and songwriters to share a percentage of a song's royalties to fans and brands for royalty-based financing through what the company calls an "Initial Song Offering® (ISO™)".

222. The Initial Song Offering includes a particular date and time when royalty rights will be made available to the public. The ISO is intended to create a focal point for awareness, demand, and opportunity. Thank you and we look forward to hearing from Members about their national experiences with licensing of IP.

12.2 Australia

223. Australia is pleased to co-sponsor this paper and would like to thank the United States of America for its efforts in leading the drafting. This paper describes how licensing agreements can be a valuable pathway for owners of IP assets, whether they be individual inventors, artists, or businesses, to increase their markets and the revenue they can earn and in particular how licensing can be a valuable option for entities and individuals who may not have the resources or experience to develop or market their products and services.

224. Australia has laws, policies, and programmes to support creators, particularly small businesses, to explore opportunities for revenue generation, including through the licensing of patents, trademarks, copyright, and awareness-raising. For example, in the copyright space, we have a number of collective management organisations which collect and distribute royalties on behalf of copyright owners and that provide information, training and other resources to raise awareness of licensing as a tool for revenue generation. The arts law Australia's artist in the black programme provides free or low cost specialised legal advice, education, and resources to indigenous Australian artists nationally, including in licensing on IP rights.

225. We have found that selling and licensing IP continues to be a valuable pathway for small companies and individuals to earn a profit from innovation for example, rights holders can allocate IP rights to licensees that are best positioned to enforce those rights – which can reduce the need for legal action. IP Australia is currently undertaking research to assess whether there are developed markets for patents and trademarks in Australia this will inform our understanding of how policies that promote IP trade can complement traditional enforcement mechanisms.

226. We would be interested to understand how licensing is tracked in other Members' jurisdictions, and whether Members have seen changes in licensing behaviour over the years. We look forward to further exchanges with Members on their experiences of licensing IP in particular, on different licensing models and the benefits and drawbacks of each. We would also be interested in sharing experiences on the ways we can raise awareness of licensing as a tool for revenue generation for small businesses, inventors, and artists.

12.3 Uruguay

227. We wish to congratulate and welcome the co-sponsors of document IP/C/W/691. We understand that the proposal is in the direction that the TRIPS Council should take so that the private sector, which is the final user of IP rights, can benefit from our work. We would like to call the attention of Members on a matter of interest with concrete outcomes, visible to our entrepreneurs. At the end of the document, there are a series of questions to guide the debate. Paragraph 8(f) contains the question "what are some ways to raise awareness of IP licensing as a tool for revenue generation for small businesses, inventors, and artists?"

228. We are starting to discuss these issues in the Informal Working Group on MSMEs , here at the WTO; and WIPO is developing a network with UNCTAD, ITC and the WTO to assist entrepreneurs to monetize their IP assets. This would be one of the themes during the WIPO General Assemblies and there will be a specific event on MSMEs and IP monetization, at WIPO on 1 November. This could lead to synergies with the work of this Council.

12.4 Singapore

229. Singapore would like to thank the United States for its efforts in preparing the discussion paper on IP licensing opportunities, and we are pleased to be a co-sponsor of this paper. As of 2021, the value of Singapore's receipts and payments for the use of IP totalled USD 29 billion – or 7.8% of Singapore's GDP. Singapore supports the development of a healthy IP licensing ecosystem. When conducted well, IP licensing is a powerful tool to unlock the value of innovation. It supports the wider use and dissemination of innovation, while ensuring that innovators are rewarded for their contributions.

230. Next, we would like to share briefly on what Singapore has done to facilitate public-private IP licensing and commercialisation. Given the importance of building consistent practices across the public sector to encourage IP commercialisation, an IP expert group within the Singapore government developed a baseline IP licensing agreement template, as well as templates for research collaboration agreements.

231. These templates are meant to guide public agencies in navigating IP licensing negotiations and research collaborations with industry partners. These templates will also enable companies to gain easier access to IP generated from publicly funded research and development, whilst balancing the interests of the government. The templates include optional clauses and internal explanatory notes to aid agencies in customising the templates where appropriate, based on factors such as the type of IP, field of use, industry sector, and desired outcomes. Singapore looks forward to hearing and learning from other Members on their national experiences in IP licensing and we once again thank the United States of America for this paper.

12.5 Chinese Taipei

232. We want to thank the United States for the paper, and we are pleased to be co-sponsors. For enterprises, inventors, and creators, securing funding through licensing patents, trademarks, and copyrights is an important source of income. We have detailed provisions on the form and subject matter of licensing in relevant intellectual property laws and regulations for reference to intellectual property rights owners.

233. According to our intellectual property regulations, depending on whether the rights owner and third-party use are excluded after licensing, there are two types of licensing of patents, trademarks, and copyrights - "exclusive licenses" and "non-exclusive licenses." In addition, "sole license" also exists in practice, which means that the rights owners authorize only one licensee without excluding their own use during the license period.

234. With respect to licensing organizations, provisions for copyright collective management organizations are in place. Collective management groups manage copyright for copyright owners, administer royalty rates and methods for distribution of royalties, and establish license agreements with users, with music and sound recordings as the main categories. For other types of copyrights, trademarks, and patents, licensing agreements are usually handled by rights owners themselves.

235. Convenience store brand owners expand their business territory through trademark licensing, which should be one of the best practical examples of using intellectual property licensing in the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu. According to statistics, by the end of 2020, the top five convenience store chains had a total of 11,985 stores, with an average of 0.34 stores per square kilometre. The crucial factor for the rapid expansion of convenience store chains is the opening of franchises, and the authorization of trademarks is undoubtedly one of the key points of such franchising contracts. The franchisee obtains a complete set of business model and is able to use the trademark owned by the headquarters under certain conditions; the franchiser can reduce the cost required for store expansion through such cooperation framework, allowing their brand and business territory to expand rapidly. Besides convenience stores, similar models can also be seen in our beauty and apparel industries.

236. The Intellectual Property Office conducts annual information sessions on trademark applications for start-ups and small and medium-sized enterprises. It also provides counselling and consultation services to assist start-ups and MSMEs in gaining a deeper understanding of relevant provisions and equips them with the information necessary to utilize the licensing mechanism effectively. It is of paramount importance to us to figure out the means to assist rights holders in obtaining funds through licensing and encourage continuous innovative development. We welcome Members to share relevant measures and experiences.

12.6 Japan

237. First of all, the delegation of Japan would like to thank the delegation of the United States of America for introducing the document IP/C/W/691. As introduced therein, licensing has been widely practiced as one means to use patent rights. In particular, start-ups, small businesses, and universities or research institutes that are not capable or willing to engage in their own manufacturing can utilize licensing to monetize their patent rights without having to create products at their own expense. Licenses have also been utilized not only for monetizing trademark rights, but also for improving brand recognition, which means that trademark licensing has an important role to play in the area of a company's marketing strategies.

238. On the other hand, in addition to the fact that IP licensing can take a variety of forms and can often be complicated, making full use of licenses often requires profound legal knowledge and abundant practical experience. For this reason, it can be a challenge for companies or institutes without sufficient knowledge or experience to conclude a fair and reasonable licensing agreement, and to effectively monetize and improve their brand recognition through IP licensing.

239. In this regard, the Japan Patent Office (JPO) published in 2020 the "Model Contracts for Promoting Open Innovation", together with explanatory booklets, to serve as guidance for business entities and universities to conclude fair IP licensing agreements. Based on the assumption of a specific fictitious story, each of these models provides desirable contract provisions such as those regarding definitions, granting of a license, royalties, attribution of rights, treatment of undisclosed information, cancellation, damages, and dispute settlements. These are also accompanied by clause- by-clause explanations, as well as case studies on negotiations over terms and conditions.

240. These model contracts provide guidance in the area of fair contracts, as well as useful knowledge for conducting negotiations. While these model contracts are intended for use between domestic entities, they are also intended to serve as a reference for contracts with foreign entities. In addition to model contracts, JPO has continuously published case studies on IP utilization, which introduces actual cases including those where licenses for patent or trademark rights successfully led to gaining profit or recognition. These case studies intend to contribute to the development of strong business strategies and the enhancement of corporate value. They share various forms of IP licenses as examples and are highly appreciated by Japanese IP users as reference material providing helpful guidance when attempting to utilize IP licenses.

241. Licensing is an important issue in the field of copyright as well. The Agency for Cultural Affairs (ACA) in Japan has provided on its website "Contract Preparation Support System for Copyright Licensing" that semi-automates the creation of a contract template so that even those who are not familiar with copyright licensing can easily make a contract concerning the copyright licensing. And in April this year, in order to respond to the recent situation of increasing production and secondary use of copyrighted works on internet platforms such as SNS, the system was renewed.

242. It is important for each stakeholder involved in the production and distribution of content to secure appropriately remuneration through contracts. From this point of view, ACA conducted a survey on the cases of international expansion in each of the fields of characters, animes, mangas, games, and drama films, and have prepared and published the case studies summarizing key points in copyright licensing. We hope that today's introduction will be useful to other Members. The delegation of Japan also looks forward to sharing experiences with other Members.

12.7 United Kingdom

243. We would like to thank the United States of America for drafting and presenting this paper and share some of the United Kingdom's experience in this area. Firstly, on the kinds of licensing that are possible in the United Kingdom for each right: in essence, a licence is an agreement between the IP right owner and another party. It grants them permission to do something that would be an infringement of the rights without the licence.

244. IP can be "licensed-out" or "licensed-in". The rights owner can "license-out" to another company in return for a fee. A business can "license-in" if it wants to use another company's IP to develop its own business and products. In the United Kingdom, licences can be for patents, trademarks, designs, and copyright as well as trade secrets/know how. Any licence arrangement, including any financial element, is made directly between the licensee and the right owner.

245. In the case of patents, the patent holder can request that the patent be endorsed with a "licence of right" in the register. This means that the owner must grant a licence to anyone who wants one. The licence will still be an ordinary, commercial licence and the terms and fees will be a private matter between the licensee and licensor. The main advantages of having a patent endorsed with a licence of right is that it lets other people know that the owner is willing to licence the patent. Annual renewal fees are also reduced to half the usual cost if the patent is endorsed with a licence of right.

246. Though notifying the UK Intellectual Property Office of the grant or assignment of a licence for patents is not mandatory, it is recommended and will be recorded in the patents register. Trademarks can also be licensed by the owner to give a licensee permission to use their registered mark. This can form part of a wider commercial arrangement, such as a franchise agreement. The terms of the licence are also between the licensee and the licensor, for example if the licence is exclusive, so the mark cannot be used by anyone else, including the registered owner, or limited to a particular geographical area. Again - notifying the UK Intellectual Property Office of the grant or assignment of a licence for a trademark is not mandatory but is recommended and will be recorded in the trademark register.

247. A design owner can give someone else permission to use their registered design by granting them a licence, and in this instance, notifying of the grant or assignment of a licence for registered designs is required and will be recorded in the designs register. Licences can also be granted for unregistered designs. In addition to usual licensing arrangements, a licence of right must be made available to third parties in the last five years of the term of protection for a UK unregistered design right.

248. A copyright owner may decide whether and how to license use of their work, and any licence agreed can relate to one or more of the rights granted by copyright, and can also be limited in time, geographical extent, or any other way. An exclusive licence can also be granted, which enables the licensee to use the copyright work in the manner specified by the licence to the exclusion of all others, including the copyright owner. Notably, licensing may be carried out by direct negotiation, or through agents or Collective Management Organisations (CMOs). A copyright owner may also

prefer to allow limited access to, and use of, their work without charge – and one way to do this is by using a creative commons licence.

249. In instances where a copyright owner is unknown or cannot be found, individuals or businesses may apply to the UK Intellectual Property Office for an "orphan works" licence. Subject to completion of a diligent search, and payment of appropriate fees, such a licence will be limited to the United Kingdom for a maximum length of seven years and will be non-exclusive. The paid licence fees are retained for eight years in case the right holder comes forward.

250. We would also like to note that the United Kingdom is also considering IP licensing as part of its futures programme, to anticipate potential evolution in the kinds of IP licensing that may occur due to emerging technologies and new business models. The United Kingdom would also like to briefly look at the benefits of IP licensing: when a company licenses the right to manufacture and sell products. the costs and risks are shared between the licensor and the licensee. The licensor will receive revenue from licensing but will not take the risk of manufacturing, promoting, or selling the licensed products. The licensee will have the right to use the IP without incurring the expense and risk of undertaking research, or the cost of developing the product.

251. Some of the potential benefits to the licensor will include increasing revenue by broadening the reach of IP into different markets. Market penetration would be increased by licensing another business to sell in territories that the owner cannot cover. Though exceptions and limitations exist within the IP framework, a licence usually provides a higher degree of business certainty than relying on an exception.

252. The potential benefits to a licensee include reducing research and development costs by "licensing-in" innovation. By taking a licence, a business may tap into expertise that it does not have in-house. A business may save time and get its products or services to market more quickly by acquiring a licence to use existing IP, rather than starting from scratch. Acquiring a licence to use existing IP may help a business obtain a competitive advantage over its competitors. So, both licensors and licensees can benefit from collaboration to develop new products and services, creating a highly beneficial partnership.

253. I hope that these highlights from how licencing of IP works in the United Kingdom have been of interest to Members, and I would like to again thank the United States of America for their paper on this topic.

12.8 European Union

254. The European Union delegation is pleased to co-sponsor this agenda item together with the Delegations of Hong Kong, China; Japan; Singapore; Switzerland; Australia; Chinese Taipei; Canada; the United Kingdom; and the United States of America.

255. We thank in particular the United States of America for its active role in the drafting of the document submitted today to the TRIPS Council. We also thank them for their full and constant involvement in the coordination of the Group. The Intellectual Property Rights (IPRs) play an increasingly important role in corporate strategy. The intangible assets created through innovation and creation represent a major share of the value of today's businesses.

256. At the last TRIPS Council in March, we focused on the access to finance and the role of IPRs, notably for the SMEs. On this occasion, we mentioned the EUIPO SME scoreboard of 2019 which states that only 13% of SMEs owning IP rights tried to use intangible assets to obtain finance: 9% successfully and 4% unsuccessfully. Additionally, only 25% of medium-sized IPR owners have professionally valued their intangible assets, and this drops to 20% for small and micro-sized IPR owners.

257. The IPRs associated with intangible assets are the legal guarantee for potential returns on investment in innovation and a means to get funding. IP assets are economic resources that have no physical presence and can include patents, trademarks, trade secrets, designs, or copyrights. Just like other assets owned by a company, IP assets have a value. Such assets have the capacity to be converted into higher profits and value for the company. However, quantifying that value can

be a challenge, notably for SMEs, and the valuation of IP, in particular industrial property, remains a major obstacle to IPR being considered as tradable assets, ready to be licensed.

258. The EUIPO, through its European Observatory on Infringements of IPRs has carried out some EU-wide studies on the subject of IP and financing, notably one dedicated to the licensing activities by SMEs. This Study focus more on trademark and design but other IPRs are covered, notably patent and copyright. It is worth noting that generally the studies or other surveys tend to focus on the large companies, ignoring the smaller firms, which are the backbone of the EU's economy. SMEs in general do not have a stock price or market valuation, this is why the valuation of IPRs in the EUIPO study is based on the objective results of a survey administered to SME owners of IPRs.

259. The general conclusion is that the economic benefit derived from licensing IPRs can be used to calculate the capitalised value of the IPRs as the total income expected to be realised over its economic lifespan. The revenues obtained from licensing any IPR is an annual flow received by a firm and can be used to estimate the value of the intangible asset represented by the ownership of the IPR. As said the capitalised value of an asset is the total income expected to be realised over its economic lifespan.

260. Licence agreements concluded by the European Union SMEs include mainly the use of European Union Trademarks (EUTM), but not only. The average total annual revenue from licence agreements (some firms declare more than one type of agreement) is in terms of annual averages EUR 68,929 per firm during the period 2013-2017. SMEs in the service sector are more likely to license out their EUTMs and earn higher revenues from those licences, both in absolute terms and relative to average turnover, than firms in the manufacturing and trade sectors.

261. Licences by micro firms represent a high share of their average turnover (around 29%) and are thus an important revenue source for such firms. The annual licence agreement is the type of licence associated with the highest annual revenue, followed by multiyear agreements and royalty deals. The annual estimated average revenue from licensing an EUTM during the period 2013-2017 is EUR 64,924, equivalent to 5.7 % of the average turnover for SMEs in the European Union. The estimated annual revenues from licensing out EUTMs during the period 2013-2017 by all SMEs is EUR 1.9 billion. The gross capitalised value of EUTMs licensed by SMEs along their entire expected life is EUR 38 billion.

262. I would like now to describe briefly one of programmes managed and financed by the EU which will aim at making the IP licensing more efficient: Toolbox for efficient IP licensing for market uptake and societal value creation (CSA). IP and use of different types of collaboration contracts, licenses and pooling agreements are key elements of the process by facilitating technology sharing, increasing scaling up and thereby creating new capacities and industries.

263. In line with the EU IP Action Plan and the Report on an IP action plan to support EU's recovery and resilience by the European Parliament, this action will promote better IP management in research and innovation in view to materialise excellent research into innovation that is benefitting the society and businesses in the EU.

264. The proposals included in this Toolbox are expected to contribute to promote effective use and deployment of IP ensuring easier access to and sharing of IP-protected assets. It also provides models to improve the preparedness to respond to future emergencies via efficient technology licensing.

265. This IP toolbox will help companies, public research organisations including universities and the relevant intermediary entities to establish quick and efficient co-operation and licences with businesses, as well as practical examples of incentives which can motivate private sector to commit voluntary licensing for other areas e.g., climate change emergency.

266. This action will harvest the lessons learned as well as practical experiences and assess how these new practices and tools could be transferred to other emergencies e.g., addressing climate change effects (floods, droughts, fires etc). and helping the society to increase preparedness for any future emergencies.

12.9 Switzerland

267. The Swiss delegation would like to thank the United States of America for introducing submission IP/C/W/691 for the TRIPS Council's discussion today. Switzerland is pleased to co- sponsor the agenda item, as well as the Submission addressing the opportunities of licensing IP rights. Licensing can be implemented for patents, copyright, trademarks, and designs. All IP owners are able to employ licensing in different ways and to various extents. In this sense, it is important to actively promote this topic and understand the dynamics and the needs of the participants in this ecosystem.

268. Licensing plays a central role for many intermediaries in the IP ecosystem and can be implemented in different ways and for various reasons. The importance of the issue for the Swiss economy is most evident in the trade of services. Services account for more than a third of total Swiss foreign trade and have increased sharply in the last decade. In terms of exports in the service sector, license fees for the use of IP are the most important with a share of 23% and, along with R&D, demonstrate the highest growth. Licensing fees also account for 14% of imports.[5] In this context, licensing is used by spin-offs, artists who want to spread their work to a larger audience and large companies that are active at the international level. There exist no specific obligations on licensing contracts in Swiss legislation; the parties to a licensing agreement are free to negotiate all aspects of it. Due to the diversity and freedom in licensing, there are different services available to provide assistance during the licensing process.

269. Firstly, at Swiss universities, technology transfer offices manage and negotiate the terms and conditions for the licensing of IPRs. Secondly, in the area of copyright protection, five collective management organizations help to make licensing more efficient. The technology transfer offices and the collective management organizations use their knowledge to help design an optimal licensing strategy and support the actual rights holders in the respective area.

270. The Swiss Federal Institute of Intellectual Property (IPI) conducted a study on IP support services for SMEs which not only examined the existing IP services, but also the needs of SMEs and close intermediaries. In this context, those surveyed highlighted the importance of active licensing – not only for generating revenue but also for encouraging collaboration and taking advantage of synergies between partners with different key competencies. However, the study also highlighted a number of challenges associated with licensing. As mentioned, under Swiss legislation, license agreements, which are *sui generis* contracts, can be freely negotiated between the parties, which can put smaller, inexperienced companies at a disadvantage vis-à-vis larger partners with the support of legal departments specialized in the field. Therefore, some participants in the study asked for legislation that provides standard solutions and binding templates for licensing agreements. This in turn is considered undesirable by other stakeholders who emphasize the individual features licensing contracts should be able to incorporate in order to appropriately reflect the needs of different partners in a specific license agreement.

271. The IPI is also active in respect of awareness raising. With regard to the previously mentioned challenges, the IPI recommends that businesses and organizations retain a specialized attorney for negotiating and writing licensing contracts. A list of specialists in this field is available on the IPI website, which should help right holders to work out the best possible licensing strategy for their needs.[6] General information as well as a checklist with the most important considerations for a licensing strategy are also available on the IPI's website. For Swiss IP specialists and patent attorneys, the IPI offers specific training modules on the subject of licensing.[7]

272. Licensing can provide tremendous opportunities for a wide variety of businesses and is applicable for all IP rights. Due to the wide variety in licensing contracts, it is important to identify the needs of a specific organization first in order to use this legal instrument in a beneficial and efficient manner. We are looking forward to learning from the other delegations on their national experience and to sharing best practices with one another. We would like also to thank all the Members that have already made a statement on this agenda item.

[5] Die Volkswirtschaft. 2021.
[6] IGE Checkliste. 2022.
[7] IGE Modul. 2022.

12.10 Canada

273. Canada is pleased to take part in today's thematic discussion on "IP licensing opportunities", under the agenda item of "IP and innovation". Canada would like to thank the United States of America for drafting the discussion paper for this topic under document IP/C/W/691, as well as the co-sponsors for their valuable insights today regarding national experiences on the topic of IP licensing. Canada would be also pleased to take this opportunity to share some initial reflections and national experiences on this topic.

274. As the discussion paper for this topic sets out, and as some delegations have already noted today, if a creator or innovator has an idea that is commercially viable and possesses the IP rights necessary to enter the market, a key consideration is to decide how to do so. Of course, one option is to sell IP-protected goods or services directly to customers, or indirectly by way of an online platform. Similarly, an innovator or creator may decide to develop an export strategy and to sell their goods or services to other markets, in order to reach an even broader and global consumer base. However, for those creators and innovators that do not have the resources to manufacture and sell their IP-protected goods and services directly, such as small and medium-sized enterprises (SMEs), IP licensing can serve as an important strategy for those seeking to commercialize their ideas and bring them to market. IP licensing can also be an important tool for businesses that may need to license goods or services as inputs into production along a value chain. Licensing can also be useful for those SMEs seeking to enter a foreign market, where it may be easier to operate with a local licensee.

275. Ensuring that IP rights holders, including SMEs, have the appropriate educational tools and resources at their disposal is important in helping them decide which forms of licensing may be best suited to their particular IP strategy. As noted in previous meetings of the TRIPS Council, the Canadian Intellectual Property Office (CIPO) recently launched an online IP academy, which features a suite of informational materials and interactive learning resources for businesses and entrepreneurs. Notably, for the purposes of today's discussion, the IP Academy includes a recently- developed "Massive Open Online Course" on the "Foundations of IP Strategy", as developed with the Canada-based Centre for International Governance Innovation, which offers a learning module on the topic of IP licensing. This learning module, which is available for free online at the website cigimooc.org, provides an overview of IP licensing agreements, including basic principles to consider when entering into a licensing agreement, IP licensing agreements as they related to specific types of IP, overviews of innovative licensing approaches like creative commons and open-source licensing, and general considerations for enforcing IP licenses.

276. In addition, CIPO also maintains an online web resource on IP licensing, which provides an overview of licensing types, including exclusive and non-exclusive licenses, as well as sole licenses. This resource also provides important considerations for both licensors and licensees, such as on common forms of licensing payment, as well as on topics like sub-licensing and franchising. While today's thematic discussion may not permit time to go into detail on each of these interesting topics, we would encourage interested delegations to visit CIPO's dedicated web page on this topic online, by searching for the title "Ways to take your idea to the market" and CIPO.

277. Finally, Canada would like to briefly draw attention to the ways in which governments can encourage and facilitate the licensing of IP, including by way of resources to help increase awareness of available IP among prospective licensees. For instance, in August 2019 as part of Canada's national IP Strategy, the Department of Innovation, Science and Economic Development (ISED) launched ExploreIP, an IP marketplace tool for tool to help businesses, creators, entrepreneurs and innovators discover IP held by public sector institution. Through ExploreIP, users can easily contact IP holders to discuss and negotiate a licensing arrangement. Users can also use the database to locate and contact research organizations with technology relevant to a specific industry for potential collaborations.

278. In addition, Canada also maintains a dedicated web page on "Commercialization and licensing opportunities" in respect of technologies developed by ISED, the National Research Council, Agriculture and Agri-food Canada, and Defense Research and Development Canada. For instance, Agriculture and Agri-food Canada maintains online resources related to licensing opportunities for crops, environmental technologies, bioproducts and bioprocess technologies that are available for commercialization. Similarly, with respect to technology in emerging sectors like green technology, CIPO maintains a database of green technology patents, which provides details on patents granted

in this area. Online marketplaces and related resources can serve as useful tools for prospective licensees, helping collaborators identify the range of available opportunities for licensing, as well as providing innovators and creators with a platform to reach a broader base of potential collaborators.

279. Canada would again like to thank the co-sponsors of this informative topic, and other Members for sharing their valuable insights and national experiences on IP licensing as part of today's thematic discussion. Canada would be pleased to share any of the above-noted resources with other delegations upon request and looks forward to informally exchanging further insights with other Members on this topic going forward.

12.11 Hong Kong, China

280. The paper before us today provides an overview of possible licensing across a range of IP assets, including patents, copyright, trademarks, and know-how. Licensing is one of the most dynamic forms of IP trading which enables more flexible and diversified use of IP rights, thereby unleashing fully their economic value. The creativity of international licensing agents and licensees can often turn a popular cartoon figure or a trendy graphic into a wide range of merchandise products ranging from clothing, stationeries, houseware to games.

281. As one of the co-sponsors of the paper, I would like to briefly share the IP licensing landscape in Hong Kong, China. Hong Kong, China positions itself as a regional IP trading centre. We have a sound legal system, sophisticated financial markets, world-class professional services, close ties with the Mainland of China, as well as rich experience and expertise in working with the rest of the world. We also provide robust protection for IP rights. According to the 2019 Global Competitiveness Report released by the World Economic Forum, Hong Kong, China was ranked 5th out of 141 economies in terms of IP protection.

282. The relevant authorities in Hong Kong, China have been implementing a wide range of measures to promote IP commercialisation and IP trading. Such measures include:

a. Organising large-scale IP forums and licensing conferences, such as the Business of Intellectual Property Asia Forum to promote Hong Kong, China's competitive advantages in IP trading, as well as the Hong Kong, China International Licensing Show, and the Asian Licensing Conference to assist licensors and licensing agents to search for partners (i.e., match making) and look for business opportunities;

b. Supporting small and medium-sized enterprises, the backbone of the Hong Kong, China economy, by providing IP training programmes and free IP consultation service, assisting them in building up their IP manpower capacity and boost competitiveness through IP management and commercialisation;

c. Promoting the resolution of IP disputes through arbitration and mediation, as part of the wider effort to develop Hong Kong, China as an international legal and dispute resolution services centre. Among other things, amendments were made to the local laws to clarify that disputes over IP rights may be resolved by arbitration;

283. Looking ahead, the IP licensing landscape in Hong Kong, China will continue to thrive and evolve. We will continue to strengthen Hong Kong, China's role as a regional IP trading centre. We look forward to hearing from other Members their experiences in the field of opportunities in IP licensing.

12.12 China

284. China would like to thank the co-sponsors for their continued attention and efforts in the field of IP and innovation. The discussion on this topic would contribute to extensive exchanges among Members and hence help promote good practices. We would like to share our practices as follows.

285. The first is about patent open licensing. In IP licensing, under agreed terms and conditions, the IPR holders grant licensees use of patent for specific purposes within prescribed region and time. IP licensing could generally be categorized as general licensing, exclusive licensing, and sole licensing. In 2020, China carried out the fourth revision on the patent law, adding patent open

licensing system, which has been implemented since June 2021. The system is designed to facilitate relevant market players to obtain patent licensing and reduce transaction costs by solving the problem of information asymmetry between suppliers and demanders of patented technologies. In patent open licensing, a patent holder could voluntarily declare to competent authority in writing that he is willing to license any entity or individual to implement his patent and publish the announcement, then any entity or individual could gain the patent license by paying license fee according to the patentee's requirement. To date, China has carried out pilot projects in several provinces. 3,165 cases of patent open licensing from 72 universities and enterprises have been registered and then accurately matched with 18,631 small and medium-sized enterprises. Among them, the province of Zhejiang has achieved 118 licensing transformation projects, with a total of 306 small and medium-sized enterprises registered so far. Moreover, we will revise the implementing regulations of patent law to ensure effective implementation of patent open licensing system.

286. The second is about patent dispute settlement mechanism. In order to ensure the implementation of patent licensing system, China has established relevant dispute settlement mechanisms. For example, in July 2021, China established an early resolution mechanism for pharmaceutical patent disputes. This mechanism deals with patent dispute regarding drugs in the process of premarket review and approval, so as to protect the legitimate rights and interests of drug patent holders and reduce the risk of patent infringement after generic drugs enter the market.

287. The third is about trademark licensing. According to the trademark law, a trademark holder could allow another person to use his registered trademark by signing a trademark licensing contract. Where a registered trademark is used with permission, the name of the licensee and the origin of the goods must be indicated on the products. In order to standardize the relevant procedures, the competent authorities also issued guidelines, stipulating detailed provisions on trademark license filing procedures. China attaches great importance to IP protection and is on the way to implementing the intellectual property power strategy. We would like to from other Members so as to further the discussion in the future.

12.13 Chile

288. First of all, we would like to thank the sponsors for introducing this interesting subject for the consideration of Members. IP licensing is fundamental in promoting an ecosystem which favours innovation, and which serves as a tool for development. The various areas where this occurs in a country, as well as the intensity and frequency, have provided us with useful information to identify the strengths and weaknesses in national systems for promoting and transferring technology, knowledge diffusion, culture, and arts. In our case, trademark licensing is one of strongest areas in the country thanks to a high level of knowledge in the private sector. In terms of copyright and collected rights, we should mention the work of the collective management entities, which assist their members in the licensing process. We are of the view that in order to ensure a successful participation in the fourth industrial revolution, the use of science, technology and innovation is required in relevant areas to develop the public and private sectors in our country. Undoubtedly, licensing of patents and transfer of know-how are fundamental elements for achieving these objectives. With this in mind, the universities have strengthened their units and teams to foster the use of the knowledge generated in these universities by the productive areas of the country, and their strategies to protect these assets. We should note that, according to information provided by the National Institute of Intellectual Property (INAPI), universities submitted almost 20% of patent applications in Chile between 2000 and 2020. A successful system requires improving the knowledge and strategic value of industrial property knowledge for entrepreneurship and innovation, particularly in SMEs. This is why INAPI has provided advisory services on strategic management of IP assets and has advised more than 30 entrepreneurs in the Start-Up Chile Programme and ProChile. These trainings prioritize the strategic use of IP assets, focusing on their commercial use through licensing tools.

289. Finally, we would like to highlight a programme, which was launched in March this year by the national mining company, CODELCO, which is called "Open CODELCO". This programme allows selected companies, natural and legal persons, and organizations to access licenses to develop, use, manufacture and/or commercialize patents held by CODELCO in a mutual benefit framework. Listening to the good practices developed by other Members, as well as the challenges they are facing to realize the opportunities offered by licensing, is of fundamental interest for our delegation, and this is why we would like to reiterate our appreciation to the co-sponsors.

12.14 World Intellectual Property Organization

290. The World Intellectual Property Organization (WIPO) created a new sector in 2021 – the IP and Innovation Ecosystems Sector – that is designed to provide comprehensive support to member states and stakeholders in strengthening national innovation ecosystems. We provide support to national authorities in developing IP strategies and plans. The idea is to enable various stakeholders to leverage IP for bringing ideas to the market. We have programs that help innovators, research institutions, universities, knowledge and technology transfer organizations, incubators, and accelerators to protect and commercialize their innovations. We help start-ups and enterprises, especially small businesses, to increase their competitiveness through the use of IP, expand into new markets and utilize IP for securing capital. Our alternate dispute resolution services and support to judiciary help resolve disputes efficiently and often out of court, which saves time and money.

291. Licensing, and disputes over licensing relate to a number of areas of the Sector's work. The following three areas may be highlighted:

292. The IP for Innovators Department (IPID):

a. The Technology Transfer Section (TTS) of WIPO supports the overall delivery by the IP for Innovators Department and contributes specifically tailormade IP licensing technical assistance for the Member states.

b. The contributions include the assistance to Technology Transfer Offices (TTOs)/Universities, in the area of drafting their IP policies; the organization of trainings/online courses on IP licensing featuring world renowned experts (e.g. the Licensing Executives Society International (LESI)); the development of training materials, such as the Successful Technology Licensing Guide (STL Guide) - a user-friendly manual aimed primarily at the business community, technology managers and academia dealing with licensing in the course of their work.

c. In 2022, a review/update of the STL Guide was undertaken, and is planned to be disseminated by the end of the year. The revision aims to provide additional insights into recent information and highlight new trends in licensing and technology transfer that have emerged in the post COVID-19 period, particularly in the pharmaceuticals and biotechnology areas.

d. More information about TTS activities can be found here: https://www.wipo.int/technology-transfer/en/index.html.

293. The WIPO Arbitration and Mediation Centre:

a. A large part of the WIPO Arbitration and Mediation Centre (WIPO Centre)'s mediation and arbitration caseload relates to IP licensing agreements (including patents, trademarks, copyright and software), as well as Research and Development (R&D) and technology transfer agreements. Most of these cases are international in scope, and increasingly involve parties based in developing Member states.

b. The WIPO centre collaborates with relevant stakeholders and organizations in the development of Model Research and Development (R&D) Agreements including WIPO Mediation and WIPO Expedited Arbitration clauses, and regularly administers cases submitted under such clauses. This includes, for example:

   i. European Union: DESCA 2020 Model Consortium Agreement for the European Union research funding program Horizon 2020

   ii. Germany: Sample Agreements for Research and Development Cooperation by the Federal Ministry for Economic Affairs and Energy

   iii. Spain: Spanish Patent and Trademark Office (OEPM) Model Agreements

c. Nearly 15% of WIPO mediation and arbitration cases involve parties from the life sciences sector, including vaccines. As part of the WIPO COVID-19 Response Package, the WIPO centre has recently launched new ADR options to facilitate contract negotiation and dispute management in long-term life sciences licensing agreements and collaborations.

294. The IP for Business Division (IPBD): The work of the IPBD in particular, relates to tools, guides and clinics:

a. The IPBD develops easy to understand business-oriented tools and materials that enable small businesses and start-ups to understand the IP system and use it to support their business strategies. It's flagship series of guides is the IP for Business series of guides https://www.wipo.int/publications/en/series/index.jsp?id=181. These explain the different IP rights and how they may be identified, protected, exploited and managed. The latest in this series is a guide for start-ups taking the start up from idea to market and the intersection of IP in that journey. This is also supported by infographic that follows the contours of the guide. https://www.wipo.int/sme/en/enterprising-ideas/

b. IPBD also developed an online IP self-assessment tool https://www.wipo.int/ipdiagnostics/en/index.html which consists of two levels of questionnaires about different aspects of a business and the answer to these questions results in an automatically generated report which allows the user to get a preliminary idea as to the existence of IP assets, if they are protected and how they may be exploited. It is a preliminary step to developing an IP strategy. This tool is available in all United Nations languages and Japanese.

c. Another service provided by the division is the IP Management Clinics which brings together a select number of businesses, usually from a specific sector/industry, with the goal of assisting the companies to develop their IP commercialization strategy and provide them with guidance on how to use the IP system across the various stages of their business development from concept to market.

13 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

13.1 WTO Secretariat

295. 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.

296. Since our last report during the TRIPS Council Meeting in March, the following Trade Policy Reviews have taken place: United Arab Emirates, Pakistan, Switzerland and Liechtenstein, New Zealand and Ghana. During these reviews, delegations engaged in the discussions and sought further details on:

a. The domestic implementation of the TRIPS Agreement;

b. Institutional arrangements for the administration and enforcement of intellectual property;

c. Copyright and related-rights regimes;

d. Trademark regime;

e. Protection of geographical indications;

f. Patent regime;

g. Protection of new plant varieties;

h. Enforcement, online and at the border; and

i. Measures taken in response to the COVID-19 pandemic.

297. The Secretariat has also contributed with the chapters on Intellectual Property for the upcoming G20 and WTO wide Director-General's Monitoring Reports. We would like to thank Members and Observers that sent information about the measures that were implemented since October 2021. These inputs by delegations are essential in assisting the Secretariat to prepare the reports in the most accurate and comprehensive manner.

14 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

14.1 China

298. We would like to repeat our position on this issue. The relationship between TRIPS and the Convention on Biological Diversity (CBD) is an important issue in the TRIPS Council. Inviting the CBD Secretariat as an observer to the TRIPS Council will update the CBD Secretariat on the discussion and developments in the Council, and correspondingly help WTO Members better understand the principles, requirements and work of the CBD. We believe that the mutual support and deep communication between the CBD secretariat and the WTO will contribute to our discussion at the TRIPS Council.

299. Again, with regard to the South Centre, its role in serving the progress and development of developing Members has been widely recognized, and it has carried out numerous research in the fields of intellectual property, technology transfer and knowledge accessibility, which has enhanced developing Members' understanding and application of the TRIPS Agreement.

300. Therefore, China would like to reiterate our support for granting the CBD Secretariat and the South Centre observer status, at least on an *ad hoc* basis.

14.2 Bangladesh

301. Bangladesh supports that the CBD Secretariat and South Centre should be invited with observer status in the TRIPS Council.

14.3 Indonesia

302. Indonesia would like to reiterate our support to the request made by the South Centre and the Secretariat of the CBD to be accorded observer status at the TRIPS Council. We believe that a closer cooperation and liaison between the WTO and both organizations will enrich and mutually support each other's work accordingly.

14.4 Venezuela, Bolivarian Republic of

303. Venezuela reiterates its support to have these organizations be observers at the TRIPS Council.

14.5 United States of America

304. The United States of America cannot join the Members seeking to include the CBD or the South Centre as an Observer either on a permanent or *ad hoc* basis. The United States values the contributions of Member states and is satisfied with the current set of *ad hoc and* permanent observers. We do not see a gap that needs filling by adding new Observers at this time.

14.6 Egypt

305. Egypt supports the statements made to support the request made by the South Centre and CBD Secretariat to become observers at the TRIPS Council.

14.7 Tanzania, on behalf of the African Group

306. We echo the position of the African Group that we have been in support of granting observer status for these two organizations and our position has not changed and I would like to ask other Members to be flexible in granting these organizations the observer status, at least on an *ad hoc* basis as a starting point.

14.8 South Africa

307. We would like to, as made by the distinguish delegate of Tanzania on behalf of the African Group, once again express our support for the inclusion of these two entities and we also would like to indicate that our delegation has a great interest in having bilateral discussions with those which are not in a position to join consensus to admit these institutions because we feel it will be useful to have a better appreciation of the reasons and perhaps with the bilateral engagement we could seek to address any obstacles.

15 OTHER BUSINESS

15.1 Annual Review of the Special Compulsory Licensing System

308. No statements were made under this agenda item.

15.2 20th Annual Review under Paragraph 2 of the Decision on the "Implementation of Article 66.2 of the TRIPS Agreement"

15.2.1 WTO Secretariat

309. The Secretariat is now planning to organize the annual Workshop on the Implementation of Article 66.2 of the TRIPS Agreement in early 2023. The exact dates and programme will be communicated to Members at the later stage.

310. As you might recall that, to assist with the Secretariat's preparations for this annual workshop, we have invited LDC Members to answer a survey questionnaire on current areas of needs and priorities for technology transfer in their respective countries since 2021. Since then, we have received responses from 18 LDC Members. The detailed survey results have been presented to our Members in the annual workshops in 2021 and 2022. The survey results have been very valuable in guiding the Secretariat in preparing the annual workshop and to ensure that the workshop are grounded in the practical needs of the LDC Members concerned.

311. At the TRIPS Council's meeting of March this year, the LDC Group requested the Secretariat to compile a list of priority technologies as identified by the LDCs in the annual workshops, as well as in the survey questionnaire and to report this to the next TRIPS Council meeting. They also indicated that the information provided should be of use to the Secretariat in designing future technical assistance programmes, and to the reporting countries for their attention.

312. Upon this request, the WTO Secretariat has started to compile these responses received from 18 LDC Members. After the consultation with the LDC Group, we have circulated the updated survey questionnaire among LDC Members and invited them to answer the questionnaire by 2 September 2022 through their respective permanent missions in Geneva. This will allow the Secretariat to have a sufficient time to prepare a comprehensive compilation of the survey results and to prepare the workshop the programme according to the needs and priorities identified by the LDC Members. It will also enable the reporting countries to have sufficient time to prepare their contributions to this annual workshop.

313. Last, I would like to emphasise that the survey questionnaire is an optional tool to assist with preparations for the annual workshop. It has no bearing on WTO Members' rights and obligations under the WTO TRIPS Agreement.

15.3 Work Programme on Electronic Commerce

314. No statements were made under this agenda item.

15.4 Date of Next Meeting

315. No statements were made under this agenda item.