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

# MINUTES OF MEETING

HELD IN THE CENTRE WILLIAM RAPPARD ON 12-13 OCTOBER AND 15-16 DECEMBER 2022

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

*Addendum*

The present document contains the statements made during the Council for TRIPS meeting held on 12-13 October and 15-16 December 2022.

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**AT THE MEETING OF COUNCIL FOR TRIPS 12-13 OCTOBER AND 15-16 DECEMBER 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 Thailand

1. Thailand thanks the WTO Secretariat for circulating and assisting us in preparing the notification IP/N/1/THA/6 referring to the notification of the Ministry of Commerce regarding the determination of counterfeit goods and pirated goods as goods prohibited from export, import and bringing in transit, which entered into force on 29 July 2022.

2. This notification of the Ministry of Commerce was intended to modernize and streamline the legislation and procedures for the determination of counterfeit goods and pirated goods as goods prohibited from export, import and bringing in transit, in line with relevant international agreements to which Thailand is a party including the TRIPS Agreement and the recent Regional Comprehensive Economic Partnership Agreement, in order to strengthen border control measures to combat intellectual property rights infringement more efficiently. Kindly refer to the notification for details, including the translation of the legislation.

3. To conclude, I would like to reiterate Thailand's commitment to fulfilling its obligations under the TRIPS Agreement to ensure efficient protection and enforcement of IP rights.

## 1.2 Seychelles

4. The Seychelles first would like to thank the Secretariat for the assistance provided in processing the notification IP/N/1/SYC/11 and IP/N/1/SYC/O/4. The Seychelles Fair Trading Act, 2022 (Act 12 of 2022), entered into force on 1 August 2022 and was notified to the WTO on 29 July 2022 under Article 63.2 of the TRIPS Agreement (other Laws and Regulations). A little background in the notifying text. The Government of Seychelles, through the Fair-Trading Commission, sought funding for a consultant to address the shortcomings of the previous Fair- Trading Acts, following which a report with feedbacks were provided, and the draft Fair-Trading Bill was prepared.

5. An Independent Fair-Trading Tribunal was set up as an effective redress mechanism for all consumer and competition cases and chaired by a chairperson who is a full-time magistrate. The investigative powers of the Commission have been enhanced to create a new level of enforcement. In that pursuit, this Act repeals the Fair-Trading Commission Act (Cap 267), the Fair Competition Act (Cap 266), and the Consumer Protection Act (Cap 257).

6. Seychelles does not foresee any substantial changes in the immediate future, as this new Act will give confidence to businesses through the provision of consistent application, enforcement, and adjudication of competition and consumer matters.

7. The main elements of the new Act: The Fair-Trading Commission is the central institutional organ for the effective administration of the Act. The Commission is tasked with several functions, including enforcing compliance with the Act; advising the Government on laws affecting fair trading, competition, and consumer protection, and making recommendations to the Government on the actual or likely anti-competitive effects or consumer protection issues that arise out of the implementation of the Act.

8. It establishes the Fair-Trading Tribunal to deal with appeals against the decisions of the Commission's complaints of alleged prohibited conduct, applications for breaches of undertakings, and applications for the authorisation or permission of proposed mergers recommended by the Commission. The introduction of the Fair-Trading Tribunal is not only commendable as a principle of best international practice but is also good for democracy and the rule of law.

9. In case of consumer protection and fair competition, the Act extensively makes provisions for the protection of consumer protection rights. Accordingly, it protects, amongst many others, the rights to fair, just, and reasonable terms and conditions, disclosure of information, fair and responsible marketing, fair and honest dealing, choice, safety, fair value, good quality, and safety for the performance of services and supply of goods.

10. Regarding fair competition, the Act makes provision for, among others, the abuse of a dominant position, restrictive horizontal and vertical practices, mergers, and factors to be considered for determining the aforementioned practices and market inquiries.

11. Offenses and penalties for contravening the provisions of the Act are also clearly specified in the Act. Finally, the Act mandates the minister responsible for trade in consultations with the Fair-Trading Commission to make regulations for all matters which are required or necessary to be provided for in giving effect to the provisions of the Act.

12. Briefly about the main features of the Act:

a. it is tailor-made and recognises the particular circumstances of Seychelles;

b. considers tried and tested mechanisms, draws on their successes, and learns from their failures;

c. provides for the imposition of a fixed penalty in certain cases;

d. strengthened and included additional enforcement provisions;

e. increase in penalty quantum;

f. introduction of a corporate immunity provision which is an effective tool to fight cartels;

g. introduces more provisions into regulations for greater flexibility given the dynamics of competition and consumer laws;

h. exclusion of financial consumer protection from the Bill;

i. remitting the final decision on mergers in the financial sector to the Central Bank and other regulatory financial bodies;

j. provides for a tribunal rather than a Board of Commissioners for an accessible, effective and efficient system of redress for consumers and businesses;

k. Any decision or order of the Tribunal may be served, executed, and enforced in the same manner as a judgment or order of the Supreme Court under the Seychelles Code of Civil Procedure (Cap 213);

l. provides a mechanism for continuity so that the current unheard cases before the Board of Commissioners can be heard;

m. Introducing a cap of SCR 5 million on complaints for consumer protection;

n. Time limitation on bringing complaints to the Commission reduced from three years to two years.

13. In term of next steps, in order to ensure the full functioning of the Fair-Trading Act 2022, new regulations are required under the new Act. These regulations are being drafted, and as such, we expect they will be available by the end of December 2022.

14. In order to ensure transparency, these regulations may be shared with WTO Members at the appropriate time.

### 1.3 European Union

15. The European Union is pleased to present to you the regulations and measures adopted in the area of GIs, and more particularly of GIs concerning the European Union itself. I am going to hand over the floor to two people and I will then take the floor again as we are also going to cover, on behalf of Italy and France, the regulations and laws that have been passed in these two countries. I

now hand over to Mr. Klaus Blank of the Directorate General for Agriculture of the European Commission.

16. As regards the European Union notification IP/N/1/EU/38: this is Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December 2021 amending Regulations (EU) No 1308/2013 establishing a common organization of the markets in agricultural products, Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, Regulation (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatized wine products and Regulation (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union.

17. The text of the regulations modifies the primary EU legislation on geographical indications in the sectors of food, wine and aromatized wines and the EU legislation on traditional specialities guaranteed. Regulations (EU) No 1151/2012 on Geographical Indications in the food sector and on Traditional Specialities Guaranteed, Regulation (EU) No 1308/2013 (for the part concerning Geographical Indications in the wine sector) and Regulation (EU) 251/2014 (for the part concerning Geographical Indications in the aromatized wines drink sector) have been modified. The new rules affect the scope, the definitions, the content of the product specification, the procedures for registration, amendment and cancellation, the extent of the protection, the labelling, the use of logo and the checks of the Geographical Indications (GI) in wine and food sector. Procedures for registration and amendment of Traditional Specialities Guaranteed in the food sector have also been modified. The Aromatized Wines GI sector has been merged into the food GI sector. The Regulation entered into force on 7 December 2021.

18. Second, as regards to document IP/N/1/EU/39 this concerns the Commission Delegated Regulation (EU) 2022/891 of 1 April 2022 amending Delegated Regulation (EU) No 664/2014, supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules.

19. The text of this delegated regulation modifies the existing Commission Regulation (EU) No 664/2014, which is the Commission Delegated Regulation of the Regulation of the European Parliament and of the Council (EU) No 1151/2012 on geographical indications in the food sector, which has been amended by Regulation (EU) No 2021/2117. In particular, the text concerns specific rules for applications for approval of Union amendments and for approval and communication of standard and temporary amendments. This Regulation entered into force on 11 June 2022.

20. Finally, as regards the notification in document IP/N/1/EU/40 this concerns the Commission Implementing Regulation (EU) 2022/892 of 1 April 2022 amending Implementing Regulation (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs.

21. The text of that Commission Implementing Regulation modifies the existing Commission Regulation (EU) No 668/2014, which is the Commission Implementing Regulation of the Regulation of the European Parliament and of the Council (EU) No 1151/2012 on geographical indications in the food sector, which has been amended by Regulation (EU) No 2021/2117. In particular, the text concerns specific rules for applications for approval of Union amendments and for approval and communication of standard and temporary amendments, for the use of specific digital system of managing the applications and communicating with the Commission, and for the establishment of the electronic register. This Regulation also entered into force on 11 June 2022. I will now hand over to a colleague.

22. Good morning, colleagues. It will be me who will present the notification by Italy that I think was circulated in the meantime, and Pierre-Yves, my colleague from Brussels, will then introduce after me the French notifications. So, as regards the Italian notification, Italy is notifying several pieces of legislation affecting IP covering a wide time frame from 2001 until 2020. Some of these legislative pieces have been taken recently, to adapt the legislation to technological improvements or to introduce new digitalized and streamlined administrative procedures for applicants. Other instruments were adopted some years ago to improve judicial or administrative procedures or to implement EU directives at national level. Some of the acts notified relate to primary law (laws or

legislative acts), some others relate to regulations or implementation acts, mainly aimed at procedural and operational improvements. The overall objective is to modernize and simplify substantive IP rules and procedures in line with the international and European practice and standards.

23. I will start with the notification IP/N/1/ITA/6. The most relevant and recent modification took place in 2019 with the Ministerial Decree of 13 November, concerning a new examination procedure for international applications for patents. This new procedure allows the Italian patent office to examine an international patent application designating Italy as the country of protection. Previously, an international application for a patent to be protected in Italy had to be submitted only through the European Patent Office. This is an improvement in the application of the "Patent and Cooperation Treaty" of WIPO and an additional option for international businesses seeking patent protection in Italy.

24. The next notification is IP/N/1/ITA/8. In 2020, the Industrial Property Code of 2005 was amended by the Legislative Decree No. 34 of 19 May as regards the historic national brand. The procedure introduced in 2019 concerning companies owing historic national brands deciding to relocate abroad was repealed, together with the corresponding support fund.

25. The next notification is IP/N/1/ITA/7. A decree of 3 April 2018 established the on-line platform named "PAGO PA" for the online payment of the administrative fees related to most administrative procedures of the Italian Patent and Trademark Office. This makes available a digital payment, whereby before the payment was possible through bank transfer or postal bulletin.

26. The next notification is IP/N/1/ITA/4. In 2003, a legislative decree of 27 June established, in civil tribunals and courts of appeal, 12 divisions specialized in industrial and intellectual property. In 2012, the specialized IP divisions were increased to 21. This amendment allows judicial cases concerning IP rights to be reviewed directly by competent IP judges, speeding up the judicial procedure and better serving business interests.

27. The next notification is IP/N/1/ITA/9. In 2001, Italy transposed the EU Directive 1998/71 concerning the legal protection of industrial designs. National provisions dating back to 1940 were modified in the substance and in procedures. New definitions of design, industrial model and industrial design were introduced, as well as a definition of access to the public. A reference to the Locarno international classification for design applications was also introduced. Finally, registration requirements and criteria were changed and modernized in line with the EU framework.

28. The penultimate notification is IP/N/1/ITA/5. In November 2019, a joint ministerial decree was adopted: it introduced new procedures for the registration of new plant varieties and a new method to pay the related fee. This implementing decree improved and streamlined the procedures to register new plant varieties.

29. Last but not least IP/N/1/ITA/3. In March 2020, Italy enacted a law with provisions for the organization of the winter olympic and para-olympic games in Milan and Cortina d'Ampezzo in 2026. Such law contains also a provision concerning the prohibition of activities of ambush marketing and misleading advertising. These activities are prohibited on the occasion of sport events or trade fairs of national or international relevance if they are not authorised by the organising bodies and when they are aimed at gaining an economic or competitive advantage. The prohibition aims at preventing unfair competition in marketing and advertising during big sport events. That's all from me and I give the floor to my colleague Pierre-Yves.

30. Now the regulations and legislation that have been adopted by France, from IP/N/1/FRA/2 to IP/N/1/FRA/17. I will illustrate these notifications with four laws: The "Pact" Law No. 2019/486 of 22 May 2019 on the growth and transformation of companies and its implementing regulations introduce various measures to modernize and safeguard the intellectual property framework in France:

a. Some measures concern patents: filing of a provisional application for a patent to facilitate access to intellectual property, particularly for SMEs and start-ups; creation of an opposition procedure before the intellectual property office and strengthening of the patent substantive examination procedure to ensure greater legal certainty.

b. Other measures concern trademarks and stem from the transposition of EU Directive No. 2015/2436 to approximate the laws of the Member States relating to trademarks: creation of new types of trademarks (sound, motion (animated) or multimedia); changes to the opposition procedure and creation of a procedure for the invalidation or revocation of trademarks before the intellectual property office.

31. The second law I would like to present to you is Law No. 2018/670 of 30 July 2018, which transposes Directive No. 2016/943/EU of 8 June 2016 on the protection of undisclosed know how and business information against their unlawful acquisition, use and disclosure. Order No. 2018 341 amends the French Intellectual Property Code to ensure that French legislation is compatible with European regulations on the unitary patent and the Agreement on the Unified Patent Court.

32. Lastly, other legislation notified concerns copyright: Law No. 2019/775 of 24 July 2019 creates a right related to copyright for the benefit of news agencies and press publishers; Law No. 2021 1382 of 25 October 2021 on the regulation and protection of access to cultural works in the digital age aims to better protect creators' rights (by providing for a system for blocking or dereferencing mirror sites and an ad hoc interim mechanism to tackle sports streaming websites); and Order No. 2021 1518 introduces mandatory exceptions to copyright in order to allow for text and data mining, digital uses of works for the purposes of illustration for teaching, and the preservation of cultural heritage. With this, we have finished with the EU notifications, including those from France and Italy.

### 1.4 Chinese Taipei

33. The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to make a brief introduction of our three notifications circulated recently. The first one is IP/N/1/TPKM/33 (Amendments to the Patent Act). In compliance with the Patent Linkage System introduced into the Pharmaceutical Affairs Act and implemented on 20 August 2019, Article 60-1 of the Patent Act was added to stipulate the legal basis for patent holders to sue generic drug manufacturers that make a P4 declaration for patent infringement. The Article also provides that in a case where a patent holder does not file a suit within the stipulated time period, the generic drug manufacturer may file a declaratory judgment to ascertain whether any infringement has occurred.

34. The second one is IP/N/1/TPKM/34 (Amendments to the Copyright Act). The amendments to the Copyright Act were ratified in response to digital technology advancements that have boosted education results, the increasing need for digital school bags, and the objective to digitize collections and provide digital services within libraries - promoting knowledge equity and meeting the needs of our current education policy in the digital age.

35. The third one is document IP/N/1/TPKM/35 (Amendments to the Copyright Collective Management Organization Act). The amendments to the Copyright Collective Management Organization Act were made to ensure smooth operation, increased transparency, and prudent management of our collective management system. Provisions added stipulate the need for internal controls to manage personnel, finances, operations, etc. within CMOs and set forth the competent authority's supervision mechanism and the penalty clauses envisaged for the CMOs' non-compliance with its provisions. The amendment has strengthened TIPO's supervisory and guidance capacity, providing it the power to revoke CMOs' establishment permit and order the dissolution of any not adhering to prudent management practices.

### 1.5 Brazil

36. Allow me to make a brief introduction of Brazil's notification IP/N/1/BRA/10. In general terms Law 14200 of 2 September 2021 which has been notified, amends Article 71 of Law 9279 which is the Brazilian Industrial Property Law. This revision is part of an effort from the Brazilian Government to update and reinforce our national framework of intellectual property and should be read together with other notifications made to this Council such as IP/N/1/BRA/7 and IP/N/1/BRA/8. The 2021 Law that has been notified now, regulates the employment of temporary non-exclusive compulsory licences on patents under specific conditions, such us during states of national or international emergency or public calamity. It further details internal procedures for identifying instances where compulsory licenses may be applied.

### 1.6 Ukraine

37. Ukraine would like to present its notification of the Law No 2174-IX adopted to the purpose of protecting intellectual property interest of stakeholders during the martial law regime. We would like to reiterate that the martial law was imposed in Ukraine on the 24 February 2022 due to the unprovoked and unjustified military aggression by the Russian Federation against Ukraine. It has been prolonged for the fourth time because of ongoing escalation of the Russian Federation's military aggression with the use of terrorist methods by Russian troops in the territory of Ukraine, delivering missiles and artillery attacks on our infrastructure and civilians, holding fake "*referenda*" in the occupied territories of Ukraine and recent announcement of Russia Federation's mass mobilization.

38. Just last Monday 10 October the whole world had witnessed the unprecedented terrorist attack by the Russian Federation. While more than 80 missiles were launched into 20 cities all over the territory of Ukraine. The launch of the Russia Federation's war led to disastrous repercussions, huge human suffering and losses, adversely affected all economic activities, including in the field of intellectual property, causing uncertainty and lack of understanding relating to possibilities of proper application of established procedures concerning maintenance and requisition of intellectual property rights during the war time.

39. To protect intellectual property interests of right holders and applicants, on the 1 April 2022 Ukraine adopted the above-mentioned Law. It refers to all categories of intellectual property. Its provisions provide for peculiarities for maintaining the validity, terms of use and enforcement of intellectual property rights during and after the state of war. The Law also suspends deadlines for examination procedures of applications as well as for other actions related to granting of intellectual property rights during the martial law regime. The Law entered into force on the 13 April 2022. It is effective now and it will be in force until the Russian Federation stops the war once and for all.

40. To conclude, we would like to reassure WTO Members that, despite the brutal war launched by the Russian Federation, Ukraine is doing its best to ensure efficient protection and enforcement of intellectual property rights, developing the Ukrainian intellectual property system in accordance with the international commitments, as well as by improving its institutional capacities. The government of Ukraine will also continuously fulfil its obligation to ensure the transparency of our intellectual property legislation.

### 1.7 Saudi Arabia, Kingdom of

41. Our delegation does not intend to make any statement about its notification today but we would be happy to receive any question about it.

### 1.8 Tonga

42. I thank the Council for the opportunity to provide a brief introduction on Tonga's notification under Article 63.2 reference IP/N/1/TON/2 to 10. This also serves to update Members of Tonga's notification since the 2 June 2009 reference IP/N/1/TON/1. Amendments to legislation vary from minor modifications, such as reaffirming the minister responsible, the short title and commencement date, to modifications such as that under the Industrial Property Act to ensure compliance with WTO commitments under the TRIPS Agreement.

43. Title one: Customs and Excise Management Act [Chapter 11.03] (2020 Revised Edition). First notification under the TRIPS Agreement. In the Act, Section 2 elaborates on the Interpretation of "counterfeit goods" while Section 94 outlines the penalties for importing or selling counterfeit goods.

44. Title two: Protection of Layout-Designs (Topographies) of Integrated Circuits Act [Chapter 17.13] (2020 Revised Edition). 2020 Revised Edition includes all amendments made before 30 October 2020. Amendments included:

a. Act 18 of 2002 Amended by Act 5 of 2012

b. Modification of Short title to commence as of date 30 July 2012

c. Commencement of Act is 1st September 2008

d. "Minister" means the minister of labour, commerce and industries modified to read "Minister" meaning the minister responsible for commerce; and

e. "Registrar" means the Registrar of Industrial Property, holding office, under the Industrial Property Act 4.

45. Title three: Protection of Layout Designs (Topographies) of Integrated Circuits Regulations [Chapter 17.13.01] (2020 Revised Edition). Tonga's notification under 63.2 in 2009 stated that draft regulations were still being finalised. This regulation includes all amendments made before 30 October 2020 and are made under section 21 of the Protection of Layout-Designs (Topographies) of Integrated Circuits Act [Chapter.17.13]. The Regulations provide for the payment of fees in connection with applications for the registration of layout-designs of integrated circuits and matters related thereto. Commencement date of Regulations is 8 December 2009.

46. Title four: Protection of Geographical Indications Act [Chapter 17.12] (2020 Revised Edition). 2020 Revised Edition includes all amendments made before 30 October 2020. Amendments included:

a. Act 17 of 2002 amended by Act 5 of 2012

b. Short title

c. Commencement date of Act is 1 September 2008

d. "Minister" means the minister of labour, commerce and industries was modified to read "Minister" meaning the minister responsible to commerce

e. "Registrar" means the Registrar of Industrial Property holding office in terms of section 37 of the Industrial Property Act.

47. Title five: Protection of Geographical Indications Regulations Chapter 17.12.01 (2020 Revised Edition). Tonga's notification under 63.2 in 2009 stated that draft regulations were still being finalised. This regulation includes all amendments made before 30 October 2020 and is drafted under section 20 of the Protection of Geographical Indications Act [Chapter. 17.12] to provide for the payment of fees in connection with applications for the registration of geographical indications and matters related thereto. Commencement date of Regulations it is 8 December 2009.

48. Number six: Industrial Property Act [Chapter 17.07] (2020 Revised Edition). Tonga's notification under 63.2 in 2009 stated that an Industrial Property Amendment Bill 2009 was still being finalised. 2020 Revised Edition includes all amendments made before 30 October 2020. Amendments included:

a. Act 5 of 2012

b. In section 2, replace the word "Minister" and its definition with ""Minister" meaning the minister responsible for commerce"

c. Act 6 of 1999

49. Section 46 of the Principal Act is amended: firstly by inserting the following new subsection as subsection (1A) which reads: (1A) Notwithstanding subsection (1), the Registration of United Kingdom Trademarks Act is deemed to be in force as from 31 January 1997 until the Minister notifies in the Gazette a date for regulations under this Act to come into force." And in subsection (2):

a. by deleting the commas and words "on the date of entry into force of this Act," in line 1;

b. by deleting the words "entry into force of this Act" in line 5 and substituting therefor the words "the repeal of the United Kingdom Trademarks Act".

50. Title seven: Industrial Property Regulations [Chapter 17.07.01] (2020 Revised Edition). First notification. 2020 Revised Edition includes all amendments before 30 October 2020. These Regulations are made under section 44 of the Industrial Property Act [Chapter 17.07] made on 8 October 1998. Amendments included:

a. Substituted by 2010 amendment Regulation.

b. The first schedule of the industrial property regulations 1998 is then repealed and replaced by the new schedule of payable fees in respect of the matters such as Patents and Utility Model Certificates, Industrial Designs, Marks and general.

51. Title eight: Copyright Act [Chapter 17.05] (2020 Revised Edition). 2020 Revised Edition includes all amendments before 30 October 2020. Act 17 of 2002 amended by Act 5 of 2012. Amendments included:

a. Modification to the Short title

b. Commencement date of Act 1 September 2008

c. Also modified was and I quote "The Minister responsible for copyright may, with the consent of Cabinet, make Regulations for the implementation of the purposes and provisions of this Act" was modified to read "Minister responsible for commerce".

52. Lastly, title nine: Protection Against Unfair Competition Act [Chapter 17.11] (2020 Revised Edition). 2020 Revised Edition includes all amendments before 30 October 2020. Amendments included:

a. Modification to the short title to commence as of date 30 July 2012

b. Commencement date of Act modified to 1 September 2008

53. Should you have any questions, I kindly ask to provide written questions to submit to capital.

### 1.9 Russian Federation

54. My delegation did not plan to intervene on this item of the agenda, however I wanted to attract the attention that unfounded and misleading political statements made by some Members, especially artificially integrated in this item agenda one more time, are out of mandate of this TRIPS Council. We consider such practice inappropriate; they impede the work of the Council. My delegation asks you Mr. Chairman to take appropriate measures.

### 1.10 European Union

55. The European Union just wanted to support the Ukraine in condemning in strongest possible terms the brutal, unprovoked and illegal invasion and war that the Russian Federation unleashed in Ukraine. The recent Russian blind, senseless and terrorist attacks on non-military targets including universities and children's playgrounds are particularly despicable. These terroristic attacks reflect the true nature of what the Russian Federation calls a "special military operation".

### 1.11 United States of America

56. The United States of America also wanted to speak in support of Ukraine. We reiterate our condemnation of Russia's brutal, unprovoked and unjustified war of aggression against Ukraine. The Russian Federation is solely responsible for the catastrophic loss of lives and human suffering in Ukraine and for rising threats to food security around the world, particularly in developing countries. The United States will continue to support Ukraine's courageous efforts to defend itself, uphold its territorial integrity and protect its population. We call on the Russian Federation to immediately cease the war, withdraw all of its forces from Ukraine and allow a return to peace and stability.

## 2 REVIEWS OF NATIONAL IMPLEMENTING LEGISLATION

57. No statements were made under this agenda item.

## 3 IP AND COVID-19

### 3.1 South Africa

58. We note with appreciation, 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)".

59. We also would like to thank the Secretariat for hosting a seminar in which it presented the study to a broad range of stakeholders including Geneva-based delegates and patent offices. Certainly, the feedback we received from the Companies and Intellectual property Commission (CIPC) – which is South Africa's IP office – is that the presentation was most useful. Similarly, we also value the Secretariat publication entitled "Patent-related Actions Taken in WTO Members in Response to the COVID-19 Pandemic".

60. We would encourage the periodic updating of these important publications to reflect recent relevant developments. On this note, a recent review by US-based institution Knowledge Economy International (KEI) looked into contracts between the United States Government and private companies. This study revealed 62 contracts containing government authorizations to use patented inventions without the permission of patent holders. Presentation of such information can provide useful best practice for Members.

### 3.2 Switzerland

61. Just to add our voice to the delegate of South Africa to thank the Secretariat and express our appreciation for all the events and work and publications that they have produced under this important topic, so relevant to this Council, and we certainly could support South Africa proposal to update these Secretariat publications regularly. I think they assist Members tremendously.

### 3.3 Sri Lanka

62. Sri Lanka reiterates its position and welcomes both outcomes from MC12 on the TRIPS Decision and the WTO response to the COVID-19 Pandemic and Preparedness for Future Pandemics document. Particularly, by adopting the WTO response to the COVID-19 pandemic Decision, Ministers have clearly highlighted the need for addressing IP-related challenges for expanding production and providing equitable and affordable access to all COVID-19 products, including vaccines, therapeutics, diagnostics, and other essential medical goods including their inputs, for the current and future pandemics.

63. We believe that these Ministerial Decisions have re-affirmed 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.

64. Sri Lanka would like to thank the Secretariat for the compilation of the IP measures in the context of COVID-19 imposed by Members, and it is important to flag that these measures highlight the need for effective solutions to IP-related challenges in the context of COVID-19, and also in the context of Members' preparedness for future pandemics.

65. Such compilation also reveals the obvious inadequacy of the existing flexibilities within the TRIPS Agreement to cater for current health emergencies and reiterates the need for effective solutions to be found in case of future pandemics to address an array of challenges, including IP 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 WTO Agreements.

66. Further, we suggest the WTO Secretariat to compile specific IP measures and tools that can facilitate the use of TRIPS flexibilities, including patent landscape reports, early publication of patent

applications etc., and specific instances of use of TRIPS flexibilities in the context of COVID-19, both by developed and developing countries, and finally the country level analysis of the legal status of patents and patent applications relating to COVID-19 vaccines, therapeutics and diagnostics as well.

67. We look forward to continuing our constructive work to fulfil the Ministerial mandates in this regard and support this item to remain on the TRIPS Council agenda to allow us to be updated by the measures taken by Members.

## 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 South Africa

68. Following your advice, we will not give a not exhaustive statement under this agenda item. We will submit our statement to the Secretariat. We will just perhaps like to recall our request for the CBD Secretariat to brief the TRIPS Council as well as our call for the updating of the notes that you made reference to.

### 6.2 India

69. Traditional medicine has been an integral resource for health across world communities for millenia and remains a mainstay for these communities facing inequities in access to conventional medicines. The sociocultural practices and biodiversity heritages of traditional medicine are invaluable resources to evolve inclusive, diverse, and sustainable development. India reiterates its long-standing demand of an international enforceable regime to contain misappropriation. Patents should not be granted for existing traditional knowledge (TK) associated with genetic resources. Further where TK associated with 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 not only help address concerns of biopiracy but also strengthen and add to the Members' commitment to transparency mechanism, which should not be understood as limited to notification obligations.

70. The TRIPS Agreement continues to ignore numerous IPR-related obligations in the CBD which are of interest to developing countries. Despite several submissions like the disclosure proposal (document IP/C/W/474) submitted in 2006, document TN/C/W/52 submitted in June 2008 followed by document TN/C/W/59 in April 2011, calling for a decision to enhance mutual supportiveness between the TRIPS Agreement and the CBD proposed by a majority of the Membership, it is regrettable that progress remains elusive. The WIPO IGC process has also been unable to make much progress in these years. Given the enforceability of the TRIPS Agreement, there is a need and clear mandate to build the linkage between the TRIPS Agreement and the CBD under the *aegis* of this Council and we must ensure that substantive discussions on the TRIPS-CBD linkage is revived. We also reiterate our demand for a formal briefing by the CBD Secretariat in the interest of most Members. We also support updating the three factual briefs by the Secretariat.

71. The 2030 Agenda for Sustainable Development Goals (SDGs) calls for promoting access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge in Targets 2.5 and 15.6, we need to expeditiously work towards these goals. We wish to share with the Membership steps taken by India in this regard. The Indian Government in August of this year has decided to open up India's Traditional Knowledge and Digital Library (TKDL) database to users beyond patent offices. This will enable the TKDL to drive research and development, and innovation based on India's valued heritage across different fields.

72. Indian TK offers immense potential to serve national and global needs, by providing societal benefits as well as assisting in economic growth. For example, the traditional systems of medicine and wellness from our country, namely Ayurveda, Siddha, Unani, Sowa Rigpa, and Yoga are serving the needs of people from India and across the world even today. The recent COVID-19 pandemic has also been witnessing extensive use of Indian traditional medicines whose benefits range from

immune-boosting to symptoms-relief to anti-viral activity. Earlier this year, in April, the World Health Organization (WHO) established its first off-shore Global Centre for Traditional Medicines (GCTM) in India. These demonstrate the continued relevance of TK in addressing the current and emerging needs of the world. The decision emphasizes on integrating and co-opting TK with current practices towards enhancing innovation and trade. The TKDL will act as an important source of TK information for advancing knowledge and technology frontiers.

73. At last, India is committed to continue our efforts in building momentum on the issue of TRIPS-CBD linkage in light of important developments, namely the finalization of the SDGs and the ratification of the Nagoya Protocol.

### 6.3 Bangladesh

74. 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 previous statements delivered at the TRIPS Council meetings. Bangladesh stands ready to engage constructively with Members.

### 6.4 Sri Lanka

75. The protection of biological resources, traditional knowledge and folklore are important development issues for developing countries including Sri Lanka. These three issues are currently being discussed in detail at WIPO as well. However, our delegation would also like to support to keep these issues on the TRIPS Council agenda, considering the substantial importance of these issues for developing countries. 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.

76. Sri Lanka also believes that it is important for the TRIPS Council to give adequate attention to address these issues. Against this backdrop, a formal briefing by the CBD Secretariat on the latest developments of the Nagoya Protocol will be useful for Members and we also support updating the three factual briefs by the Secretariat on these issues.

77. Therefore, considering the mandate from the Doha Ministerial Declaration and the 2030 Sustainable Development Goals, Targets 2.5 and 15.6, it is our responsibility to take these discussions forward towards to a meaningful outcome. Sri Lanka stands ready to engage constructively with Members on these important issues.

### 6.5 Indonesia

78. At the outset, we would like to recall our previous statements on agenda items 4, 5, and 6 of which our position remains unchanged. Our delegation further stresses the need to amend Articles 27.3(b) and 29 of the TRIPS Agreement in order to prevent misappropriation and misuse of genetic resources and traditional knowledge through effective and complimentary international arrangements.

79. On that note, in order to provide us with the necessary information to move forward based on evidence, facts, and objective data on this longstanding issue, it would be in our best interest to agree on updating the long overdue Secretariat summary notes and to invite the CBD Secretariat to brief the Council on the Nagoya Protocol and its developments.

80. Indonesia urges that we move from this stalemate, starting with an "information session" involving relevant organizations, which we will also be doing in other Committees, and we are ready to engage constructively with Members on these matters.

### 6.6 Brazil

81. Brazil's long-standing positions regarding agenda items 4,5 and 6 remain unchanged to date. We remain committed to explore options, alternatives in this Council to discuss the relationship between the TRIPS Agreement and the CBD as well as the possibility of an amendment to the TRIPS Agreement that contemplates a mandatory disclosure requirement of the origin of genetic resources in patent applications. A multilateral provision on disclosure would be the most effective

means to protect genetic resources as determined by the CBD, increase the legal security of the system as a whole, and provide a framework to the rights of countries hosting a rich biodiversity.

82. We also take this opportunity to invite Members to engage constructively in the promising discussions taking place in the WIPO IGC in preparation of a diplomatic conference on that matter.

### 6.7 Nigeria

83. I wish to recall our previous statements regarding agenda items 5 and 6. We reiterate the importance for Members to engage in discussions with the aim to promote traceability and requirement of prior informed consent as well as benefit sharing in respect of any product manufactured through the use of genetic components or traditional knowledge and folklore. We believe the requirement of disclosure contained presently in the TRIPS Agreement remain grossly inadequate. Hence the need to improve existing provisions. In addition, we urge Members to consider collaborating regionally and internationally, in order to achieve this mutually beneficial goal. We also stand ready to engage constructively on this matter.

### 6.8 Peru

84. In relation to agenda items 4, 5 and 6, Members are already aware of Peru's position. However, we believe it is important to note that, for Peru, addressing the question of how the implementation of the TRIPS Agreement and the CBD can be mutually reinforcing and supportive and is becoming increasingly urgent.

85. We wish to point out that my country has seen a rise in biopiracy cases in recent years. According to information provided by the National Anti-Biopiracy Commission (CNB), 248 biopiracy cases have been identified in relation to 41 genetic resources of Peruvian origin and associated traditional knowledge of indigenous peoples. A quite significant increase was identified in 2021. We believe that the disclosure of source requirement would be the most effective way to address the international problem of misappropriation of genetic resources and traditional knowledge. We associate ourselves with the request to invite the CBD Secretariat to brief Members and update its factual notes.

### 6.9 United States of America

86. I think our position on these issues are well known as stated in previous meetings. Just to streamline our position regarding genetic resources, traditional knowledge and folklore we continue to believe that the World Intellectual Property Organization (WIPO) serves as the best forum to trust these issues, and as noted by colleagues, the WIPO IGC is looking at addressing unresolved issues and working on a common understanding of core issues using an evidence-based approach and examples of national experiences. While the WIPO General Assembly recently took a decision to convene a diplomatic conference to conclude an international legal instrument related to intellectual property, genetic resources and traditional knowledge associated with genetic resources no later than 2024, significant gaps in views, positions and scope of the subject matter remain on these topics. The United States will continue to engage in technical discussions at WIPO IGC. 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 the TRIPS Council meetings.

### 6.10 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. In addition, this delegation believes that the WIPO IGC is the most appropriate forum for holding technical discussions on genetic resources, traditional knowledge and folklore from the IP perspective. Given that detailed discussions have been continuously held at the WIPO IGC, we should avoid duplication of discussion. The delegation of Japan remains willing to contribute to evidence-based discussions on these issues in a constructive and effective manner.

### 6.11 South Africa

89. I just would like to thank the distinguished delegate from the United States of America for bringing to our attention the recent decision taken by the WIPO General Assembly to convene a diplomatic conference on genetic resources. We would like to reiterate our perspective that discussion at the WIPO IGC and this forum are complementary and not mutually exclusive, and given this recent development , the time will be right for the WIPO, as an observer , to brief us on the discussions at the IGC pertaining to genetic resources.

### 6.12 Korea, Republic of

90. Regarding Article 27.3(b), our position remains unchanged. With regard to the possible alignment of the TRIPS Agreement and the Convention on Biological Diversity (CBD), we believe that TRIPS and CBD have different purposes and oversee different aspects. So the amendment is unnecessary. Regarding the protection of folklore, we are of the position that the WIPO IGC is the right forum to address these issues to avoid overlapping discussions.

### 6.13 China

91. China's position on this issue is well-known and remains unchanged, we are glad to hear that the WIPO IGC is carrying out work on these issues, but China still believes that the discussions and negotiations carried out at the WIPO IGC do not contradict with Members' discussion at the WTO.

### 6.14 South Africa

92. 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 instructed that the TRIPS Council, as part of its work programme to review Article 27.3(b) as well as examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore. These are important mandated issues which remain an integral part of the Doha Round single undertaking. 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 this regard, we welcome the progress made at the recent WIPO General Assembly where consensus was reached on a diplomatic conference dealing with genetic resources. The WTO Membership would certainly take note of such developments. Our delegation would welcome a briefing from WIPO in this regard.

93. Similarly, it would be useful for the CBD Secretariat to brief the TRIPS Council on the CBD and other implementation issues under the Nagoya Protocol as well as any new developments. Finally, we wish to raise once more, the issue of updating the three technical notes contained in documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1. It would be appropriate for the Secretariat to update the information contained in these notes in a neutral manner to further facilitate discussions among Members.

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

94. No statements were made under this agenda item.

## 8 NON-VIOLATION AND SITUATION COMPLAINTS

### 8.1 India

95. India's position on the issue remains unchanged. We further reiterate that in our understanding, until there is a consensus on the scope and modalities of the applicability of NVSCs to TRIPS, these will not apply to the TRIPS Agreement. India is committed to engaging with like-minded Members in making non-violation and situation complaints inapplicable to the TRIPS Agreement.

### 8.2 Switzerland

96. Just to recall that our delegation believes that no additional modalities are needed for the application of such complaints under the TRIPS Agreement next to those already contained in the Dispute Settlement Understanding. This said, our delegation is ready to discuss in a constructive spirit any such proposal from Members, should they consider modalities in addition to those included in the Dispute Settlement Understanding necessary.

### 8.3 Argentina

97. The position of Argentina with respect to non-violation and situation complaints remains unchanged. In line with the arguments presented in document IP/C/W/385/Rev.1, which Argentina co-sponsored together with other Members, these complaints raise systemic concerns and, as affirmed in paragraph 57 of this document, complaints provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 must not be applied to the settlement of disputes under the TRIPS Agreement. Lastly, my delegation would like to express once again its willingness to hold multilateral discussions that can lead to permanent and consensual solutions.

### 8.4 Sri Lanka

98. Sri Lanka reiterates its support to the Ministerial Decision adopted on 17 June 2022 on the extension of the Non-Violation and Situation Complaints Moratorium stipulated under the Article 64.2 of the TRIPS Agreement until MC13, which would permit Members to refrain from bringing any unintended violations of provisions, including in use of compulsory licences, of the TRIPS Agreement to the WTO dispute settlement system.

99. Sri Lanka's position on this issue remains unchanged as a co-sponsor of the document IP/C/W/385. Accordingly, Sri Lanka supports the decision to instruct the TRIPS Council to continue its examination of scope and modalities, and to make appropriate recommendations to the MC13 and we look forward to working with like-minded Members in making non-violation complaints inapplicable to TRIPS and come up with a way forward and a permanent solution for these long-delayed issues.

### 8.5 Brazil

100. Brazil remains open to assess proposals on scope and modalities of NVSCs applied to the TRIPS Agreement. We are ready to discuss any contributions that Members might have that could lead to an agreed solution on this topic.

### 8.6 Canada

101. Canada's longstanding position on this issue remains unchanged, and notes that the availability of NVNI claims under TRIPS would create legal uncertainty for WTO Members. Canada recognizes that Members have worked constructively to arrive at a consensus-based decision on this matter as recently as MC12 and encourages the TRIPS Council to continue to similarly engage in a constructive manner to identify consensus-based solutions to other important issues facing the WTO Membership going forward.

### 8.7 Bangladesh

102. On non-violation and situation complaints, my delegation is in favour of establishing a permanent moratorium before MC13. To avoid repetition, I refer to my delegation's previous statements delivered on this issue at the TRIPS Council meetings. Having said that, Bangladesh is ready to constructively engage with Members on this issue further.

### 8.8 South Africa

103. It is well established that proponents of the application of NVCs under the TRIPS Agreement have not provided concrete examples of the kind of scenarios under which an otherwise TRIPS-consistent measure would impair or nullify benefits beyond those arising from the obligations

set out in the Agreement. Having said this and as we indicated previously, we stand ready to discuss our ideas with delegations on this matter.

### 8.9 United Kingdom

104. As this is the United Kingdom's first intervention today, we would like to start by saying that as we meet here to discuss issues arising under the global rules-based system, we cannot sit by and ignore the egregious violations of international law and the UN Charter committed by one WTO Member, the Russian Federation, against another, Ukraine.

105. Putin's illegal annexation of regions of Ukraine constitutes a new low point in Russia's blatant flouting of international law. The United Kingdom unreservedly condemns this outrageous and illegal act. What happens in Ukraine matters to the work of this organization and matters to us all. Russia's actions will prolong the impact on the global economy, have global consequences and jeopardize prospects of peace The United Kingdom and the international community have made it clear to President Putin that his attack on the Ukrainian people must stop and that he must withdraw from Ukraine and restore regional and global stability.

106. On this item, the United Kingdom would like to state that given the lack of substantive discussion on this long-standing issue preceding the pandemic, the TRIPS Council in October 2021 made the right decision to extend the NVSCs moratorium until MC13. The United Kingdom believes it is important that the TRIPS Council can begin substantive discussion on the scope and modalities of the NVSCs before MC13.

### 8.10 Nigeria

107. We wish to recall our previous statements under this agenda item. We take note of the MC12 Decision adopted on 17 June 2022 to extend the moratorium contained in document WT/L/1137 instructing the Council to continue its examination of scope and modalities, and to make recommendations to MC13. We remain open to working with other Members to consider modalities for the application of non-violation and situation complaints. However, in the absence of any proposals, we are of the view that the current moratorium should be made permanent because we believe that complaints in this context should be made in the case of an actual violation.

### 8.11 Indonesia

108. Indonesia welcomes the adoption of the Ministerial Decision on June 2022 to extend the moratorium to the upcoming MC13. Indonesia's position, as in previous meetings, remains unchanged. We would also like to reiterate our concerns on the negative impacts that non-violation complaints in TRIPS can have on existing TRIPS flexibilities. Having said that, we are ready to discuss this issue in order to come up with a way forward and solution on this long-delayed issue. Rest assured, Indonesia is committed to engage constructively in the discussion of this matter.

### 8.12 Chile

109. The latest extension reflects the fact that consensus has not been reached on this matter in the past and shines light on the need to continue dialogue and the search for a consensual solution to this issue, bearing in mind all its repercussions and the link between this moratorium and others within this Organization. Chile, like other delegations, considers that this type of complaint should not be applicable at the multilateral level in the context of the TRIPS Agreement, given the lack of legal certainty that it creates for users and creators of the innovation ecosystem.

### 8.13 United States of America

110. The United States of America remains open to considering specific proposals from Members wishing to further examine the scope and modalities for complaints of these types.

### 8.14 Peru

111. Peru's position on this item is also fairly well known. We support a permanent moratorium on non-violation and situation complaints in view of the specific nature of this Agreement and the fact

that to do otherwise could result in inconsistencies between the WTO Agreements by allowing the arrangements under the TRIPS Agreement to be challenged or by affecting the functioning of the flexibilities contained in the Agreement. However, we are open to considering any proposals that Members may submit in order to address their concerns.

### 8.15 Russian Federation

112. The Russian Federation is a co-sponsor of the document IP/C/W/385. We want to reiterate our position that non-violation and situation complaints should not be applicable to the TRIPS Agreement.

### 8.16 Bolivia, Plurinational State of

113. Bolivia's position on this issue remains unchanged and I have stated it at previous meetings of this Council. We consider that the benefits derived from the Agreement can be adequately protected by applying the letter of the Agreement, in accordance with the principles of international law and without introducing a legally uncertain notion, such as the one before us. In no way does the moratorium jeopardize the flexibility of TRIPS-related rights and obligations. On the contrary, applying non-violation complaints could put the rights of intellectual property owners at odds with the ability of governments to legitimately implement their regulatory policies, even limiting their sovereign capacity to introduce new social, economic and health-related development measures. We reiterate that there is no precedent for the application of these complaints. Furthermore, no concrete examples have been given of instances in which an otherwise TRIPS-consistent measure would impair or nullify benefits, beyond the obligations already set out in the Agreement, so it is unnecessary for us to even continue this discussion. However, we remain committed to moving constructively towards a definitive and consensual solution before the MC13.

### 8.17 Korea, Republic of

114. Our position remains unchanged. We have concern that the application of NVSC o the TRIPS Agreement may increase the legal uncertainty given that the legal systems of WTO Members vary. However, we will constructively engage with Members to continue to discuss this matter.

### 8.18 Panama

115. My delegation joins others in welcoming the Ministerial Decision extending the moratorium until MC13. As other delegations have stated, we believe that it is time to begin discussions on scope and modalities in the TRIPS Council, in whichever format is deemed appropriate, and to issue recommendations.

116. We must move away from this repetition of statements and on to concrete proposals that allow us to start these discussions. We therefore consider it appropriate for the Chair to hold consultations with Members that can guide the way forward on this issue.

### 8.19 Hong Kong, China

117. Hong Kong, China sees it is important that this Council continue its examination of the scope and modalities for non-violation and situation complaints cases as mandated in the TRIPS Agreement. We remain open to proposals on how to take forward this discussion.

### 8.20 European Union

118. The European Union also remains open to hear and discuss any possible solution on this matter in the future and ahead of MC13.

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

119. No statements were made under this agenda item.

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

120. No statements were made under this agenda item.

## 11 TWENTIETH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT

### 11.1 European Union

121. The European Union and its member States have taken their commitments under Article 66.2 of TRIPS Agreement very seriously since the beginning. The European Union and its member States provided proof year after year of having promptly and attentively reacted to natural, social, health, climate, food and economic changes by implementing projects specifically tailored to the current needs of LDCs individually or their regional organisations.

122. The European Union has submitted its annual report which provides a detailed update on EU technology transfer programmes, both the European Union and its member States. This document was circulated in accordance with the Decision of the Council for TRIPS in 2003, according to which developed country shall submit annual reports on actions taken or planned in pursuance of their commitment under Article 66.2.

123. Our programmes cover the period from July 2021 to July 2022 and can be found in the e--TRIPS Portal. Besides the EU-financed programmes, this year Austria, Czech Republic, Finland, Germany, Ireland, Spain and Sweden sent reports to the European Commission on technology transfer programmes funded by these countries. The report submitted by the Commission is not an exhaustive list of all the technology transfer programmes provided but gives a vast range of examples of these programmes. The report has a total of 123 technology transfer programmes, including 24 projects funded by the EU institutions, Horizon Europe mainly, and 99 projects funded by the EU member States, notably by Germany.

124. Today we would like to focus on three examples of the EU's and its member States' technology transfer programmes, but please don't hesitate to have a look at the report itself when it will be translated. So now I give the floor to my colleague Martin, in the room, to present very important programmes we managed in the European Union the "E-SHAPE".

125. Thank you, Pierre Yves, and yes indeed I will describe three out of the 123 programmes included in the EU report. The first is E-SHAPE comprising showcases of the Group on Earth Observations (EO). The E-SHAPE programme is driven by the need to develop operational EO services with and for the users and to create a conducive environment whereby the strengths of Europe are exploited towards addressing societal challenges, fostering entrepreneurship and supporting sustainable development in LDCs. The proposed objectives are:

a. to develop operational EO services with and for users active in key societal sectors;

b. to demonstrate the benefits of EO pilots through coordinated downstream exploitation of EO data and utilization of existing EO resources;

c. to promote the uptake of pilots at national and international scale, across vertical markets (private and public) and amongst key user communities;

d. to enable the long-term sustainability of numerous pilots, their penetration in public and private markets and support their upscaling;

e. to increase uptake by raising awareness on solutions developed through tailored and well-targeted communication, dissemination and outreach activities.

126. The proposal aims at setting-up and promoting a sustainable organization dedicated to users' uptake of European EO resources, building on Copernicus and the Group on Earth Observations (GEOSS) through the development of co-design pilots (i.e. application-oriented products, services or solutions) built on a user-centric approach and delivering economic, social and policy value.

Through the development of 27 pilots organized in seven showcases, it aims to deliver information that will contribute to the three Group on EO engagements: SDGs, Paris Agreement and Sendai Framework. The field of technology is the Vegetation-Index Crop-Insurance.

127. E-Shape provides a financial service delivery to smallholder farmers in some LDCs with a geodata-driven, risk-mitigation insurance product that offers a basic safety net to protect them against weather-related perils. The provision of the service will be supported by on-site training, eSupport to create a long-duration product sustainability and a country-specific independence in knowledge and skills. The overall budget is over EUR 15 million.

128. The second project is Vaccine Against Schistosomiasis for Africa, a Phase 1 clinical study in Burkina Faso and Madagascar. Schistosomiasis is a poverty-related neglected tropical disease, impacting one billion people in 74 countries. Science ranked a schistosomiasis-vaccine as one of the top-10 vaccines urgently needed. Chemotherapy is the preferred method for schistosomiasis control; but the effectiveness of mass-treatment programmes is compromised by reinfection requiring regular re-treatment. Schistosoma mansoni, causing intestinal and hepatic schistosomiasis, and Schistosoma haematobium, causing urinary schistosomiasis, are endemic.

129. An efficient vaccine, with long-lasting protection against all schistosomiasis forms, would impact disease control. This programme funds clinical development of the SchistoShield®-vaccine in Burkina Faso and Madagascar. In baboon studies, SchistoShield® has been effective against all major schistosome species. It is the only vaccine candidate having consistently exhibited potent prophylactic, anti-fecundity, egg-induced pathology resolving, transmission-blocking and therapeutic efficacy. The objectives are manifolds:

a. to assess the safety/immunogenicity of SchistoShield® in a Phase I clinical study in healthy adults from Africa;

b. to refine and develop a female worm schistosome human challenge model;

c. to identify correlates of protection, innate and adaptive immune signatures, gene expression and the role of antibodies in the prevention/control of Schistosoma infections; and

d. to foster a global consortium for advancing research on schistosomiasis disease burden, vaccines and addressing downstream access constraints in resource-poor settings.

130. The funding granted allows the clinical development of SchistoShield®. African site research capacity will be improved and epidemiological burden data using novel diagnostic techniques will be used to advance clinical development to Phase 2 and potential future elimination project. The Consortium VASA comprises French public research centres and private companies.

131. And the last example is an agricultural development programme in Burkina Faso funded by Germany. In selected value chains in the programme's intervention, the famers and micro or SMEs should increase their income and improve their nutritional basis through increased and improved sustainable production in selected value chains. With this programme, the framework conditions for sustainable development of the agricultural sector, in particular, the supported value chains are improved and the competencies of producers and entrepreneurs and their organizations in the supported value chains are strengthened for an environmentally sound management of their farms. Furthermore, the services offered along the value chains of rice, cassava and soybean are strengthened and the people supported in these selected value chains have improved their knowledge about balanced nutrition and good hygiene.

### 11.2 Australia

132. Australia was pleased to submit its Article 66.2 report to the Secretariat on 12 September 2022. We acknowledge the important role that technology transfer plays in supporting all WTO Members, particularly LDC Members, to develop and achieve greater prosperity.

133. Australia recognises the need for developed countries to continue to step up our efforts to support technology transfer in response to COVID-19 to ensure that LDCs can develop the sovereign

capabilities necessary to manage the impacts and support their populations. Our report focuses on Australia's efforts to help LDCs create the conditions essential to allow the transfer of technology, including the technology necessary to assist WTO Members access and administer COVID-19 vaccines. We would be happy to discuss our report further with Members at the next available opportunity.

### 11.3 United Kingdom

134. The United Kingdom remains committed to implementing Article 66.2 of the TRIPS Agreement to promote and encourage technology transfer to LDC Members. We welcome the opportunity to provide insight into one of the projects undertaken by the United Kingdom, to promote such transfer.

135. The AgriFood Africa project (a part of the wider Global Challenge Research Fund programme) is a project to boost collaboration between the United Kingdom and Africa to develop sustainable management of food production systems in Africa. This project aims to enhance food security, nutrition, and welfare through greater involvement of the private sector, both UK and African, in innovation for agriculture and food systems. For example, through feasibility studies and industrial research projects or social science studies into barriers to the adoption of, or investment in, technologies and innovations in the agriculture sector. AgriFood Africa is delivered through three strands:

a. The first is a technology accelerator programme including Seeding Awards delivered by Biotechnology and Biological Sciences Research Council (BBSRC); and industry focussed Research and Development and demonstration activities through the Agritech Catalyst, which is delivered by Innovate UK. The purpose is to accelerate the transition from discovery research to translational development projects by supporting preliminary work or feasibility studies in agri-food technology;

b. The second is by linking world-leading knowledge and expertise of academics to business--critical projects, through AgriFood Africa Knowledge Transfer Partnerships, delivered by Knowledge Transfer Network (KTN);

c. The third is by connecting the United Kingdom and Africa through events, funding, information sharing, partnering, and networking to increase the impact of AgriFood funded projects and align UK expertise to African challenges, through AgriFood Africa Connect.

136. Overall, the project aims to fund a portfolio of projects with the potential to accelerate the development and scale of adoption of agricultural and food system innovations to address the challenges faced by agriculture and food systems in Africa.

137. We hope Members found the highlights of this project informative as agricultural development is fundamental to achieving many of the SDGs in Sub-Saharan Africa.

### 11.4 New Zealand

138. Thank you for the opportunity to speak to New Zealand's report on the implementation of Article 66.2, document IP/C/R/TTI/NZL/2. New Zealand encourages technology transfer to LDCs through various methods, including:

a. promoting an economic environment that enables New Zealand enterprises and institutions to transfer technology abroad;

b. encouraging global trade in goods, services and labour mobility;

c. facilitating a strong intellectual property environment; and

d. through various bilateral and regional development programmes.

139. At the heart of our technology transfer efforts is the New Zealand Aid Programme. We see technology transfer as fundamental to achieving sustainable development and poverty reduction in

developing countries, through the investment of money, knowledge and skills. With a strong focus on the Pacific, New Zealand's Official Development Assistance (ODA) was boosted in 2018, with an additional funding commitment of NZD 714 million, increasing the overall ODA funds to NZD 2.218 billion for the period 2018 – 2021. 60% of our ODA went to the Pacific during this period, but there are multiple examples of technology transfer projects beyond our immediate Pacific neighbours. To provide a few examples:

a. in Zambia, New Zealand has undertaken a 7-year, NZD 7.4 million dairy activity to strengthen emerging dairy value chains through knowledge transfer on animal health and dairy business practices. Approximately 600 participating farmers have experienced improved yields, reduced costs of production and increased profits.

b. in Myanmar, Plant and Food Research, a New Zealand Crown Research Institute, is partnering with Proximity Design, a Myanmar Social Enterprise, in a six-year NZD 7.9 million project to improve the productivity, income and resilience of smallholder vegetable farmers and to reduce post-harvest losses.

140. The New Zealand – Africa Geothermal Facility (NZ-AGF) is a NZD 10.2 million partnership with the African Union Commission. Since the 2017/18 financial year, it has provided geothermal technical assistance to support the development of the geothermal sector in East African countries. It is open to 11 eligible countries including ten LDCs.

141. These projects not only directly provide for the transfer of technology and know-how but enable commercial operations which attract further technology transfer through partnership with the private sector. New Zealand remains committed to technology transfer efforts and encouraging and enabling enterprises and institutions to further their technological collaboration.

### 11.5 United States of America

142. The United States of America attributes great importance to this review with respect to the obligation under Article 66.2. Our submission this year, is an update to our 2021 report, detailing progress in the past year to programmes aimed to support LDCs in fostering the necessary environment to encourage the effective, voluntary transfer of technology to LDC Members on mutually agreeable terms. The United States submission details programmes ranging from intellectual property and trade capacity building to the health, labour, and environmental sectors. Similar to previous submissions, this report includes comments from host country governments and private sector representatives regarding the value of several programmes listed in the report.

143. We believe that for Article 66.2 of the TRIPS Agreement to function effectively, there must be a robust dialogue between developed countries and LDC Members. Strong communication between partners is critical to ensuring targeted incentives remain responsive to the self-identified technology transfer interests and needs of LDC Members. The United States strives to make this a priority in all our engagements with our host government partners around the world and will continue to explore ways to improve upon the process as we go forward.

144. Please allow me to mention some elements contained in our 2022 report, highlighting a few programme updates. Health research through biomedical and behavioural funding activities of United States agencies, have contributed to technology transfer and research capacity strengthening in many LDCs. For new technologies developed by US scientists, NIH licenses biological materials and/or patent rights to institutions that can bring products to the market in or for LDCs.

145. In Bangladesh, the USAID MaMoni Maternal and Newborn Care Strengthening Project (MNCSP) activity will reduce maternal and neonatal mortality and increase contraceptive prevalence by strengthening the capacity of health systems and facilities through the provision of quality maternal and new-born health care, postpartum planning, and nutrition services. The activity will further strengthen new-born care at all levels. In fiscal year 2022, USAID continues to support the International Federation of the Red Cross and Red Crescent to increase the resilience of vulnerable communities in the Solomon Islands and expand the ability of the Solomon Island Red Cross Society (SIRCS) to support its own disaster risk management and community-based health programmes.

146. The USAID TradeHub supported exporters in Lesotho with trade enhancing services such as organic certifications, and product testing to enhance their competitiveness for entry into the US market. Social compliance certification is becoming central to market-entry requirements, with buyers increasingly considering humane and ethical factory standards, compliance with national laws, and the treatment of garment workers. A private sector partner said, "I would like to thank USAID TradeHub for being very supportive to us as we are now doing a photoshoot of products that we are shipping to the US for Amazon".

147. Our report describes over 135 programmes just like these, that shows how the US government transforms lives. No report can truly represent every activity that directly or indirectly incentivizes enterprises and institutions for the purpose of promoting and encouraging technology transfer. This report attempts to describe the most significant activities and programmes and to convey the breadth and depth of efforts by the United States of America.

148. We look forward to further discussing our technology transfer programming with the LDC Members at the annual workshop and we commend the Secretariat for putting together another fantastic workshop during the pandemic.

### 11.6 Japan

149. The delegation of Japan recognizes the importance of Article 66.2 of the TRIPS Agreement for LDCs, taking into account their economic, financial and administrative constraints . From such a perspective, Japan is earnestly engaged in improving the business environment for technology transfer to LDCs.

150. We would like to briefly describe this year's report on our implementation of Article 66.2, document IP/C/R/TTI/JPN/3. This report consists of four sections, namely:

a. Activities undertaken by technical cooperation organizations;

b. Activities in the field of climate change;

c. Activities in the pharmaceutical sector; and

d. Activities in the field of intellectual property rights.

151. This report was submitted through the e-TRIPS submission system and contains an annex providing detailed information on each activity involving technology transfer to LDCs. Japan understands that incentives to enable technology transfer include a variety of measures such as financial support and business environment support, because one of the main obstacles for enterprises and institutions in developed countries to transfer technologies to LDCs is the lack or insufficiency of business environment in LDCs. Furthermore, improving the business environment helps create incentives that are stable and self-sustainable, which is especially important considering that technology transfer often takes time.

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

153. Japan will continue to make its utmost efforts to improve the business environment and make it even more conducive to transfer technology.

### 11.7 Switzerland

154. Switzerland's 2022 report contains an updated list of the measures and programmes that Switzerland has implemented to incentivize technology and knowledge transfer to LDCs. The report lists the projects financed by Swiss official development assistance (ODA) as funded by the Swiss Agency for Development and Cooperation and the State Secretariat for Economic Affairs.

155. We would like to briefly mention one example of a current project listed in our Article 66.2 report. This project is called REPIC, a Swiss Platform for Renewable Energy, Energy Efficiency and

Resource Efficiency Promotion in International Cooperation. This platform is jointly managed by the State Secretariat for Economic Affairs, the Swiss Agency for Development and Cooperation, the Federal Office for the Environment and the Swiss Federal Office of Energy.

156. Its main objective is the transfer of know-how and technologies with the aim of developing renewable energies, energy efficiency and resource efficiency, such as solar, wind and geothermal energies especially in LDCs.

157. Since its launch in 2004, REPIC has supported more than 150 projects in 50 different countries, including the following LDCs: Uganda (biomass), Mali (biomass, photovoltaic), Benin (biomass, resource efficiency), Nepal (small hydro), Madagascar (mall hydro ), Bangladesh (photovoltaic), Senegal (photovoltaic), Zambia (photovoltaic), Haiti (energy efficiency, resource efficiency), Liberia (resource efficiency), Tanzania (resource efficiency) and Cambodia.

158. Last but not least, we would like to inform Members that last spring we worked, with the Secretariat - which we would like to thank for its valuable assistance - on some technical improvements regarding the submission of the Article 66.2 reports via the e-TRIPS Submission System. These improvements will ultimately benefit all stakeholders, including LDCs.

159. Switzerland will continue to make all efforts to provide relevant information on the incentives it provides under Article 66.2, in as transparent, consistent, and comprehensible manner as possible. We look forward to participating in the dedicated workshop on Article 66.2 scheduled before the first regular TRIPS Council meeting in 2023, and to receiving the preparatory information ahead of the workshop in order to allow for adequate preparation.

### 11.8 Canada

160. Canada is pleased to report on its work under Article 66.2 in providing incentives to enterprises and institutions to promote and encourage technology transfer to LDC Members in order to enable them to create a sound and viable technological base.

161. Canada's 2022 report on the implementation of Article 66.2 of the TRIPS Agreement (document IP/C/R/TTI/CAN/3) updates on the range of projects and initiatives undertaken by Canada over the past year. Before discussing some of the more noteworthy projects included in this year's report, we note that Canada's report on Article 66.2 focuses primarily on non-market projects, as financed by Canadian departments, agencies, and institutions, through official development assistance (ODA), grants, and other concessional financings. For instance, Canada provides financial incentives in partnership with Canadian educational and research institutions in a range of development areas like agriculture and food security, public health, artificial intelligence and education, sustainable development, as well as business development and capacity-building for SMEs.

162. In addition to updates on existing projects, this year's report includes information on a very recent grant programme, Addressing Environmental Degradation in Cox's Bazar District in Bangladesh, which launched this year and is funded in partnership with the United Nations Development Program (UNDP). This project will provide technical assistance and know-how that will result in the development of strategies, policies, and systems to address environmental rehabilitation, including the provision of alternative, clean cooking fuel and technology to all refugee households. This programme aims to contribute to environmental rehabilitation and long-term development of Cox's Bazar District through supporting an ecologically sustainable approach in host communities and Rohingya refugee camps.

163. Another notable project from this year's report, the Global Fund for Disaster Reduction and Recovery - Earth Observation Technologies, was launched in collaboration with the Global Fund for Disaster Reduction and Recovery, and is set to fund Earth Observation (EO) technology and data collection for use by coastal and Small Islands Developing States (SIDS), regional organizations, and other partners to pursue climate change adaptation and resiliency to extreme weather events. In a similar vein, the project Transforming the Market for Stoves and Clean Energy in Haiti launched with the United Nations Foundation and in partnership with Haiti, aims to restructure and boost the market for efficient stoves and clean energy in order to protect the environment, improve the health

of women and children and strengthen women's economic power within new value chains for producing and marketing stoves and clean energy.

164. This year's report also includes information on Strengthening Public-Private Partnerships in Research and Innovation in the Manufacturing Sector in Uganda. Through collaboration between the International Development Research Centre and the Uganda National Council for Science and Technology, this project supports research and innovation to address challenges facing the manufacturing value chains for various industrial products in Uganda through partnerships and collaborations between universities and industry. It aims to contribute towards the reduction of technological bottlenecks affecting the manufacturing sector, thereby increasing sector productivity and competitiveness.

165. Canada would be pleased to provide further information on these and other technology transfer projects and programmes contained in Canada's 2022 report on the implementation of Article 66.2, upon request. Canada also invites interested delegations to consult Global Affairs Canada's searchable "International Development Project Browser" for further information on these and other initiatives.

166. Finally, Canada would also like to take the opportunity to again thank the Secretariat for organizing the March 2022 workshop on Article 66.2, and to thank those Members that shared their experiences and valuable insights in this area. We look forward to the next workshop on the implementation of Article 66.2 and to further discussions with other Members on these important issues.

### 11.9 South Africa

167. I had hoped to take the floor after Bangladesh online who will be presenting this on behalf of the LDC Group, but first I would like to express our support for the statement that will be made by Bangladesh on behalf of the LDC Group. Article 66.2 of the TRIPS Agreement places a legal obligation on developed country Members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDC Members in order to enable them to create a sound and viable technological base.

168. Fulfilment of the obligation contained in Article 66.2 would contribute to the objectives of the TRIPS Agreement, in particular, Article 7 which posits that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology". This issue is key, not only in the context of the pandemic, but also in relation to longer term and structural issues such as climate change and digitalization. The Doha Decision on Implementation-Related Issues and Concerns reaffirms the mandatory nature of Article 66.2, as does the 2001 Declaration on the TRIPS Agreement and Public Health.

169. In our view, it is important that the implementation of Article 66.2 should contribute to the objectives of the TRIPS Agreement and enable LDCs to develop a sound and viable technological base. In order to home in on technology transfer related activities more precisely, clarification of various issues could assist. These include *inter alia*:

a. definitional issues around what constitutes technology transfer;

b. to what extent incentives provided can be considered additional to official development aid?

c. the robustness of evaluations undertaken to understand the impact of initiatives that have been taken.

170. LDCs have raised some of these issues, among others, in document IP/C/W/562. Subsequent submissions by the LDC Group document IP/C/W/664 and document RD/IP/24. These documents are highly instructive. Our delegation sees great value in meaningfully engaging with these issues and stands ready to work with other Members toward full implementation of Article 66.2.

### 11.10 Bangladesh, on behalf of the LDC Group

171. Under this agenda item, Bangladesh delivers this statement on behalf of the LDC Group. The LDC Group welcomes the annual reports on the implementation of Article 66.2 and the reporting Members' most sincere efforts to help create sound and viable technological base in LDCs.

172. Since most of the reports are very recently submitted, we could not go through them in detail. After examining these reports, the LDC Group will provide feedback to the respective reporting Members very soon. We believe that our last year's feedback was useful for the reporting Members to understand the technology needs and current realities of the technological base in LDCs. In the proposed reporting template (document IP/C/W/668) we underscore the need for information about the specific incentives, the incentives recipient enterprises and institutions, the specific technology that has been transferred and the name of the beneficiary LDC Member. This will help acknowledge the substantive contributions of the developed country Members with evidence and precision.

173. While we truly appreciate the initiatives of the developed country Members under Article 66.2, we also feel that LDCs should do some homework focusing their needs and challenges in terms of technology transfer. For the forthcoming workshop in March 2023 on the implementation of Article 66.2, LDC Members are currently working on a self-assessed voluntary survey on their priorities for technology transfer needs. The LDCs thank the IP Division of the Secretariat for extending technical support in this regard.

174. The LDC Group welcomes the annual workshop on the implementation of Article 66.2 of the TRIPS Agreement as an excellent opportunity. We expect that next year's workshop will bring more practical inputs for an informed dialogue between the reporting Members and LDCs. The LDCs hope that the technology needs identified by the LDCs will also be prioritized by the developed Members in their forthcoming programmes and schemes on implementation of Article 66.2. The LDC Group stands ready to engage constructively in this regard.

### 11.11 India

175. India thanks the delegations for their reports and statements made today under this agenda item. This is a positive obligation on developed country Members that emanates from the TRIPS Agreement and is an important transparency exercise.

176. However, much remains to be done under this obligation by the developed country Members, to fulfil their obligation under Article 66.2 in both letter and spirit. There is continued concern that reports generally do not focus and often lack information on the incentives that developed country Members have provided to their enterprises and institutions for promoting transfer of technology.

177. Promotion and dissemination of technology transfer becomes more relevant and critical now than ever as LDCs have been disproportionately hit by the pandemic and therefore, greater transparency, with regard to the effective technology transfer undertaken would be supportive of LDCs' efforts towards building a much-needed technological base and further help them to combat the pandemic as well as recover from its aftermath.

## 12 TECHNICAL COOPERATION AND CAPACITY-BUILDING

### 12.1 European Union

178. The European Union submitted its annual report on technical and financial cooperation programmes carried out between July 2021 and July 2022 together with the member States. The European Union carried out 14 technical cooperation activities during the reporting period and also the member States contributed as well, as I said, France, Sweden, Spain, Denmark, and Germany. The programmes covered all IP rights in the TRIPS Agreement and some of the programs were multi-annual programs consisting of many activities to the benefit of LDCs and developing countries.

179. Today we would like to highlight to these programmes, and I would like to say as well that this report is not exhausting. There are so many programmes to support and for cooperation in Africa not only but elsewhere as well that it is quite difficult to be exhaustive in this kind of report. So, we

will limit ourselves today in talking about two programmes: one is the well-known by our friends in Africa is the AfrIPI and the other one is the IP Key in Latin America.

180. As regard AfrIPI programme, AfrIPI is the pioneer Africa-wide EU-funded IP cooperation project, which commits joint action between the European Union and Africa to boost intra-African trade, and to facilitate African-European investments for economic growth and sustainable development. With a budget of EUR 17 million, the project is funded by the European Union and implemented by the EUIPO, our agency for IP, in partnership with key African continental, regional and national institutions such as the African Union Commission, of course, the AfCFTA Secretariat, the "Organisation Africaine de la Proprieté Intellectuelle" (OAPI) and the Africa Regional Intellectual Property Office (ARIPO).

181. The overall objective is to facilitate intra-African trade and African and European investment. The Specific Objective is that IPR are created, protected, utilized, administered and enforced across Africa, in line with international and European best practice and in support of the AfCFTA and the African Union's Agenda 2063. There are 4 outputs foreseen:

a. Output 1: Promoting international agreements in the area of IPR and reinforced cooperation between the European Union and Africa in order to facilitate fact-based AfCFTA negotiations.

b. Output 2: Strengthening national and regional IP institutions, networks, and tools, for more efficient and user-friendly IP protection and enforcement systems.

c. Output 3: Strengthening the capacities of Micro, Small and Medium-sized Enterprises (MSMEs)/productive sector on the importance and value of IP protection (including GIs) in the African society.

d. Output 4: Implementation of the priority actions identified by the work plan linked to the Africa Union Continental Strategy for GIs.

182. One part of what we have selected in the multitude of programmes is covered by AfrIPI, the French government and the French companies - and the French public entities are very active.

183. An illustration of the implementation of the AfrIPI by the EUIPO agency is the training programme for judges. This is a training seminar for judges in the OAPI region, including the sharing of experiences and launch of the future case law database of African court decisions in intellectual property matters. A second seminar is currently taking place in Dakar to launch a vast network of judges.

184. In addition, France is participating in a project being piloted by WIPO. In cooperation with the French National Institute for Intellectual Property (INPI) and the OAPI, the French National School for the Judiciary (ENM) is implementing this pilot programme for the training of trainers in judge academies in the following three countries: Cameroon, Côte d'Ivoire and Senegal. The aim of the programme is to train judge trainers so that each new judge graduating from the judge academy can follow the modules on intellectual property. A guide on case law is to be published to accompany this project. The modules have been developed by the French ENM in Bordeaux, and ENM trainers provide training to the judges selected (two for each country). The AfrIPI is the most ambitious programme we have on IPR in Africa.

185. Now I give the floor to my colleague Mr. Martin Gajda to deal with the IP Key Latin America. IP Key Latin America is the European Commission's programme to implement the objectives of the European Union in the area of IPR, through international cooperation with Latin American countries. Signed between the EU and the EUIPO in 2017, it is co-founded and implemented by the EUIPO and a total estimated cost of EUR 6 million.

186. The overall objective of the programme is to promote a level playing field for EU companies operating in Latin America by contributing to greater transparency and fair implementation of the IPR protection and enforcement system in there. EU businesses will benefit from improved IPR protection as well as from the achievement of adequate and effective functioning of IP administration and enforcement procedures in Latin America.

187. Furthermore, companies and right-holders should benefit from an increase in the technical expertise of Latin American countries and organizations on how to improve IPR related laws and proper implementation of trade agreements with the European Union. EU businesses will also benefit from enhanced access for EU users to IP information of Latin America IPO databases, which is crucial to their business and IP protection strategies abroad. These will be facilitated by the implementation of innovative tools and databases created by the European Trade Mark and Design Network (ETMDN).

188. The final beneficiaries will be reached mainly through active involvement of key business support and multiplier organizations operating in Europe and Latin America, as well as industry representatives and umbrella organisations. At the same time, Latin American innovative and creative business will take due advantage of such improvements in the level of protection and in the efficiency of enforcement of IPR which should, to a certain extent, enhance international trade and make the economies of the region more attractive to foreign investments. The programme has certain objectives and output and impacts:

a. First one is a substantive support for the preparation and development of FTA negotiations. The expected result of the project is to obtain data and information on local IPR legislation, protection and enforcement to assist the European Commission in the preparation, negotiation and implementation of FTAs in the region such as national or regional case law and the IPR institutional framework and resources.

b. Another one is the information collection and strategic analysis to prepare regional integration in Central America. Under this result, the project activities provide a detailed overview of the situation regarding IPR legislation, protection and enforcement and the capacity and efficiency of the IPR offices and institutions in the relevant countries. Encouraging and improving regional cooperation and integration on the processing and enforcement of IPR would support EU businesses operating across the region.

c. Third impact is the effective support for IP Dialogue and sub-committees and Implementation of FTAs. Appropriate actions are to be delivered in accordance with the decisions and indications that emerge from discussions during the existing and future IP dialogues and sub-committees held by the EU with Latin American countries. The Action also proposes interventions that assist the various countries involved in Latin America with obligations arising from the commitments taken in the context of the trade agreements with the EU. The action also includes the provision of *ad-hoc* support, in the form of support activities in relevant IP working groups.

d. Another output is the improvement of the IP administration and the enforcement of practices including the increased use of IP information technology tools and the establishment of an enforcement network. The Action is targeting an increased uptake of EU IT tools by the local IP offices to improve access to the IP system and to facilitate processing of IP applications and registrations. It will also comprise outspreading the EU approach in the elaboration of laws and development of best practices directed towards ensuring an efficient and transparent administration of IPRs. As regards enforcement, the action will be based on the development of enforcement networks in support of increasing the effectiveness of ICT tools and as well as on the exchange of best practices as regards IPR enforcement.

e. Another important objective is the awareness on the importance of intellectual property, its protection and enforcement. This outcome is attained by organising actions directed towards the promotion of the understanding of the importance of IP protection from the perspective of social and economic development, and to favour foreign investment.

f. One last objective of this programme, or output rather, is the improvement of the information sharing through information management system (IMS) and document repository. In order to ensure a sufficient institutional memory and easy accessibility by all interested stakeholders of the documents emanating from the project (such as reports, studies, surveys), an information management system will be set up and a document repository created.

### 12.2 United Kingdom

189. The United Kingdom is committed to sharing its experiences and knowledge in helping Members develop their IP systems. As an example, we would like to talk about a workshop between the United Kingdom and Viet Nam in June 2022, on working together to tackle counterfeit goods and piracy, both online and offline. This workshop sought to facilitate effective information exchange between relevant ministries and agencies in methods and best practice in preventing and combating infringement of intellectual property rights (IPRs); to continue to improve the capacity and effectiveness of intellectual property right enforcement; and to lay the foundations to build a comprehensive cooperation program on these issues.

190. Key sessions covered legal cooperation, where ministries and agencies exchanged and contributed specific ideas on ways to avoid overlapping of functions, duties, and authority. The discussion focused on the challenges of enforcement and various ways countries across the world are tackling the problem. It also focused on communication and education on intellectual property, resulting in new initiatives to raise public awareness of IPRs by local ministries and departments. We are pleased with the outcome of this workshop as a great example of learning from each other and how cooperation and sharing of experiences can benefit Members, contributing to raising IP standards globally.

### 12.3 United States of America

191. The United States continues to believe that a technical cooperation to improve IP protection and enforcement infrastructures it is crucial to countries' economic development, and it is directly linked to contributing to foreign investments and a voluntary private sector biotechnology transfer in developing countries and to fostering the ability for developing country innovators to capitalize on their creativity. We look forward to continued discussions and report in the Council concerning technical cooperation of governments and IGOs for the strengthening of IP systems.

### 12.4 Australia

192. Australia remains committed to promoting and facilitating technical cooperation and intellectual property capacity building activities. Australia fulfilled its Article 67 technical cooperation commitment through multilateral, regional and bilateral programmes and activities. Many of our activities are focused on developing and least developed countries in the Indo-Pacific region. Australia works closely with WIPO and associations of south-east Asian nations (ASIAN) secretariat and other partner to assist developing and least developed countries to build their intellectual property capacity and systems. We will be happy to discuss our report further with Members at the next available opportunity.

### 12.5 Switzerland

193. Our 2022 report document IP/C/R/TC/CHE/3 describes Switzerland's technical cooperation and capacity building activities. Switzerland is pleased to announce that it is currently partner to 12 technical cooperation bilateral projects across different regions in the field of IP. Whereas the Swiss State Secretariat for Economic Affairs is the main funder of the majority of projects through its Global Program for Intellectual Property Rights (GPIPR) set up in 2018, the Swiss Federal IP Institute implements the GPIPR.

194. Let me please recall that the GPIPR supports developing and least developed countries, as well as emerging economies, in developing an efficient and effective system for the protection and enforcement of intellectual property rights. This aims to promote economic developments, and assist our partners in the implementation of their rights and obligations under the TRIPS Agreement. Two examples of specific projects are described in a more detailed manner in our report of this year.

195. One project is the Swiss – South African IP Project, which began in 2020. Among the activities that have already been carried out, there have been workshops for patent examiners and collecting societies, and a report on the use of compulsory licenses in Switzerland for South African policy-makers was published. Another report on considerations relevant for the development of a GI strategy is underway.

196. The other project, which has started this year, is the Tunisian – Swiss IP Project. Its objective is to contribute to entrepreneurs, creators, researchers and producers in Tunisia benefitting from effective IP protection. For instance, the review of the laws relating to IP rights is one of the paths used to achieve the project's objective.

197. Switzerland continues its efforts to be a reliable partner in delivering technical assistance in the field of IP and to contribute through its technical cooperation projects, among others, to the implementation of the 2030 Agenda for Sustainable Development.

### 12.6 Canada

198. Canada is pleased to have submitted its report on the implementation of Article 67 under document number IP/C/R/TC/CAN/2. Canada's 2022 report provides an update on Canada's activities concerning IP-related technical and financial cooperation for developing and LDC Members. We thank the Secretariat in advance for its efforts in circulating Canada's report following this session.

199. Canada undertakes a number of technical cooperation activities at the multilateral, plurilateral and bilateral levels, which are outlined in this year's report. We would like to briefly take the opportunity to highlight a few notable activities from the past year. First, in May 2022, the Canadian Intellectual Property Office (CIPO) hosted and delivered its annual CIPO-WIPO Executive Workshop on IP Office Management, on management techniques in the delivery of IP services, for senior officials from developing countries. Due to the COVID-19 pandemic, this year's workshop was the second to be held virtually over the course of two weeks. The objectives of the workshop were to enhance knowledge and skills in the area of management techniques in the delivery of IP services; improve the capacity of IP officials; provide participants with first-hand experience of the nature and scope of Canada's IP expertise, products and services; and provide a forum to exchange ideas and experiences with officials from other IP offices.

200. In 2021, Canada's Expert Deployment Mechanism for Trade and Development (EDM) completed an activity in Viet Nam to strengthen protection of intellectual property rights in Viet Nam. This activity supported the IP Office of Viet Nam to implement legal and administrative reforms to better enable Viet Nam to fulfil its commitments under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The technical assistance had three major benefits for officials in Viet Nam by exposing them to:

a. how sound marks and undisclosed test data for agricultural chemical products are protected in Canada;

b. how IP rights are enforced by Canadian border officials and through criminal remedies; and

c. tools to raise public and private sector understanding of IP obligations in the CPTPP.

201. Additionally, from 2019-2022, Canada's International Development Research Centre funded a project to strengthen research and policy capacity on critical digital policy issues in Kenya. This project is supporting cyber policy research centres to develop a robust policy research agenda that addresses all facets of cyber and digital policy, including innovation, human rights, and security, and the interplay of these issues in the Global South. This project has resulted in the creation of an academic, open access, peer-reviewed journal – the Journal of Intellectual Property and Information Technology (JIPIT).

202. Also in 2019-2022, Canada's International Development Research Centre funded a project to strengthen the support the digital rights ecosystem in Latin America by building the capacity of key and emerging thought leaders with skills, knowledge, and resources; addressing critical challenges around digital rights; and promoting coordination among funders and organizations.

203. Further details on these activities can be found in Canada's 2022 report, and Canada would be pleased to discuss our report with any interested Member. Canada also remains interested in hearing views from developing country and LDC Members on the successes and challenges of technical

assistance and cooperation, as well as how priority needs have changed since Members' TRIPS implementation, and where gaps in technical assistance might remain.

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

### 12.7 New Zealand

205. Thank you Chair for providing the opportunity for New Zealand to speak to our technical cooperation activities under Article 67. The report, document IP/C/R/TC/NZL/1, identifies three avenues through which New Zealand provides technical cooperation and capacity building to developing and least developed Members.

206. The Intellectual Property Office of New Zealand (IPONZ) provides on-going technical assistance on request to developing and least developed countries. New Zealand will continue to support future work, on request, to improve the intellectual property systems of developing countries. IPONZ hosts delegations and study visits from developing and least developed countries to provide practical training and knowledge sharing.

207. New Zealand has been a member of the International Union for the Protection of New Varieties of Plants (UPOV) since 1981. As we all know, a key element of UPOV is cooperation between member states and the harmonisation of testing and examination activity.

208. The ASEAN-Australia-New Zealand Free Trade Area (AANZFTA) mandates a programme of technical assistance activities to assist AANZFTA Parties to operationalise and implement the Agreement. Until June 2022 this was known as the AANZFTA Economic Cooperation Support Programme (AECSP). Projects funded by the AECSP are available to all ten ASEAN member States. Numerous projects focus on Intellectual property. Including:

a. Assistance for ASEAN member States to accede to the Madrid Protocol and implement its post-accession, facilitating trademark registration regionally and globally.

b. Projects to strengthen ASEAN member States' institutional capacity to design and adopt a high-quality, consistent, and sustainable approach to patent examination and tailored training.

c. Development of a Regional Intellectual Property Public Education and Awareness Strategy and a pool of resources to raise awareness of AANZFTA business communities and IP creators about strategic IP management.

209. We hope the information provided today and in the report is helpful for Members in understanding the work New Zealand does in the implementation of Article 67.

### 12.8 Japan

210. The delegation of Japan would like to briefly describe this year's report on Japan's technical cooperation, document IP/C/R/TC/JPN/3, which was also submitted through the e-TRIPS submission system. This report consists of the main body and its annex. The main body highlights recent technical activities, while the annex lists the details of each activity. This report categorizes cooperative activities into four areas, namely, industrial property, copyrights, plant varieties, and border measures.

211. As for the industrial property, the Japan Patent Office organized 18 training courses for both government officials and the private sector in FY2021. More than 300 people attended in total. Moreover, based on the JPO's long history of conducting training courses, alumni associations have been established in the trainees' home countries. The Japan Patent Office continues to support the alumni associations by holding follow-up seminars in Asian countries. Japan will continue to make its utmost efforts to fulfil its obligation under Article 67.

### 12.9 Bangladesh, on behalf of the LDC Group

212. Under this agenda item, Bangladesh delivers this statement on behalf of the LDC Group. The LDC Group welcomes the reports under TRIPS Article 67 from the developed country Members and the reports of the Secretariat and other international organizations on the technical cooperation and capacity building support to the developing countries. These reports provide information on a wide range of programmes and activities customized for the beneficiary Members. These programmes are critically important for the LDCs.

213. We sincerely thank the developed country Members and the international organizations for their help and request to continue their valuable support for the developing countries and the LDCs including the graduating LDCs. In this regard, we also request delegations to explore the possibility of organizing an annual event, similar to TRIPS 66.2 workshop, to discuss the implementation of Article 67 of the TRIPS Agreement. We believe that the Secretariat can extend its support and such an opportunity will also help Members engage in informed dialogues. The LDC Group stands ready for further discussion on this issue with Members.

### 12.10 WTO Secretariat

214. The Secretariat's technical cooperation activities have the objective of assisting Members and Observers to meet their developmental and other domestic policy objectives, such as innovation and industrial policy, health, regulatory aspects, competition policy and environmental protection, through the trade and IP regime, in line with their domestic circumstances and priority needs.

215. During the review period, the Secretariat's technical cooperation activities in relation to the TRIPS Agreement continued to focus on assisting Members and Observers to understand their rights and obligations under the Agreement. Additionally, Members and Observers continued to receive tailored assistance regarding notifications and reviews of national legislation. Activities are essentially driven by demand from developing and least developed country Members, as well as from governments preparing to accede to the WTO. Partnerships and coordination with other intergovernmental organizations and key stakeholders are, of course, integral to our work and are increasingly important and valuable. Overall, the Secretariat is committed to continue its efforts to provide tailored support, subject to Member guidance, in order to respond to your needs and priorities.

216. Let me say few words about building capacity to respond to the COVID-19 pandemic. A particular priority continued to be responding to the needs of Members in relation to the COVID-19 pandemic response and preparedness. In the spirit of an integrated approach to address the pandemic, in February the Directors-General of the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the WTO reaffirmed their commitment to enhance support to Members battling COVID-19 and took stock of a number of initiatives delivered during the reporting period. Those included:

a. an updated extract of the Trilateral Study entitled "Integrated health, trade and IP approach to respond to the COVID-19 pandemic" in October 2021;

b. the second of a series of trilateral workshops on Accessing and Using Information Resources for the Pandemic Response held in February this year; and

c. the launch of the Trilateral Technical Assistance Platform in April 2022. This platform provides a one-stop shop that makes available the full range of expertise of the three organizations, and other partners, regarding the interface of public health, IP and trade matters in a coordinated and systematic manner. The objective is to build Members' capacity to effectively respond to the challenges caused by the COVID-19 pandemic.

217. To help respond to the continuing demand for interdisciplinary and integrated technical assistance on public health, trade and IP, the Secretariat also held a number of global workshops related to COVID-19 response and pandemic preparedness.

218. A brief summary of other main activities. In cooperation with WIPO, the WTO organized two flagship capacity building activities:

a. the 17th edition of the Colloquium for IP Teachers which covered a wide range of IP policy and legal issues, such as IP and public health, IP and e-commerce, IP and biotechnology, IP and artificial intelligence, and IP and blockchain, held from 1 to 12 November 2021; and

b. the Advanced Course on Topical Intellectual Property Policy Issues to equip government officials with the tools to develop and apply domestic policies that contribute to the IP development process and the achievement of domestic policy objectives, held from 28 March to 8 April 2022.

219. Another main capacity building activity included the annual workshop on the implementation of Article 66.2: incentives for technology transfer to LDCs. In our continuous efforts to improve the value and impact of this annual dialogue between LDC Members and developed country Members, this year under the guidance of LDC Members, the Workshop was devoted to specific fields of technology transfer critical for sustainable development. The Workshop featured highlights of a WTO survey on LDC needs and priorities for technology transfer, as well as a summary of developed country Members' annual reports on actions taken or planned in pursuance of their commitments under Article 66.2 of the TRIPS Agreement.

220. In terms of technical cooperation resources, the WTO produced an array of capacity building materials. For instance, a new book entitled "Trade in Knowledge: Intellectual Property, Trade and Development in a Transformed Global Economy" was published in March, the result of a process that commenced with a technical assistance workshop which drew together officials and experts from a wide range of developing countries to explore their capacity building needs in this evolving field. It complemented the launch of the WTO Trade in Knowledge portal, which provides materials aimed at helping policymakers and others keep abreast of current developments; understand the changing patterns of cross-border knowledge flows; and consider the legal, economic and policy dimensions. The WTO Secretariat also launched the report "Tackling Illicit Trade in Medical Products: Better international co-operation for better health". And finally, following from the World Health Organization (WHO), World Intellectual Property Organization (WIPO), World Trade Organization (WTO) Workshop on Accessing and Using Information Resources for the Pandemic Response in February, we also published an Inventory of COVID-19 Information Resources which can be accessed on the WTO's COVID-19 webpage.

221. The peer-reviewed academic journal, the WIPO-WTO Colloquium Papers, building on the Colloquium series, continued to strengthen scholarship and dialogue on development and other policy issues across the developing world.

222. Let me just say few words finally towards technical assistance generally at the WTO with TRIPS component just to highlight that the WTO Institute for Training and Technical Cooperation organizes many activities that include a significant TRIPS component. During this reporting period, this included two regional trade policy courses, a Virtual Executive Trade Course, a Virtual Introductory Trade Policy Course for LDCs, an in person Advanced Trade Policy Course for government officials.

223. Before closing let me just announce something which has been posted on our webpage this afternoon. Let me briefly draw your attention to a Workshop on Innovation and Access to Diagnostics for COVID-19 and Beyond, that will be held on 28 October 2022 from 2pm to 4.30pm. This capacity-building activity will be jointly organized by the WHO, WIPO and WTO secretariats. Following a factual introduction by the trilateral agencies to diagnostics, looking at the innovation and access landscape from a health, trade and IP perspective, panellists with various backgrounds are invited to discuss challenges, opportunities and the way forward to secure innovation and access in this particular area. While primarily targeting the membership of the three Organizations, the event is also open to other interested stakeholders. The registration link to attend this fully virtual workshop is included in the web announcement that you found as of now while we are speaking on our respective web pages.

224. I close by encouraging Members to continue to consult with us on priority needs for capacity building. We aim to work very closely with Members to ensure that technical assistance, and the empirical foundation of that work, continue to respond in a tailored way to their evolving needs and priorities, and bolsters capacity to undertake policymaking in IP, trade and related policy fields in a practical and focused manner that supports development goals.

### 12.11 Gulf Cooperation Council

225. At the outset, I would like to wish you and all participants to the TRIPS Council all the success. The overall objective of the Gulf Cooperation Council (GCC) technical cooperation programmes in the field of intellectual property is to contribute to the capacity building of officials from the GCC member States and to strengthen their knowledge in many IP technical aspects including the protection of intellectual property rights and supporting of invention and innovation.

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

227. The technical cooperation activities of the GCC Secretariat General during recent period was affected partially in a way or another by the COVID-19 outbreak. As reflected in the GCC technical cooperation activities report for 2022, which undertaken by the GCC Secretariat General covers the period from 1 September 2021 to 1 September 2022. The technical cooperation activities during the said period focused on various IP aspects such as enhancing the awareness of the intellectual property rights and its policies in the GCC region, cooperation in examination and IT as well as supporting innovation and invention, etc. These activities were conducted in the form of workshop, on-job training, supporting the participation in international invention exhibitions.

228. For example, cooperation with the World Intellectual Property Organization (WIPO) continues to contribute to the GCC technical assistance efforts in various IP areas. In this regard, it may be worth to mention that the GCC secretariat general, with the collaboration of WIPO organized a seminar for specialists from GCC member States titled "The WIPO virtual seminar on digital data, artificial intelligence and their connection to intellectual property" from 22 to 23 of September 2021.

229. Also, the GCC Secretariat General, in coinciding with the International Day of Handicapped organized event titled "The Exhibition for Handicapped Inventors" during 3-5 December 2021, in order to encourage and support those great people to more innovation.

230. Internationally, The GCC Secretariat General has participated to Malaysia international exhibition of inventions. The GCC Secretariat General ambitiously intended to facilitate the bilateral communications between inventors from the GCC States with those around the world and through this exhibition. The GCC Secretariat General hosts and supports all inventors from the GCC States.

### 12.12 World Intellectual Property Organization

231. Thank you for the opportunity to share some information on the World Intellectual Property Organization's technical co-operation activities conducted from September 2021 to September 2022 as set out in document IP/C/R/TC/WIPO/3.

232. WIPO remains committed to providing technical assistance to its member States so that they may progress on their developmental objectives while observing international intellectual property norms. WIPO's technical cooperation activities are needs driven and customized to countries' requirements. The activities also enable WIPO to deliver on its mission to lead the development of a balanced and effective global intellectual property ecosystem to create jobs, attract investments, drive enterprise growth, and ultimately develop economies and societies for a better and more sustainable future.

233. As set out in our report, WIPO's technical co-operation activities address three broad areas: policy and legislative advice, IP strategy, and IP office business solutions. Over the past year, there has been an increasing focus on enhancing the capacity of SMEs and young innovators to make effective use of IP. This has resulted in initiatives such as online training webinars and expert consultations on IP management and valuation.

234. The WIPO academy has continued to strengthen its extensive distance learning programs. Notably, the WIPO Academy has broadened the scope of its support to developing and

least-developed countries by focusing on building practical IP skills, transforming technical IP knowledge to real-world impact. Through new courses such as IP4Youth&Teachers, as well as programs on IP for start-ups and for app and videogame developers, WIPO aims to equip entrepreneurs, business owners and others with the necessary skills for success.

235. Ensuring IP continues to be a powerful tool to respond to global challenges remains a priority at WIPO. To support this, WIPO, WTO and WHO launched the Trilateral Technical Assistance Platform earlier this year. The objective of this platform is to help member States address their capacity-building needs in order to respond to the COVID-19 pandemic.

236. I would like to thank the Members who have acknowledged the extensive work done by WIPO in the area of technical cooperation. I would like to assure all members that WIPO remains committed to providing technical cooperation and capacity building programs, which respond to the needs of members as they seek to fulfil their TRIPS obligations.

### 12.13 World Health Organization

237. I would like to briefly mention that our communication to the TRIPS Council summarizes the technical cooperation activities of the World Health Organization (WHO) in the area of public health, innovation and intellectual property that have taken place since the last report. The overall objective of WHO's technical cooperation is to strengthen the capacity of developing countries in the areas of health innovation, access to medicines and management of intellectual property.

238. WHO's technical cooperation is based on its mandate derived from the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) as well as other relevant resolutions of the World Health Assembly, including WHA resolution 72.8 on "Improving the transparency of markets for medicines, vaccines, and other health products[1]", WHA resolution 73.1 on the "COVID-19 response,[2] "WHA resolution 74.6 on "Strengthening local production of medicines and other health technologies to improve access[3]" and WHA resolution 75.14 on the extension of the time frame of the "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property" from 2022 to 2030.[4]

239. In resolution 74.6, the Seventy-fourth World Health Assembly emphasized the need to improve access to quality, safe, effective and affordable medicines and other health technologies, *inter alia*, through cooperation with, support to and development of voluntary patent pools and other voluntary initiatives, such as the WHO COVID-19 Technology Access Pool (C-TAP). The resolution requested by Dr Ghebreyesus, WHO Director-General to continue to provide technical support, as appropriate, upon request, in collaboration with other competent international organizations, in particular World Intellectual Property Organization and World Trade Organization, including to policy processes and to countries that intend to make use of the provisions contained in the TRIPS Agreement, including the flexibilities affirmed by the Doha Declaration on the TRIPS Agreement and Public Health in order to promote access to pharmaceutical products.[5]

240. WHO, through its Headquarters, Regional and Country Offices collaborates closely with relevant international organizations on topics related to the interface between public health, innovation and intellectual property. We remains committed to provide technical assistance to member States at their request.

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

### 13.1 South Africa

241. We thank you for the schedule of meetings to engage on this important issue. The World Health Organization has been abundantly clear about the need to deal with the COVID-19 pandemic comprehensively. Dr Ghebreysus, Director-General of the WHO, has said, "Vaccines alone will not

[1] https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf
[2] https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf
[3] https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf
[4] https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R14-en.pdf
[5] https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R6-en.pdf

end the pandemic." "Many countries need diagnostics, lifesaving therapeutics — including oxygen and support for vaccine rollout".

242. The COVID-19 pandemic is ongoing. Health experts have warned that while Omicron subvariants BA.4/5 have dominated in Europe over the summer, newer Omicron subvariants are gaining ground.[6] WHO data released last Wednesday showed that cases in the European Union reached 1.5 million last week, up 8% from the prior week while hospitalization rates in Europe have increased significantly over the past few weeks. It is reasonably foreseeable that this trend will be replicated in other regions heading into the winter months.

243. As we witnessed in the initial waves of the pandemic, the interconnectedness of the global economy rendered the spread and mutation of new variants inevitable. Let us learn from the lessons of the past few years and develop a comprehensive response to the pandemic as health experts have urged.

244. The Ministerial mandate in paragraph 8 of the WTO Decision on the TRIPS Agreement is a matter of utmost priority. The 17 December deadline is fast approaching and necessitates that we act decisively on this important item that affects people's lives. The Decision reached at MC12 demonstrated what we can achieve as the Membership when we work together and adopt a solution-oriented approach to issues that affect humanity. The said Decision was a step in the right direction, but we must conclude our unfinished business.

245. The waiver proponents have provided sufficient evidence in the documents that have been submitted before on the intellectual property barriers applicable to therapeutics and diagnostics, including concerns regarding accessibility and affordability. Therefore, we urge all Members to move beyond circular Q&A sessions and expeditiously proceed with the decision entailed in paragraph 8.

246. As we stated in the General Council last week, the paragraph 8 mandate is clear: the task before us is to decide within 6 months on the extension of the WTO Ministerial Decision on the TRIPS Agreement to cover therapeutics and diagnostics. It is not an agreement to renegotiate the text.

247. Some delegations have expressed concern about therapeutics with multiple uses and have thus called for the products covered by the decision to be limited. However, the WTO Ministerial Decision contains safeguards to ensure that products produced and supplied under the authorization are for COVID-19. This is reflected, for instance, in paragraph 1 which provides that authorizations under the Decision may only be granted, "to the extent necessary to address the COVID-19 pandemic". My friend Sherif spent many hours in the green room negotiating those wordings.

248. In addition, the treatment options to be availed to patients depend on many factors, such as the disease severity, the availability of drugs, routes of administration (only intravenous for remdesivir and the monoclonal antibodies), and duration of treatment, among others. Some of these treatments can be used in combination (i.e. as for severe or critical COVID-19) while others are to be used as alternatives. The evolution of the virus and patterns of vaccination affect the efficacy of therapeutics thus raising the importance of adapting the treatments to local contexts. We caution against an approach that ties the hands of health authorities on the ground and therefore defeats the very purpose of the waiver Decision.

249. At the TRIPS Council meeting of 19 September, a number of questions were posed to the co-sponsors and we thank delegations for these questions. They are, however, similar to the questions that have been repeatedly asked and answered since October 2020. We suggest that delegations go back to the submissions that we have already made. However, as we did at the informal meeting on 3 October and in the spirit of constructive engagement, we offer some reflections on some of the most pertinent of these recent questions. So I have selected some of them and will read them out and give some responses. Two of them read as follows:

a. In which countries and for which products have the prices been prohibitively high so that they have posed a barrier to access?

[6] https://www.reuters.com/world/europe/covid-wave-looms-europe-booster-campaign-makes-slow-start-2022-10-06/.

b. Do these prices reflect the lower prices that many pharmaceutical companies offer via their tiered pricing systems?

250. In response we would posit the following: equitable access means that therapeutics and tests are available and affordable for all who need them at the same time everywhere. Currently, many therapeutics and diagnostics, which are widely available in high-income countries (HICs) are not so in low- and middle-income countries (LMICs). Developing countries are kept waiting for donations or for companies' decisions on whether:

a. to enter into a voluntary licence and the conditionalities that companies impose on their voluntary actions, e.g. geographic limitation;

b. to donate some products to countries or populations of the company's choice;

c. to lower the price to a level and for countries of the company's choice.

251. Clearly this is not a sound public health policy to leave LMICs subject to the largesse of companies' decisions.

252. There are two important issues related to access to COVID-19 therapeutics and diagnostics:

a. supply in terms of the quantity of the product available for LMICs to procure; and

b. the price. Like vaccines, pharmaceutical companies prefer to supply the high-income market where they can sell for higher prices and maximize their profit than in LMICs where profit will be less.

253. That is why access to therapeutics and diagnostics is repeating the inequitable situation seen in vaccines. For example, as of April 2022, 66% of Merck's anti-viral medicine (Molnupiravir) was sold in high-income countries.

254. Other medicines such as monoclonal antibodies are not available in many LMICs. When available, the price is prohibitive. For example, Roche's price of a 600 mg dose of tocilizumab is USD 646. The main patent on tocilizumab expired in 2017, yet several secondary patents remain on the medicine in a number of LMICs that cause uncertainties about the potential of production of biosimilars. Shortages of tocilizumab have been observed in many countries that have already started using it for COVID-19 treatment. It has been documented by Médicins Sans Frontières that during the second wave, in one developing country[7], the distributor ran out of the medicine and not a single vial was available in that country for critical patients.

255. WHO recommended the monoclonal antibodies (mAbs) casirivimab and imdevimab for people at high risk of developing serious COVID-19 diseases and defined these groups as: a) older age b) have immunodeficiency or chronic disease or c) are unvaccinated.[8] The medicine is the subject of patent applications filed in at least 11 LMICs.

256. These medicines are examples where the producing companies dictate supply, allocation, and price. Supply is not adequate, and the prices are too high in LMICs. Since the real cost of R&D and manufacturing are not known due to a total lack of transparency, it is difficult to assess the prices offered except in terms of countries' affordability to purchase. In the case of repurposed drugs it is particularly difficult to justify monopoly prices as an incentive for research and development. Many LMICs would not consider the current prices of most COVID-19 therapeutics and diagnostics to be affordable.

257. Turning to the next question, it is more of a statement than a question: there are many therapeutics for which patent rights do not exist, or which are royalty-free. In response, we would posit that there are medicines such as dexamethasone that have been produced by generic companies in several countries. Generic competition of this medicine has led to lower prices and

[7] https://msfaccess.org/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and-inaccessible.

[8] https://www.who.int/docs/default-source/coronaviruse/poster_casirivimab-and-imdevimab.pdf.

wider availability. This is precisely the situation that we would like to create for newer therapeutics and hence extending the WTO Decision of June to therapeutics would be helpful in this regard. There are not many royalty-free therapeutics for COVID-19 and, as we pointed out before, treatments that are suitable for patients differ and are based on a number of factors.

258. Patent barriers affect accessibility and affordability. For example, tocilizumab, which was mentioned before, is strongly recommended for treating patients with severe and critical COVID-19. It is a biological medicine manufactured by a Swiss-headquartered company.[9] Tocilizumab is in fact a repurposed drug, having been used for *inter alia* rheumatoid arthritis since it was first marketed. Its main patents expired in 2017. However, subsequent patent applications for other features have been filed leading to the extension of tocilizumab's patent thicket up until 2028 for some jurisdictions in the world.[10] These are known as "evergreening" patents. Although Roche voluntarily said that it would not enforce its patents in some developing countries and least developed countries, it leaves out key manufacturing countries.[11] In South Africa, for example, despite an expert panel finding that tocilizumab reduced deaths, the recommendation was for the medicine to not be used because it is "not affordable at the current offered price". The life-saving therapy is largely out of reach for African populations at a cost of around 2,000 dollars per patient.[12] The cost to manufacture tocilizumab is estimated to be as low as 40 dollars per dose of 400 mg.[13] Further, the demand for tocilizumab far outstrips its limited supply, jeopardising the treatment not only of COVID-19 patients but also those who use the drug for the other indications available.[14]

259. Two further questions state as follows: first, there are some COVID-19 therapeutics available to developing countries at low prices through voluntary licences including via the Medicines Patent Pool (MPP), or tiered pricing. Considering these facts, patent rights are unlikely to be the cause of rising prices or restricted access to therapeutics in developing countries.

260. The second one reads as follows: we need comprehensive information about existing collaborations and in particular voluntary licences. For instance, are there countries that would have been interested in applying for a sublicence for molnupiravir and Paxlovid but were not able to do so because they fall outside the scope of the MPP licence agreements? Which companies from those countries, that are eligible for applying for a sublicence, have been rejected in WHO's prequalification phase? Have applications been turned down for other reasons? And in which cases has it been possible for low- and middle-income countries to conclude voluntary licensing agreements?

261. In response we would say the following: there are only two anti-viral products that have been recently licensed to the MPP, molnupiravir produced by Merck and a combination drug produced by Pfizer. One generic equivalent of molnupiravir received WHO prequalification approval and several more versions of both medicines are awaiting approval. However, these licences have limitations, for example, as to the geographical scope. Although the licences allow for manufacturing worldwide, they limit where the licensees can supply these products.

262. The licences exclude most of Latin America and many Asian countries from benefiting from these arrangements directly. The extension of the June Decision would streamline the process for compulsory licensing to allow excluded countries to access lifesaving treatments at affordable prices.

263. Outside the MPP, bilateral voluntary licences between producing companies and generic companies lack transparency and have several conditionalities on supplies and geographic allocation. For example, a bilateral licensing agreement for remdesivir excluded nearly half of the world's population from benefitting from price-lowering generic competition.[15]

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[9] https://app.magicapp.org/#/guideline/nBkO1E.

[10] See IP/C/W/670.

[11] In countries where there is no such waiver of patent implementation, it is reported that Roche has kept the price of this therapeutic very high in most countries, ranging from 410 dollars in Australia, 646 dollars in India to 3,625 dollars in the USA per dose of 600 mg for COVID-19.

[12] https://www.twn.my/title2/intellectual_property/info.service/2021/ip211011.htm.

[13] https://reliefweb.int/report/world/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and.

[14] https://msfaccess.org/tocilizumab-second-drug-ever-recommended-who-covid-19-will-remain-unaffordable-and-inaccessible.

[15] https://www.msf.org/governments-must-support-proposal-waive-coronavirus-covid-19-patents.

264. Other medicines, especially monoclonal antibodies, colloquially knows as mAbs, such as baricitinib, are not available due to exclusive rights held by the originator.[16] The originator holds patents in more than 50 developing countries, e.g. Latin America, Asia and Africa, which are hit hard by the pandemic.

265. Problems with access to mAbs are not limited to LMICs. For example, the drug bebtelovimab is recommended for immunosuppressed patients with COVID-19. It is not available in Europe because the company that holds the IP rights refuses to register and market the product for patients in Europe.[17] This is discussed extensively in an open letter by Michel Goldman, President of the Institute for Interdisciplinary Innovation in Healthcare, Université libre de Bruxelles, Belgium. This open letter dated is 5 August 2022.[18]

266. Many of these details that we provided today are available in our written submissions document IP/C/W/670-674. We urge delegations to consult these submissions.

### 13.2 Maldives

267. The Maldives would like to reiterate our commitment to assist in enabling universal, equitable and affordable access to COVID19 vaccines, including therapeutics and diagnostics. In this regard, we believe it is important that urgent and concrete action be taken by the TRIPS Council to help diversify production of COVID-19 vaccines, diagnostics and therapeutics and contribute to improve the health and wellbeing of all people, everywhere around the world.

268. The World Health Organization still considers COVID-19 as a pandemic. They have recently announced that there are entire regions of the world that are at risk of the pandemic because of vaccination gaps, low rates of testing and sequencing, and lack of access to antivirals. Therefore, we believe it is important that diagnostics and therapeutics are made available promptly, in sufficient quantities and at affordable prices to meet global demand.

269. The Maldives welcomes the schedule put forward by the Chair on 21 September 2022 to discuss paragraph eight of the 12th Ministerial Decision on the TRIPS Agreement. We encourage the Chair to continue the discussions as planned and also facilitate bilateral meetings as we now have less than three months to come to a decision. In these discussions, we request Members to engage constructively in the spirit of cooperation and solidarity, to strengthen the MC12 Decision on the TRIPS waiver agreement for the COVID-19 pandemic by including diagnostics and therapeutics.

### 13.3 Kenya, on behalf of the ACP Group

270. I deliver this statement on behalf of the ACP Group. The ACP Group commends the commitment of Members during the 12thMinisterial Conference and welcomes the Ministerial Decision on the TRIPS Agreement with respect to COVID-19 vaccines, and the need to extend this Decision to therapeutics and diagnostics.

271. It is important to emphasise that COVID-19 remains a health threat to populations, and that the use of vaccines is limited in scope in the fight against this disease. Access to therapeutics and diagnostics is therefore essential to sustainably address this pandemic. Moreover, the rate of vaccination in many of our countries is still very low compared to developed countries.

272. We have agreed to reach a decision no later than six months after the Ministerial Conference. In order to achieve this, it is essential to start serious textual discussions on the possible contours and content of such a decision. To refrain to engage in textual discussions is to choose inevitably to reach a negative decision and to close doors and windows to a positive consensus.

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[16] https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments.

[17] https://www.thepharmaletter.com/article/weak-demand-leads-lilly-to-withdraw-covid-antibody-in-europe.

[18] https://www.ft.com/content/36b1d91d-6b0c-453e-b4a0-37f3d21912e4?accessToken=zwAAAYO8xn4ikc82sdkdawxFPtO0oDfz0hkS5A.MEUCIQDif6JgTk6nWXumorWb6HvIjWbna_iFasMLcQMwq_rIEwIgDVwZ4rJXBB83PJmoEHCKHgq24j0N44Z4MQg4F3X_v1A&sharetype=gift&token=d2901bba-041a-456c-b04a-32a6acdc3b13.

273. The ACP Group remains firmly confident in the strength of mutually beneficial dialogue and calls on all Members to work towards the commencement of formal negotiations on the draft text submitted by the co-sponsors. Please be assured of our readiness to work diligently with the other parties to advance this discussion and to reach a mutually beneficial outcome.

### 13.4 Malaysia

274. At the outset, allow me to thank Dr Ngozi Okonjo-Iweala, Director-General of the World Trade Organization, and you, Chair, for the collective leadership in this discussion. In the TRIPS Ministerial Decision, we view that vaccine equity can be further improved in vulnerable parts of the world in a timely manner. We remain cognizant of the role of intellectual property rights in research and development. Nonetheless, the COVID-19 experience tells us that addressing the threatening pandemic situation now and in the future warrants more comprehensive and decisive interventions. Therefore, we will continue to support Dr Ngozi Okonjo-Iweala, Director-General of the World Trade Organization and you, Chair, in our endeavour to deliver an inclusive WTO response to the pandemic.

### 13.5 Bangladesh, on behalf of the LDC Group

275. Bangladesh delivers this statement on behalf of the LDC Group. The LDC Group supports the initiative and the presentation by South Africa on behalf of the co-sponsors, which includes the LDC Group.

276. The LDC Group welcomes the temporary MC12 TRIPS waiver Decision to support the production and affordable and timely supply of COVID-19 vaccines with an opportunity to extend the decision to therapeutics and diagnostics. This is already a delayed decision after the outbreak of the pandemic. We sincerely hope that the MC12 Decision will help scale up COVID-19 vaccine production and make those vaccines affordable for all of us. Without further delay, we must extend the Decision to therapeutics and diagnostics as desired by the Ministers. In our understanding, no new conditions are required to extend the same decision resulting from a long negotiation.

277. In this regard, the least developed countries (LDCs) thank the TRIPS Council Chair for his schedule to facilitate dedicated informal discussions and also appreciate the oral status report in the General Council. The LDCs hope that the TRIPS Chair may kindly continue presenting his oral status report in the General Council as the TRIPS Council is yet to complete this work, as instructed by the Ministers at MC12.

278. We urge Members to engage constructively in order to fulfil the mandate of the MC12 Decision on the TRIPS Agreement regarding the inclusion of therapeutics and diagnostics. Our Group stands ready for further work to agree on a favourable decision as soon as possible before the deadline ends in December 2022.

### 13.6 Colombia

279. Just after MC12, at our first subsequent meeting before the summer break, Colombia expressed its support for the extension of the waiver to the production and supply of COVID-19 diagnostics and therapeutics. On that occasion, Colombia further noted that the best alternative would be a simple extension of the Decision to the new product category, as a lengthy discussion reopening all the arguments would be extremely complicated.

280. Today, we are concerned about precisely that. We have two major concerns about this discussion process. The first is that there seems to be an impasse over arguments regarding the process. We seem to be reaching a point in the discussion where everyone is asking for general evidence on the role of IP in innovation, by some, and in access, by others. This is not about resolving such a complex and potentially TRIPS Agreement-wide issue. It is more simply an emergency redistributive measure, which does not have a general impact but a specific impact on individual production chains. The responses are not, and cannot be, general but are always context-specific.

281. We are concerned that the focus is shifting from an exceptional measure to a general discussion about the role of IP in access to health, or to innovation. Ideally, we should get back to the particular context of this discussion: we need to recognize the seriousness of what happened and is still happening, and simply recognize the political importance in general, and limited to some

countries in particular, of what the limited vaccine waiver could do once extended to therapeutics and diagnostics. Moreover, this impasse has immediate consequences for how the WTO and the TRIPS Agreement are seen from outside, and their legitimacy, because they will be perceived as inflexible, as disconnected, as incapable of contributing effectively to a global problem. We should be more strategic, and more specific, collectively recognizing that this is an exceptional case, and adopt a simple extension of the MC12 Decision, as soon as possible.

282. If there are no obstacles, then it should be easy to extend the Decision, and if there are obstacles, then extending the Decision should be paramount. Secondly, we would like to express our concern about a particular technical issue. This is the considerable legal uncertainty surrounding the licensing processes for the production of therapeutics and diagnostics, as this is the most frequently mentioned alternative to extending the Decision in paragraph 8. Indeed, many of you have noted that voluntary licensing has been shown to be a swift and effective way to increase production and access, without infringing on the rights of patent holders.

283. Regardless of whether this is true or not on a case-by-case basis, which is debatable as South Africa has shown, what is indisputable is that all current licensing processes that will allow for increased production with conditions are also shrouded in the considerable legal uncertainty stemming from the so-called patent wars. Indeed, there is a patent lawsuit war going on in the major markets. There are lawsuits and counter lawsuits of tremendous importance for vaccines, therapeutics and diagnostics. Depending on the outcome of these lawsuits, patents may immediately become an obstacle to access to vaccines, diagnostics and treatments, as these decisions will have an immediate effect on voluntary licensing schemes. Against this background, both because of the specific and contextual nature of what we are discussing, and because of the problems that are likely to emerge with the alternatives, Colombia reiterates its position on a simple extension of the MC12 waiver Decision. Let us move forward with your meeting schedule to achieve this.

### 13.7 Indonesia

284. Before starting with our statement, I would like to begin by extending our appreciation to the Chair for the report at the General Council meeting as well as for setting up a schedule to discuss and follow up this much-needed, live-saving outcome of the MC12.

285. Unlike the COVID-19 waves we experienced in 2020 and 2021, where a single variant, such as Delta, rapidly outpaced all others and spread across the world, virologists are currently tracking the growth of multiple immune-evading subvariants for these coming months.

286. About 80% of people in high-income countries have received at least one vaccine dose compared to only 23% of those in low-income countries. Those who have not been vaccinated are facing bigger health risks than those who have. Vaccines are only part of the solution.

287. In this regard, therapeutics and diagnostics are inseparable parts of the countermeasures devised in the WHO's four-pillar strategy, and have been proven to be effective in the prevention, containment, and treatment of COVID-19 and subsequent pandemics.

288. Dr Ghebreyesus, Director-General of the World Health Organization, once stated that it is simply not acceptable that innovative treatments that can save lives are not reaching those that need them, while manufacturers are posting record high profits. In fact, for both testing and therapeutics, the ACT-Accelerator report notes with concern the challenge that manufacturing is highly concentrated and the need for diversification in production, in particular through local production.

289. The evidence is out there, and to be bogged down by providing evidence in a circular manner is to repeat the same mistakes we have made, where it took us 18 months to reach a decision that is partial, conditioned, and narrow in scope to respond to COVID-19. Are we going to follow the same old pattern or are we going to become an organization that is relevant and responsive in addressing this global issue?

290. Lastly, no one is safe until everyone is safe and that means everyone needs access to, and the availability to use, if needed, the medical tools to stay safe at affordable prices, which includes

vaccines, tests, and treatments. Indonesia, as always, stands ready to engage constructively on this issue.

### 13.8 Sri Lanka

291. The Sri Lankan delegation would like to thank you, Chair, for initiating discussions on the way forward on this issue, as this is a very important decision to take from a public health perspective.

292. We would like to highlight that on 15 June 2021, the Directors-Generals of the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) issued a joint statement in which they underscored their "commitment to universal, equitable access to COVID-19 vaccines, therapeutics, diagnostics, and other health technologies".

293. Further, on 27 September 2021, WHO, WIPO and WTO jointly organized a workshop which addressed the importance of realizing global equitable access for vaccines, diagnostics, therapeutics and other COVID-19 health technologies; mechanisms and processes to support technology transfer and intellectual property licensing; and enabling factors and policies for technology transfer.

294. On 29 June 2022, Dr Ghebreyesus, Director-General of the WHO noted "on COVID-19, driven by BA.4 and BA.5 in many places, cases are on the rise in 110 countries, causing overall global cases to increase by 20% and deaths have risen in three of the six WHO regions".

295. On 16 February 2022, the International Monetary Fund recognized that "in this environment, our best defense is to move from a singular focus on vaccines to ensuring each country has equitable access to a comprehensive COVID-19 toolkit with vaccines, tests, and treatments".

296. The world is now experiencing an evolution of the COVID-19 pandemic. It is observed that antibodies triggered by vaccination are less effective in responding to new variants of the pandemic, and even vaccinated people with boosters are vulnerable to multiple infections of new variants. Still people continue to die from COVID-19 and new variants of the pandemic due to limited access to life-saving treatments in many parts of the world.

297. Besides that, the crucial role of therapeutics and diagnostics in controlling COVID-19 is undisputed. Diagnostics are critical for effective use of therapeutics. Testing helps to identify new COVID-19 variants and to develop effective vaccines and therapeutics. They are recommended increasingly by WHO as well as by national strategies as part of test-and-treat strategies.

298. However, testing in developing countries, especially in least developed countries (LDCs), remains absurdly low. Therapeutics and diagnostics for controlling COVID-19 recommended by the WHO are either unavailable or unaffordable for most developing countries, mainly due to significant supply constraints and limited numbers of manufacturers, particularly for new therapeutics.

299. We fully concur with the concerns expressed on the low level of daily COVID-19 tests per thousand people reported in many developing countries. If I speak of the situation in my country, it stands at 0.06% in Sri Lanka as of June 2022. The hospitals are not carrying out PCR tests on suspected cases and they can only rely on rapid antigen tests (RATs) in view of the high cost involved in PCR testing, as the government cannot continue to afford and fund the provision of such facilities to its population free of charge.

300. Such empirical data reveals the imbalance in the area of use of diagnostic tests, as they are not easily accessible for low and lower middle-income countries. If these countries had access to generic versions of PCR testing kits at affordable cost, then PCR testing could be increased for tracing the positive cases for further treatment. In Sri Lanka, though the daily new confirmed cases due to COVID-19 remains at somewhat low levels, the actual situation may reveal a different picture, if we can test cases using PCR test methods.

301. It is also important to note that the treatment landscape is constantly evolving. Many clinical trials are underway and thus no single therapeutic is sufficient. It has been identified that different therapeutics are applicable at different stages of COVID-19.

302. Intellectual property monopolies, especially relating to patents, remain a major barrier to scaling up production and to facilitating equitable access. According to WIPO, there are considerably more patent filings related to therapeutics than on vaccines, at an approximately 4:1 ratio.

303. For some therapeutics, there may not be a need for voluntary licences that are required for supply. In some cases voluntary licences exclude supplying many developing countries, and even for countries included, voluntary licences are subject to various conditions that are often difficult for developing countries to comply with. Supply constraints are expected to continue even for products for which voluntary licences do exist.

304. Therefore, extending the scope of the TRIPS Decision beyond vaccines to cover therapeutics and diagnostics could secure the availability of compulsory licences to override the patent barriers to production and export, as equitable and affordable access to therapeutics and diagnostics still remains a massive challenge for developing countries and LDCs. In this backdrop, the Sri Lankan delegation would like to re-emphasize that the TRIPS Decision needs to be extended to cover the production and supply of COVID-19 diagnostics and therapeutics.

305. Sri Lanka echoes the concerns expressed by co-sponsors of the proposal document IP/C/W/669/Rev.1, particularly in relation to a lack of clarity on the way forward and dragging of the process by some Members, which might delay reaching the final outcome on the remaining Ministerial Decision by the end of 2022.

306. It is commendable that the TRIPS Council has already started discussions on this matter and aims to make progress, however, we believe that the TRIPS Council should provide clarity on how discussions will be taken forward and accelerated so that a meaningful decision may be taken within the stipulated time frame as per the MC12 Decision.

307. We believe that studies and reports presented by reputed international organizations working on these issues, including WHO and WIPO and several submissions put forward by the co-sponsors, have already emphasized and shown enough evidence through facts and figures to prove the importance of addressing IP-related challenges to expanding production and providing equitable and affordable access to all COVID-19 products including vaccines, therapeutics, diagnostics, and other essential medical goods including their inputs, for the current and future pandemics.

308. Substantial discussions have already taken place on this matter during the negotiations prior to MC12 and there is no justification for exploratory factual discussions which can delay the adoption of this decision, which contributes to addressing a public health emergency.

309. Further, our ministers emphasized this decision by adopting the Ministerial Declaration on the WTO response to the COVID-19 pandemic and preparedness for future pandemics at MC12 as well. Therefore, we urge Members to seriously consider this timeline ahead of us and work positively, constructively and meaningfully to deliver this significant decision within the stipulated time.

310. My delegation would continue to engage in all future discussions on this very important file constructively, as this matter is about public health of human life on this planet. We would like to emphasize that any process going forward should be open, inclusive, and transparent and allow all Members to be heard.

### 13.9 Egypt

311. This intervention is going to be very brief and to the point, having heard the statements made by South Africa on behalf of the co-sponsors, Sri Lanka, Indonesia and others, which we support. My intervention is based on some of the information that our negotiator sitting next to us, Sherif, has provided in the preparations for this meeting.

312. We recall that at a certain point in time when we were negotiating prior to MC12, the cosponsors, together with our trade partners, had an agreement. And this is mentioned even in written submissions provided by our trade partners. In one of the submissions in the run up to MC12 it was acknowledged that therapeutics and diagnostics, together with vaccines, are one of the pillars of a comprehensive approach. I am referring to documents that were submitted by the European Union, document numbers IP/C/W/680 and IP/C/W/681. Its preambular part, paragraph number

three states that "recognizing that pandemics affect all countries and therefore require concerted global efforts to ensure that all people in all countries have access to safe and effective vaccines and medicines as soon as possible". As you see, it says "medicines". Reference was made to therapeutics in document IP/C/W/680. Everybody here is aware that the definition of medicines is quite broad and comprehensive, and it may include therapeutics and diagnostics. So, the question today is, has this position changed? If so, then why?

313. Again, for the sake of time, and to be brief and practical, I wonder when our trade partners will finalize their data and evidence-gathering process and analysis, given that we have a deadline that we need to honour. What will happen if we miss that deadline? This is a question that I am posing to the membership, especially our trade partners. What will happen if we miss the deadline? Are we ready in this Council to miss the deadline? This is a very important question to answer. My delegation is not ready to miss the deadline. We request our trade partners to provide answers to those questions as soon as possible. We also refer to the answers that we provided to the questions in the course of the informal meeting [of 3 October 2022].

### 13.10 Argentina

314. The Argentine Republic wishes to align itself with the statement made by the distinguished delegate of South Africa on behalf of the co-sponsors. Our country has faced numerous barriers in terms of access to health technologies during the pandemic, as have many developing and least developed countries. This is why we stress the importance of fulfilling the mandate under paragraph 8 and extending the Ministerial Decision to cover COVID-19 diagnostics and therapeutics. In doing so, we will help achieve more affordable and equitable access. In this regard, I would like to refer to the statement made by my delegation at the previous General Council session. The deadline stipulated in the mandate expires in less than two months. We need to move forward in constructive debates to fulfil, in due time and form, the multilateral obligation assumed in June.

### 13.11 Bolivia, Plurinational State of

315. We thank the delegation of South Africa for the statement made on behalf of the co-sponsors, and those made by other co-sponsors, which we support. As we said in the General Council last week, we regret that no concrete progress has been made to fulfil the mandate, adopted by Ministers last June, to extend this decision to therapeutics and diagnostics.

316. It is our understanding that the pandemic is not yet over, and, although our response to it has not only been belated but also limited, it is evident that the pandemic was and is still ongoing, albeit in abeyance, otherwise it would have made even less sense to make so much effort to reach a consensus. We refuse to believe that those efforts were made only to impress the international community and the world. We made those efforts because we are truly concerned about human life and those who have been impacted the most by COVID-19, the most vulnerable populations.

317. Accordingly, ensuring equitable access to therapeutics and diagnostics at fair and affordable prices is an essential part of this response. We could spend another two years discussing whether or not intellectual property is a barrier, how to define therapeutics and other countless questions, to which answers may not even be found in this room. But the fact remains that the pandemic continues and infections are up again, so we need to anticipate our response and increase production capacity in the event of an obvious emergency.

318. During the pandemic, the high cost of essential medical supplies to combat the disease became evident, and many countries face major challenges in accessing these medicines and oxygen for intensive care, hospitalization and prevention, as well as diagnostic tests, the procedures for which, such as those required for the PCR tests, are complex, lengthy and costly. As we have said on several occasions, in the case of Bolivia, like other developing and least developed countries, the shortage of medicines, tests and oxygen was critical, and urgent actions had to be taken to overcome this problem. In this context, for example, we stepped up the planning and acquisition of medical supplies through the Office for Health Commodities and Supplies (CEASS), an entity overseen by the Ministry of Health and Sport, which has allowed health system procurement to be managed properly and ensured that they were used for COVID-19 patients. This shows that there are ways to manage these matters at the national level that allow for the controlled use of therapeutics and diagnostics.

319. Lastly, we believe it is urgent to implement our mandate. We therefore ask delegations to commit to working in good faith in order to reach a comprehensive response on the basis of the adopted timetable and to carry it out in an inclusive and transparent manner, without excluding Members' legitimate interests, so as to give effect to the Decision as soon as possible.

### 13.12 Brazil

320. Brazil is committed to a robust trade and health framework for the World Trade Organization, one that offers meaningful, timely and comprehensive solutions to the COVID-19 pandemic and beyond.

321. I would like to reiterate our commitment to work under your leadership, Mr Chair, on fulfilling the mandate created by paragraph 8 of the Ministerial Decision on the TRIPS Agreement to extend its scope to COVID-19 therapeutics and diagnostics.

322. We call on all Members to work together with flexibility and good faith to find common ground and reach a balanced outcome, within the agreed timeframe, that preserves the integrity of the TRIPS Agreement, while improving the relevant dispositions and providing for affordable and inclusive access to COVID-19-related products in developing and least developed countries.

### 13.13 China

323. COVID-19 and its various variants remain a major challenge to the world, in particular for developing Members. China, as a developing Member plagued by similar difficulties, fully understands the positions of the co-sponsors and firmly supports the efforts to increase the accessibility and affordability of diagnostics and therapeutics for developing Members. Therefore, we call upon the further coordination among Members and relevant international organizations, so as to make greater contributions to help developing Members fight against the pandemic. China stands ready to work with all Members to continue our active and constructive engagement in follow-up consultations and pursue an early decision on this issue.

324. Meanwhile, we have also noticed the diversity and complexity of COVID-19 diagnostic and therapeutic products. We believe an early and scientific clarification of the product scope would help our discussion in a more focused and targeted manner. Again, we would like to reiterate our concern for the transparency and inclusiveness of the consultation process. The consultation process is aimed at implementing the multilateral consensus of MC12; therefore, the whole process should be transparent and inclusive. In addition, any possible outcome through this process should be non-discriminatory and conducive to helping the world conquer the COVID-19 pandemic at the end of the day, so as to highlight the crucial role of the World Trade Organization in this regard.

### 13.14 Uruguay

325. Firstly, it is important to acknowledge and commend Members who have submitted questions on the reasoning behind the extension to the waiver for COVID 19 diagnostics and therapeutics, as well as the reasoning behind its possible implementation. We thank those Members who have tried hard to respond to some of them. The intervention by a colleague from South Africa is a good example of this.

326. In our case, we are particularly interested in access to medicines for medical diagnostics and treatment. We believe that these medicines must be easily accessible in international trade, which means that unnecessary distortions, such as export bans and excessive bureaucracy in registering new drugs or trade facilitation disciplines, should be limited as far as possible. Moreover, transparency about the availability of these medicines, and having a very clear logic for the trade flow of these goods, is key to being able to serve the target populations.

327. Thirdly, affordability is a factor that must always be given the highest consideration. Overpricing and misuse of the law of supply and demand are not welcomed by developing Members, and organizations such as the World Trade Organization (WTO) or the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO) must work on this. In this regard, we note the event scheduled for 28 October 2022 and will take part online. This is a discussion that

we already had at length in the negotiations prior to the Ministerial Conference on the response to the pandemic and on the Decision finally adopted.

328. It is still unclear to us how an extension of the TRIPS waiver currently in force would be implemented. In the case of vaccines, we are talking about an easily identifiable product but, in this case, it is a whole new, practically unfathomable universe, according to the specialists. We believe that a discussion based on questions and comments is vital in helping Members to visualize how this extension of paragraph 8 would actually benefit COVID-19 patients in a reasonable time frame. We therefore again urge Members to work on practical, easy to achieve and focused issues for the benefit of our peoples, in a way that that will ensure we see rapid outcomes.

### 13.15 Peru

329. Peru wishes to thank those who have already shared questions and answers to shed light on this matter. In Peru, we are still engaging in consultations at the internal level to gather information for discussion, because we believe that any decision should be based on current and objective data. Given that some Members may share the difficulties that we are facing with respect to the availability of data, we suggest considering the possibility of inviting experts from other international organizations to share with us any statistical information they have that might be relevant to the matter at hand so as to provide a better foundation for our discussions.

### 13.16 Singapore

330. The TRIPS waiver Decision at MC12 has demonstrated Members' ability to work together and exercise flexibility when the time calls for it. As we are faced with a deadline for a decision in approximately two months' time, we should engage in a constructive, pragmatic, and balanced manner. Allow me to elaborate.

331. In order for us for us to have constructive and informed discussions on the issue, the facts and evidence must be clearly laid out on the table. On that note, we thank the proponents for their time and effort in responding to the questions posed during the informal TRIPS Council meetings which have given us more to reflect upon. Singapore and other Members have highlighted the existence of voluntary licences and sublicences for therapeutics such as Pfizer's oral COVID-19 treatment under the Medicines Patent Pool, and Gilead's Veklury which are available to many low and lower-middle income countries. However, we have yet to hear from Members the reason why they have not been successful in applying for these licences, and we look forward to receiving a response on this.

332. In addition, we must be pragmatic in recognizing that there are other barriers to accessing COVID-19 diagnostics and therapeutics which can be addressed domestically and more expeditiously. According to an ACT-Accelerator report, these barriers include regulatory bottlenecks, the lack of demand forecasting, and low awareness and demand for diagnostics and therapeutics. Singapore had pointed out at the General Council meeting last week that our experience with vaccines has proven that addressing supply side factors would not be sufficient. As governments have the authority to address these issues within their jurisdictions, this should be the first recourse.

333. In closing, we must take a balanced approach in our discussions to ensure that we do not disincentivize innovation which is critical to fighting future pandemics. This means that the scope of diagnostics and therapeutics covered under the extension cannot simply be "any diagnostic or therapeutic used to treat COVID-19", bearing in mind that many diagnostics and therapeutics have multiple uses for other diseases. We must not inadvertently undermine the intellectual property system by having a broad and undefined scope of diagnostics and therapeutics covered under the extension. Singapore remains committed to continue engaging constructively and working with Members to find a way forward on this issue.

### 13.17 Switzerland

334. Your process of dedicated informal meetings of the Council is helpful. It provides Members with an inclusive venue and the opportunity to exchange views on whether to extend the MC12 TRIPS Decision to cover also the production and supply of COVID-19 therapeutics and diagnostics.

While we have made progress, we have not reached a point where we would be in a position to take a decision.

335. As my delegation has mentioned in past meetings, including at MC12, we are convinced that the intellectual property system is part of the solution to fighting this and future pandemics. IP is not a barrier; it works as a bridge in fact, across which development and manufacturing partnerships can connect. This of course is true equally in relation to vaccines as it is in relation to therapeutics and diagnostics. Having said this, let me reiterate that my delegation is fully committed to engage actively and constructively in fact- and evidence-based discussions in this format. We need to get a better understanding of the situation on the ground, regarding access to and supply of COVID-19 therapeutics and diagnostics.

336. At the last dedicated informal meeting of the Council, we have received a number of responses by the proponents of an extension to questions posed by Members. In order to facilitate our exchange, the delegate of Egypt kindly agreed to share his long and rather technical statement with other delegates. We are looking forward to receiving this and other relevant statements so that we can study them in detail. Receiving detailed oral replies in writing in a timely manner will facilitate and accelerate our discussion and allow us to make progress. In the same way we therefore also request the delegate from South Africa to make available his statement today made in this Council in writing so that we can examine the information provided in more detail.

337. While we await this information, allow me to make two preliminary remarks at this point. First, several proponents have mentioned in their statements in past and today's meeting that there is a shortage of COVID-19 therapeutics. Factual data recently published on the situation on the ground does not support this. Data from the health analytics company Airfinity shows, for example, that Pfizer produces its COVID-19 therapeutic Paxlovid at only 35% of manufacturing capacity, and Merck its molnupiravir at a capacity of 45%. More than half of their manufacturing capacity remains idle due to a lack of demand for these COVID-19 therapeutics. Reuters reported lagging demand already back in April. We would therefore like to ask the proponents to provide us with additional data where exactly they meet with a shortage of COVID-19 therapeutics and how far that shortage is actually caused by IP barriers.

338. Second, we have heard claims that global production capacity needs to be increased so that therapeutics and diagnostics can be produced in sufficient quantities and in the region for the region. According to the proponents, the extension of the MC12 Decision to therapeutics and diagnostics is necessary because inventors are reluctant to share their IP and do not grant licences for the production of generic versions. However, statistical data again provided by Airfinity highlights that this is not actually the case. As of August 2022, 187 voluntary licence agreements for the production and distribution of COVID-19 treatments have been signed. Sixty agreements alone were signed with Indian generic pharmaceutical companies. The remaining agreements were signed with companies in developing countries all over the world, e.g. Viet Nam, Egypt and South Africa.

339. Furthermore, via the Medicines Patent Pool (MPP) sublicences for the production of therapeutics can be obtained. molnupiravir and Paxlovid can, for example, be sublicensed in 106 and 95 countries, respectively. In the case of molnupiravir, already 23 generics companies make use of such a licence; in the case of Paxlovid the number stands at 36. For both products, the sublicences facilitated by the MPP are granted on a royalty-free basis.

340. Against this background, we would like to ask the proponents of an extension to provide further explanations why the production of COVID-19 therapeutics in developing countries and export to other developing countries is not feasible and where IP barriers actually exist.

### 13.18 Chinese Taipei

341. We thank the proponents and thank all Members which have contributed to the discussions on this topic. The discussions are very useful. We consider saving lives and health important and we are serious on the discussion of the possible extension of the TRIPS Decision.

342. We have launched our domestic consultations with stakeholders to find the best way to tackle the pandemic in a realistic and practical way and, at the same time, to respect patent rights as much as possible. In addition, we have the following suggestions.

343. The TRIPS issues with respect to vaccines, on the one hand, and those with respect to diagnostics and therapeutics, on the other hand, might not be necessarily identical. Therefore, discussions on various aspects to address different concerns in relation to diagnostics and therapeutics is not an unnecessary repetition, but is needed to help our discussion move forward.

344. Our sincere belief is that clarification of the scope of diagnostics and therapeutics is necessary. There are no clear definitions for diagnostics and therapeutics in the fields of medicine or medical devices. During the past negotiations on the TRIPS waiver discussions, Members had not proposed a working definition for discussion.

345. Since an extension of the MC12 Ministerial Decision on the TRIPS Agreement will be binding in nature, we need to be sure about the exact product coverage so as to provide certainty for its future application and for the affected and benefiting industries to conduct their business.

346. In addition, some COVID-19-related diagnostics and therapeutics have broad and multiple uses. They might not be exclusively for the purpose of diagnosis or treatment of COVID-19. From this perspective, it could be overly broad and could have unexpected adverse implications if the dual-use products are covered.

347. We note that many Members might have encountered problems with diagnostics and therapeutics. There might be various factors contributing to these difficult situations. We still believe that when the actual problems involved in supply, production and distribution, as well as the reasons why demand is not matched can be identified, Members will be able to come to a conclusion on possible extension in a more swift manner. We stand ready to engage constructively in the transparent, inclusive and evidence- and science-based discussions.

### 13.19 United States of America

348. The United States of America recognizes that the pandemic is still ongoing. So, in addition to our work at the WTO, we are also continuing with our broader efforts to respond to the pandemic, including through donations, pilot test and treat programs, and other health and humanitarian assistance, to help ensure communities around the world have the resources that they need.

349. We are continuing to conduct our domestic consultations on whether to extend the TRIPS Decision to cover the production and supply of COVID-19 diagnostics and therapeutics. As part of our consultations, we are in the process of gathering information on the use of diagnostics and therapeutics to treat COVID-19. We are also gathering information on other related issues, such as supply, production, demand, and distribution as they relate to COVID-19 diagnostics and therapeutics.

350. We support the ongoing discussions convened by you, Chair, and appreciate your leadership. As we continue our consultations, we look forward to continuing to engage with WTO Members.

### 13.20 Mexico

351. I would like to thank the co-sponsors of document RD/IP/49 for the replies to the questions submitted by Mexico during previous meetings. However, we would have preferred the replies in writing in order to share them with our capital. In that regard, in order to be able to further analyse the issue with our capital and stakeholders, we would like to seek some more clarity on the replies provided on the following points:

a. Some Members shared the definition of therapeutic product as set out in their national legislation. Those definitions are general for all diseases, not only for the COVID-19 virus. Therefore, in order to be able to define the scope of the discussion, we would like to know the definition of therapeutic product for the COVID-19 virus.

b. Also, one of the definitions shared during the last meeting included medical devices. In this regard, we would like to confirm whether such products are intended to be included in the list of therapeutic products.

352. During the last meeting, the delegate from Egypt raised an excellent question on how intellectual property has facilitated trade in these products. In this regard, we would like to share the following information, as one of many examples: since October 2020, work has been ongoing to make the therapeutic remdesivir available, also in its generic version, to 11 million patients worldwide. Of these, 7.2 million have been made available in developing and least developed countries (LDCs).

353. The way to achieve this rapid production and distribution of therapeutics has been through voluntary licensing. The manufacturer has entered into a number of voluntary licensing agreements with manufacturers of generics to ensure the supply and distribution of the generic product in 127 developing countries and LDCs. These licences are royalty-free. As another example, I would like to share that Mexico has been one of the beneficiary countries in the negotiation of voluntary licensing agreements, and we are currently producing Pfizer's therapeutic.

354. Mexico is convinced that the intellectual property system is part of the solution to address this and future pandemics, as it is a key driver of innovation and investment in technology. We would therefore welcome written responses and are committed to participating constructively in all discussions.

### 13.21 European Union

355. Thank you for the discussions and explanations and information that has been provided today by various Members. These explanations will certainly be very helpful and will lead us into further discussions on this issue and help us in our ongoing internal consultations. The European Union at the moment continues its internal consultations both with the EU member States, and by the European Commission. We note that some member States are also conducting consultations on this issue at the national level.

356. We have heard some of the explanations, in particular by South Africa today, which were very helpful and help us in answering some of the questions that we have, and some of the factors that we are looking at as well in these consultations. We see that a number of factors affect the complex situation on both access and uptake of therapeutics and diagnostics, as already mentioned by Singapore earlier: regulatory matters, manufacturing capacity, distribution, funding, the role of global, regional and national initiatives to promote equitable access, forecasting and demand issues. We believe that all of these factors are important for the evidence-based debate.

357. For example, we understand that the demand for products, in particular therapeutics, is low at the moment. It would be important to understand the reasons behind it. We heard the South African delegate mention that some of the products are not available everywhere, including in the European Union. These are exactly the factors that we are considering in our consultations.

358. Answering the question by Egypt, posed specifically to the European Union on the communication of the European Union to the Council for TRIPS in June 2021: indeed, that communication as it was quoted spoke about vaccines and medicines. We note, however, that this communication was an introduction to a draft declaration that the European Union proposed at the same time, and the draft declaration concerned the existing TRIPS flexibilities and the existing TRIPS framework. Namely, it proposed certain clarifications of the flexibilities that are already there and available to every WTO Member. The Decision that was agreed in June is of course a different type of decision. It is a waiver of an obligation of WTO Members. Therefore both the legal basis and the legal consequences of that Decision are different from the explanation. I hope that answers the question that was posed. Thank you for the discussions and we will continue engaging with all WTO Members further in this forum.

### 13.22 Japan

359. Japan appreciates the efforts made by the Chair and the Secretariat to continuously provide us with opportunities to discuss this important matter. Intellectual property rights and the TRIPS Agreement play a crucial role in the development of COVID-19 vaccines, diagnostics, and therapeutics. According to the Ministerial Decision on the TRIPS Agreement at MC12, Members will decide by December on an extension to cover the production and supply of COVID-19 diagnostics

and therapeutics. In the consideration of the extension, Japan believes that this discussion should be conducted based on evidence and facts.

360. We would like to draw your attention to one of the important points, that diagnostics and therapeutics are different from vaccines in their nature, distribution patterns, usage and so on. Therefore, the extension of the Decision to diagnostics and therapeutics should be considered in light of these facts. Japan appreciates the submission of the room document RD/IP/49 at the last TRIPS Council meeting in July for its discussion of this issue. We have studied the arguments presented in the document and shared our analyses on the arguments in the informal meetings held twice after the last regular Council meeting. Japan constructively participates in this discussion with Members.

361. In this context, Japan also appreciates the feedback/explanations from the proponent countries in response to questions raised by Members in the last informal meeting. Japan would like to share with TRIPS Members the factual information we have collected so far: EFPIA (European Federation of Pharmaceutical Industries and Associations) published a report titled "Factsheet on Covid-19 Therapeutics" on 29 September. Based on Airfinity's data, this report indicates the following:

a. The production of therapeutics presently exceeds demand;

b. Many voluntary licensing agreements have been in place for therapeutics; and

c. Many pharmaceutical companies offer therapeutics at tiered pricing.

362. PhRMA (Pharmaceutical Research and Manufacturers of America) also published a report on 29 September. Based on Airfinity's data, this report indicates that the quantity of therapeutics produced currently exceeds demand not only in high-income countries, but also in low-income and middle-income countries. We should collect and assess these facts reflecting the current situation or reality.

363. We would like to first discuss therapeutics and then diagnostics. At the last informal meeting, as a response to the question on how intellectual property has been the barrier to access, we listened to statements from Members insisting that high prices for products create the barrier to access in developing countries. As indicated by the EFPIA's report, tiered pricing is used in developing countries to ensure affordability. In some cases, inexpensive generics are available on the market through voluntary licensing. It has been publicly announced that Pfizer's Paxlovid would be offered to low-income and middle-income countries at a non-profit price in cooperation with UNICEF and the Global Fund, in addition to the sublicences via MPP, Medicines Patent Pool. This month, a Japanese pharmaceutical company also signed a licence agreement with MPP for the purpose of offering its COVID-19 therapeutic drug, ensitrelvir, widely to lower middle-income countries with no royalties.

364. In response to the question of how intellectual property is or has been the barrier to access, we also heard statements from Members saying that generics are more affordable and accessible than expensive original drugs.

365. However, without IP protection, there would be less hope for the development of new therapeutics for future pandemics, which requires considerable investment and effort. And if new therapeutics are not developed, there would be no generics either. In fact, it is intellectual property that incentivizes the development of new therapeutics, facilitates access to generics, and enables tiered pricing.

366. The room document RD/IP/49 argues in the paragraph on therapeutics that the number of patent applications is increasing. This means that many inventions are being produced to combat COVID-19. This is evidence that innovation is promoted by intellectual property in the field of treatment, and that there is a virtuous cycle of therapeutics development. Another fact is that some patents of therapeutics efficacious for COVID-19 have already expired. Given these facts, and especially regarding the therapeutics we mentioned above, it can be concluded that patents will not cause price increases or access limitations in developing countries.

367. We welcome any additional evidence and analyses showing that IP is or has been a barrier to access. At the last informal meeting, it was pointed out that some countries could not take advantage of sublicences via MPP due to the World Health Organization's strict prequalification requirement. However, our understanding is that the requirement aims to achieve our common goal of delivering high-quality and safe therapeutic products to patients.

368. Now we are going to discuss diagnostics. At the informal meeting, it was pointed out that patent monopolies were a significant barrier to promoting equitable access. However, as mentioned in the room document RD/IP/49, the foundational patents for the main diagnostic methods have already expired. Therefore, we recognize that not only certain manufacturers with such foundational patents, but also other manufacturers can produce COVID-19 diagnostics. In fact, the ACT-A report was mentioned at the last meeting, and the report indicates the following:

a. More than 1,500 new diagnostics for COVID-19 have been commercially available;

b. Many of the diagnostics are from companies new to the IVD (in-vitro diagnostic) market; and

c. Diagnostics are actually produced locally in several developing countries in Africa and South America.

369. The report points out that the existing challenges to expanding local production of diagnostics include:

a. Difficulties in recruiting sufficiently skilled personnel;

b. Unpredictable demand;

c. Difficulties being cost competitive with other manufacturers during the start-up period;

d. Regulatory issues in individual countries, among others.

370. If there is any specific evidence or analyses which support the argument that patent rights are barriers to access to diagnostics and therapeutics, and expansion of local production of diagnostics and therapeutics, we would like to have them for our review and analysis. Japan continues to constructively participate in this discussion.

### 13.23 Canada

371. Canada is pleased to continue participating in these discussions, and remains committed to engaging with all Members on this important matter in the coming months. Canada continues to encourage the sharing of any Member experiences in respect of the production and supply of COVID- 19 therapeutics and diagnostics, including with respect to any challenges experienced in relation to, or arising from, the TRIPS Agreement.

372. In particular, we note and welcome the Secretariat's compilation of questions raised by Members at our 19 September meeting, and distributed on 21 September 2022. Canada looks forward to continued discussion, including on the basis of these questions.

373. 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, in order to enhance Members' understanding of the issues. This discussion would allow the Council and the World Trade Organization to contribute to the broader understanding of the factors affecting the production and supply of COVID-19 diagnostics and therapeutics, and thus contribute to our collective ability to concretely and effectively address any challenges, not just here at the TRIPS Council but more broadly.

### 13.24 Korea, Republic of

374. My headquarters is currently conducting an analysis of the information presented at the previous meetings to the extent possible as well as on the current COVID-19-related situation. My

delegation looks forward to participating in fact- and evidence-based discussions with more available details.

375. One of the priority issues for the ongoing discussions is defining the scope of COVID-19 therapeutics and diagnostics, as these products involve a broader range of stakeholders and can cause a multiple use issue in comparison with COVID-19 vaccines. In this regard, we should continue fact and evidence-based discussions with a view to achieving agreeable outcomes on this issue.

376. Responding to the current pandemic is of great importance. At the same time, the pandemic response needs be in balance with the IP protection system that preserves innovation, which in turn will help us in responding to future pandemics.

### 13.25 India

377. At the outset my delegation would like to thank Dr Ngozi, Director-General of the World Trade Organization, who took cognizance of India's suggestion at the last General Council meeting to host a retreat on the paragraph 8 mandate of the TRIPS MC12 Decision, with a view to expeditiously finalizing the extension of the Decision to therapeutics and diagnostics. We hope that Members, as well as your kind self, Chair, consider this suggestion positively.

378. While the MC12 Decision is far from being a perfect one, as it comes too late and offers too little, nonetheless, we regard it as a step in the right direction. The Decision helps to lay rest to the debate on whether intellectual property is a barrier to equitable and affordable access. All Members agree that to combat the COVID-19 virus and its ever-mutating strains, a comprehensive strategy must be adopted. Apart from preventive measures, test and treat strategies continue to be relevant and important to save lives, as people continue to contract the virus and fall sick and also die in some cases despite several doses of vaccinations. Testing is not only critical to detect cases, it is essential to identify new variants to start building vaccines and therapeutics that can prevent or treat infection and to better understand the scale of infection allowing for expeditious action to be taken to break the chain of transmission and contain the spread further. The 12th meeting of the International Health Regulations Emergency Committee of the World Health Organization regarding the coronavirus disease that met in July 2022 stressed that "access to timely and accurate testing, with linkage to clinical care and therapeutics, needs to be maintained". It further recommended that "local production related to therapeutics and diagnostics should be encouraged and supported as increased production capacity can contribute to global equitable access to therapeutics".

379. Given the urgency of the mandate we call on Members to consider extending the Decision to therapeutics and diagnostics. And in this regard, we thank you for issuing a schedule of meetings of this Council to take the discussions forward. I hope that these meetings are optimally used, and avoid getting into circular discussions and the need to provide endless evidence. It is unfortunate that questions posed by some non-proponents seeking evidence to prove lack of access to therapeutics and diagnostics appear to be insincere and insensitive given that over 6.5 million lives have been lost amidst the acute shortages of masks, ventilators, PPE kits, therapeutics, vaccines, diagnostics etc. This was a global catastrophe that we all witnessed, and something that no one can deny. Substantive and protracted discussions have been undertaken on this issue since the introduction of this proposal in October 2020. In the past two years several documents containing comprehensive information and analysis have already been provided by the proponents. Today again, under this agenda item, several co-sponsors have made very detailed statements with granular details responding to the questions raised and we thank and support those statements made by the co-sponsors. I would also like to mention that there were some very poignant questions raised by Egypt that we must all seriously reflect upon.

380. To conclude, we hope that all Members work in solidarity and in good faith towards delivering on this Ministerial mandate before 17 December 2022.

### 13.26 United Kingdom

381. The United Kingdom values the discussions taking place in this forum, as WTO Members consider whether or not to extend the TRIPS Decision to COVID-19 therapeutics and diagnostics. We also acknowledge and appreciate the interventions made on the matter at informal Council meetings, where Members raised pertinent questions that provide a good basis to bring this

discussion forward. We thank proponents for the answers provided so far, including the additional details provided today. We look forward to seeing their written responses and we echo calls to share statements from today so we can analyse them accordingly.

382. We welcome the active engagement from all today including on how the COVID-19 pandemic has evolved. The United Kingdom recognizes that COVID-19 is far from over and we need to take action to respond to the evolving crisis and to learn for the future. That is why the UK welcomed the World Trade Organization's response to the pandemic from MC12 and why we are engaging actively on the pandemic instrument being developed by the World Health Organization.

383. At this Council the discussions need to explore whether there are issues for countries seeking to access COVID-19 therapeutics and diagnostics and if these relate to intellectual property. We reiterate that the decision of the membership should be based on facts and evidence. We remain committed to engaging openly and constructively, including via bilateral meetings, to assess the current situation and ultimately to inform our own deliberation on this matter.

### 13.27 World Health Organization

384. World Health Organization member states have indicated even before the pandemic, in the World Health Assembly Transparency Resolution, that they are "[s]eriously concerned about high prices for some health products, and the inequitable access within and among Member States as well as the financial hardships associated with high prices which impede progress towards achieving universal health coverage".

385. Now, more than ever, we need to ensure coherence in our response to address public health concerns. Despite our distinct mandates, we need to find complementarities and aim to achieve global Sustainable Development Goals, in particular the SDG 3 target "to ensure health for all". We are learning from this pandemic how health has a direct impact on all the other development dimensions – economic, social and environmental – of sustainable development.

386. As you know, since the beginning of the trilateral collaboration, already in the first version of the trilateral study we focused on relevant developments relating to access to medicines and other health technologies such as vaccines, medical devices, and diagnostics, due to their importance for achieving public health outcomes. We have also included relevant information in the trilateral insert on COVID-19 in all these areas because we need a comprehensive approach to deal with the health access and innovation challenges. Not only vaccines are important; the "test and treat" strategy is vital for the response. Countries are facing challenges to access affordable diagnostics. For medicines we have few voluntary licences from key technology holders to scale up manufacturing and respond to the needs in countries. Unfortunately, the scope of these licences is not sufficient; it excludes many countries, so WHO calls on the technology holders to expand the scope of these licences to facilitate the response.

387. These interfaces between public health, intellectual property and trade have been at the centre of international negotiations and policy debates in our three organizations for more than two decades. The UN 2030 Agenda for Sustainable Development calls for cooperation to support development targets and emphasizes the importance of research and development and access to medicines in accordance with the Doha Declaration. We know how essential innovation is, but at the same time we need to ensure that these technologies go to people around the world, in particular to developing countries.

388. Finally, as you probably know, all these elements are at the core of the negotiations of the pandemic preparedness and response international agreement taking place at WHO. As some delegates stated, the pandemic is not over. WHO remains at your disposal to provide additional information on the need for diagnostics and therapeutics.

### 13.28 Nigeria

389. We would like to underscore the need to intensify discussions so as to ensure that all Members decide on the extension of the waiver agreement on vaccines to therapeutics and diagnostics, as indicated in paragraph 8 of the 17 June Decision.

390. The COVID-19 pandemic remains a crisis with infections on the rise. According to an ACT-A report, without adequate emphasis on testing, treating and vaccines, the global population would lose its significant progress in its fight against the disease. In addition, the report stressed that oral antivirals can prevent hospitalization and save the lives of patients with the most likelihood of developing severe illness. The report clearly identified the main barrier hindering the introduction of oral antivirals and attributed it to limited access to the products required and the fact that the landscape of treatments and costs is ever changing. Currently, the majority of the known supply deals – to the tune of 76% – are concentrated in high-income countries.

391. Reports show that manufacturing of diagnostics and therapeutics is still predominantly concentrated in specific regions. There is a need to overcome this challenge by diversifying manufacturing activities by facilitating local production. Without comprehensive and adequate access to therapeutics and diagnostics in developing countries, the test to treat initiative as currently applied by some Members would be unavailable to developing countries. It is pertinent to note that in terms of therapeutics options for COVID-19, most of the products are either unavailable or unaffordable for developing countries.

392. The World Health Organization has clearly indicated that there have been significant shortages of recommended therapeutics, which are not easily accessible to developing countries as a result of high costs. The IMF projects that as a result of the pandemic, cumulative global output losses amount to almost USD 13.8 trillion through 2024 and therefore advises that the best defence against the pandemic will be to shift from a singular focus on vaccines to equipping each country with a comprehensive COVID-19 toolkit with vaccines, tests and treatments. The WHO has also expressed disappointment on the existence of inequitable access to COVID-19 treatments, particularly in those countries which need these treatments to save the lives of their citizens.

393. Regarding therapeutics, there is evidence that intellectual property has posed a barrier to access to COVID-19 therapeutics. For Paxlovid, containing the nirmatrelvir compound as recommended by WHO for patients with non-severe illness at the highest risk of hospitalization, research shows that patent protection has been sought worldwide by the proprietor Pfizer, particularly in developing countries. Therefore, if these patent applications are granted, it will hinder generic manufacturing or supply of the compound in the countries where patents are granted. For the patented Paxlovid, access challenges exist as a result of the high cost. The cost per treatment ranges between USD 200-500 in some developing countries, whereas the cost of its generic counterpart is only USD 73. The voluntary licence agreement with Medicines Patent Pool (MPP) signed by Pfizer excludes some developing countries. These same access challenges were also identified for WHO-recommended therapeutics, namely molnupiravir.

394. Finally, the 17 June Decision has been negotiated and it can apply *mutatis mutandis* to therapeutics and diagnostics. We recommend the extension of the 17 June Decision to therapeutics and diagnostics by Members. We would continue to engage constructively in future negotiations.

### 13.29 South Africa

395. Apologies for taking the floor again, but we thought it is very appropriate for us to acknowledge the very informative presentation that we have just received from the World Health Organization. As the only United Nations institution with the relevant competence and expertise to deal with health issues, we place great stock in the views expressed by the institution. We note in particular confirmation by WHO about supply shortages when it comes to therapeutics, as well as the inadequacy of voluntary licensing arrangements.

## Resumption of the Council for TRIPS on 15 December 2022

### 13.30 South Africa

396. We have made proposals on the text in para 5. It would be important to ensure that there is a true reflection of the issues and the different positions of Members so, other than to put it in binary, then we propose that we put in the second sentence "some Members" instead of "other".

### 13.31 Chair

397. Is that agreeable? Any objection to that? I think this is probably agreeable. I do not see any disagreement. It means only that there is no *consensus.*

### 13.32 South Africa

398. Then Chair, with regard to paragraph 7 we believe that paragraph 7 needs to be aligned to the mandate of the Ministers and we have proposed a draft that we put forward to the Secretariat. It would read as follows: "The co-sponsors of document IP/C/W/669/Rev.1 have called for the Membership to decide on the extension of the Ministerial Decision on the TRIPS Agreement to cover therapeutics and diagnostics in compliance with the Ministerial Mandate in paragraph 8 of the said Decision. Seeing no progress in adopting the Ministerial Decision the co-sponsors had no option but to reiterate the Decision taken by the Ministers through document WT/GC/W/860, also known as document IP/C/W/694. Unfortunately, there has been no consensus." And then we propose also an additional paragraph 8 referring to the World Health Organization (WHO). Then, on your paragraph 7, we will come back on that depending on the discussions.

399. It would be the new paragraph 6. It would not replace paragraph 6 but come before the current paragraph 6. And now it will be a new paragraph 9 with the reference to WHO. Of course, we would be interested to hear the Members' views in regards to how it is currently captured and we will be flexible, but I think the important issue for us is to capture the role of the WHO.

### 13.33 Chair

400. Thank you. The floor is open. I have not seen language like this in reports, so I am not sure that, to make a value judgement like this, should go into a report of the Council.

### 13.34 Sri Lanka

401. I have been raising my flag for the last 10 minutes so maybe in the middle of so many proposals the Secretariat may not have seen my flag had been raised. Thank you very much for the floor and we also fully support the formulation presented by South Africa on behalf of the co-sponsors for what we see now is paragraph 6 and paragraph 8. We fully support those formulations. Now Chair, Sri Lanka wishes to make another drafting suggestion: It is to old paragraph 7 - now it is in paragraph 8. So, I will now inject the amendments that we wish to present. After the first line please add "decide on the extension to cover therapeutics and diagnostics by the 1st General Council in 2023". So, I repeat the formulation: in light of the above discussions in the TRIPS Council will continue to decide on the extension to cover therapeutics and diagnostic by the 1st General Council in 2023. That is the formulation that we are proposing here. I think it is for the consideration of the Members and I think it is a more realistic and pragmatic way to continue this discussion because we really need Members' engagement and also desire to achieve results, so this sense of urgency is the reason why we are proposing this formulation.

### 13.35 Chair

402. Thank you. My intention was not to open the text but to make a decision on the draft text at least. But the floor is open for delegations. I think we can give this another open-up to discuss and see whether it is agreeable and reach a consensus.

### 13.36 Switzerland

403. We appreciate your efforts to come to a conclusion here. As we already mentioned in the informal setting, we also have made some suggestions for the improvement of the report. We flagged also that we would be flexible and not insist on our changes if there is a consensus on the initial text of the report. Looking at the timing and the fact that we have to agree on a TRIPS Council report today, we really wonder whether opening the text is the best way forward. So, we would still repeat our offer to join consensus on the initial or the revised Chair's text, but we would want to refrain from opening the text and have a drafting exercise at this juncture.

**13.37 Chair**

404. That would be my preference too. I had hoped not to re-open the text, quite frankly, but delegations do have the last final say.

**13.38 United Kingdom**

405. Thanks to you, the Secretariat and the team for all the efforts you put in to come to this text, and for the many hours you spent with us in informal discussions trying to get to a text that fairly represents the discussion that we have been having. We just wanted to echo Switzerland's point: the UK also had comments on the text. It is definitely not the kind of text we would draft if we were given the pen. But we recognize that in the spirit of consensus, that we need to compromise and therefore we have been able to come on board with the text that you originally proposed. Therefore, we would like to come back to the original text please.

**13.39 United States of America**

406. I am really struggling to understand this exercise. Some language, unfortunately, I do not think is appropriate for a draft report. Also, "in compliance with the ministerial mandate" again has obviously been read in many different ways, so I do not think it is helpful. If we strip those things out, aside from having the specific references to various documents, it is basically saying the same thing that it is in the first sentence of paragraph 5 already. Then, the fact that there is no consensus is covered by paragraph 6. So even when you put paragraph 5 in 6 and the existing para 6 in 7, it is just again saying the same thing, namely that there are sponsors of something, but it has not achieved consensus. But paragraphs 5 and 6 already say that.

**13.40 South Africa**

407. We do believe that those elements that are now in the new paragraph 6 are important. What we could do to address the concern that has been raised by the United States of America, is to maybe have the elements that are in para 6 come immediately after the 1st sentence of para 5 and we are flexible whether the highlighted part would come immediately thereafter or in new paragraph.

408. Then, on the suggestion by Sri Lanka, I guess the highest decision-making body in the WTO in between Ministerials would be the General Council. So, we are also flexible what we say, because it cannot be the TRIPS Council that will decide, so it is either "the General Council" or "Members" who will decide.

**13.41 Chair**

409. "Unfortunately there has been no consensus" is very obvious - and has been stated over and over again in the text. In any case, I am still unsure whether this is the language to be used in a formal report like this.

**13.42 South Africa**

410. Thank you very much, Chair. We would be flexible on that, Chair. Thank you.

**13.43 European Union**

411. On our side we have to thank you, Chair, for all efforts in bringing us up to here and I hope that we will get to a report, ultimately. It is a little regrettable that we see all these efforts by the proponents only at this stage – shortly before the end of the meeting – and not on either Monday or Wednesday. In any case, just a couple of initial thoughts and suggestions on the draft, of course without prejudice because our preference would be for your original draft. But in the spirit of compromise, we see that there are certain formulations we do not understand. It might be that English is not my first language like for most people here, but to repeat "the Ministerial Decision" is a bit strange. We also think that the words "have no option" are also a value judgement – and we saw the flexibility of South Africa on deleting another value judgement in the text as regards "unfortunately". We think that "had no option but to reiterate" should be deleted as well, and probably replaced by something like "propose the extension of the Ministerial Decision" or something

along these lines. I will not comment on the addition by Sri Lanka yet at this stage, but I think HE Ambassador Machado in his previous intervention clarified that we have a problem with the "the leading role of the World Health Organization (WHO)". I think he gave a number of reasons why we have a problem with that paragraph, so we are very uncomfortable with that provision.

### 13.44 United States of America

412. Again, I think we have two sentences saying the same thing, again with some value judgment words that should not be there. If we are just trying to be more precise, we can work with that. The sentence that was in the draft shared on 6 December 2022, "a group of 65 Members" – I understand that it is a reference to the co-sponsors of document IP/C/W/669/Rev.1, and that the document referenced in that short sentence "tabled a proposal" that is the WT/GC/W/860, and there is a footnote that refers to the IP/C/W/694 document. Again, if the desire is to be clear what the documents are and what actions were taken, I think that we can really just consolidate all this into one sentence that is factual, maybe to avoid too many clauses. Like "On 6 December 2022, the co-sponsors of IP/C/669/Rev.1 etc. … seeking a decision on the extension of the Ministerial Decision to cover therapeutics and diagnostics". Period. That is basically it.

413. I think the language "in compliance with the Ministerial mandate" gets us into the question that we have been bouncing around for a long time. So, again, just trying to understand that there may be a desire to demonstrate the steps that have been taken – and that is legitimate – but we can do that in a very factual way without getting into these additional wrinkles that create issues.

### 13.45 Chair

414. Just on a point of formality, if a Council report is adopted at all. The language "seeing no progress in adopting the Ministerial Decision, the co-sponsors had no option but to reiterate…" - that is not language that would be neutral and acceptable. It is a value judgement. It is the position of the co-sponsors and not that of the Council. This particular paragraph becomes quite superfluous in light of the rest of the text.

### 13.46 South Africa

415. We agree with the need to streamline, but we do not believe it is superfluous and we propose to properly address the concern of Members that we have been judgmental when we say "had no option but to reiterate". Let's see if this formulation works: you already have "seeing no progress", so we can rather copy, after "seeing no progress in adopting the Ministerial Decision, the co-sponsors…" and then you take what is "on 6 December 2022…" and then the rest – "had no option but to" – will then be taken out, just to also address the concern that has been raised by both the US as well as the EU.

### 13.47 Chair

416. "Seeing no progress" is, again, judgmental language. Frankly, it is meant to be a formal report by the Council, it is not the report by the co-sponsors. Let's just have that clear.

### 13.48 South Africa

417. I thought the problem was the language "there is no option but to reiterate". I think it is factual that we have not made progress, we have not reached a decision within six months, so I do believe that that is at least factual.

### 13.49 United Kingdom

418. I reiterate that our preference would be to go back to your original language. But just to come in on this "no progress" point: I do not think it is a fair reflection of the time, energy and effort that this TRIPS Council has put into this discussion. We have seen lots of Members putting forward different proposals. We have seen papers. We have had an in-depth conversation. Probably, this is the most active conversation since MC12 on any of the files. You are jumping to a judgment call that we, as the UK, do not feel is there in terms of reflecting the real effort of everybody in the room that has gone into these discussions.

**13.50 Chair**

419. Here is additional proposed text now and the previous draft that I submitted. Should we give Members ten minutes to look at it so see whether this is agreeable for adoption?

**13.51 South Africa**

420. What it is on the table now does not reflect what I have just said. I do not know whether I need to repeat it. I thought it was clear that we are asking that what was in paragraph 5 must go down to after "Decision" and then you say "the co-sponsors, on 6 December…". We do believe that will then address the concern of repetition that was raised and streamline the text. I hope that it is clear.

**13.52 Switzerland**

421. Thank you for putting together what is really meant by the co-sponsors, in terms of amendments to this text. We would just like to echo also the comment made by the United Kingdom about the progress made, or not made. I think we have maybe different views on that. Other than that, I would just like to remind that we also submitted a formal proposal for changes and if we continue this discussion, we will then also ask the Secretariat to introduce the changes to the different paragraphs that Switzerland had put forward in writing.

**13.53 Chair**

422. It seems that we have a stalemate again.

**13.54 South Africa**

423. We have no problem with Members wanting to reflect their positions, not at all, if Switzerland believes that there are aspects that they want to add. Our interest is to ensure that we have a factual report that addresses the interest of all Members. So, we do not have a problem with Switzerland adding what they believe should be reflected in the report.

**13.55 Switzerland**

424. My suggestion would be that we make a consolidated document and then we have some time so consider it. I think it is difficult to have such a detailed drafting exercise in this setting and as we said before, given also the time-constraint that we are facing. We still have basically a preference for your original text.

**13.56 United States of America**

425. I will make one last attempt, which probably will not work. So, you could say: "The co-sponsors of IP/C/W/669/Rev.1 called on the WTO Membership to decide on the extension of the Ministerial Decision on the TRIPS Agreement to cover therapeutics and diagnostics". Period. And then you begin: "On 6 December 2022, the co-sponsors tabled a proposal for the General Council to extend the Ministerial Decision through document … etc.". So, you just keep to the facts.

**13.57 South Africa**

426. We appreciate the position of the United States, but we do not think it reflects the sentiment that we, the co-sponsors, want to raise. We do believe that what is captured there is factual. You know, we have shown enough flexibility in trying to accommodate the concerns that have been raised. So in our view, the way it is currently captures – at least from the co-sponsors' perspective – what should be reflected in the factual report.

**13.58 Chair**

427. The interpreters will be leaving in 15 minutes, but I would like to suggest that the co-sponsors, Switzerland, the United Kingdom, and the United States of America may get together and see

whether they can agree on a language and then come back. Let us take a break of 30 minutes – but we have to end this today.

**13.59 Chair**

428. It seems clear that there is no agreement. There is no consensus on either version. We do not need to submit a report. So, I thank you all. There will be no formal report to the General Council, but I will be reporting under my own name on the state of play.

**13.60 Sri Lanka**

429. My delegation believes that you are rushing to make a decision. I think, as the Chair, you should give delegations more time. I think we have resolved many more complex issues than this during MC12. Give time to the Members to come together and find some common understanding and landing zone, rather than rushing and making your own decision that there is not consensus. I think we have a systemic issue in this institution. The chairs are sometimes taking certain decisions without looking at the possibility of reaching certain consensual decisions. So, I think it would be good that you – as the facilitator – are coming forward and trying to facilitate Members to come together and reach consensual decisions. Otherwise, it will be very difficult for us to reach consensual decisions. I appeal to you to give delegations more time rather than rushing to a decision like this.

**13.61 Chair**

430. I am sorry. More time is what we do not have. And this report is, in any case, not the important thing. The important thing is that there was no consensus on an extension of the Decision. I think this is the most important thing – and this report would simply state that. It is not going to change anything fundamentally and we do not have time to continue.

**13.62 South Africa**

431. We also have a day, even a weekend before the General Council. So, I do not believe that we can say we have concluded our work. There is still time to engage. We would agree with Sri Lanka that the text where we are now can be circulated to Members to reflect on and we can continue our discussions. That is the view of the co-sponsors. The 65 co-sponsors.

**13.63 Switzerland**

432. On the Swiss side we do not have the impression that you are rushing any decision. I think you just simply stated the obvious, namely, that it will be very difficult to get any consensus on a report. As others have said, we deplore the fact that the co-sponsors have made the substantive and numerous comments at this very last minute, not allowing others the necessary time to analyse, to consult, and to react to it. This is the situation that we are in, and we do not feel that you rush to any conclusion. You just state the obvious.

**13.64 United Kingdom**

433. We just want to come in and echo what Switzerland said about your efforts. I think you made a really strong effort in trying to summarize what have a been lots of in-depth detailed discussions on this issue and all the submissions made. We think it will be a shame not to have a report, because we have made so much progress and we have had such a good discussion. I think from our perspective, we do actually think there is a report from the TRIPS Council that has gotten us a long way – which is your draft. And exactly as you said, there is not very much time left. So to assess, to review, and to understand new proposals takes time in all of our systems, which we just do not have anymore. The General Council is on Monday, so from our perspective the only one that will be possible is the text that you have proposed to us. And if that it is impossible to be taken forward, then we understand, and we thank you for all your efforts.

**13.65 Tanzania**

434. We really appreciate that you are giving us an opportunity to engage, and I still believe that you will continue to engage to let the Members engage like South Africa just said. Based on the

previous experiences that we have been working - sometimes even also during the weekends – I do not see why we should not do that for this matter, considering the importance of this decision that we are going to make. We are just about to agree. I think, like the co-sponsors have said, we give more time for Members to consider the proposals that have been advanced by the Members, particularly the co-sponsors and other Members have been said that they have not had an opportunity to see the language in advance. That makes it more rational to give them more time to consider. I would like to reiterate the call of being given more time. We still have tomorrow, and we still have Saturday and Sunday, so we still have those 3 days in my view, and it will be not the first time to work on the weekend. We should be extending the same process with the same spirit of collaboration towards achieving an outcome which is really text that reflects the understanding of the Members. I wanted just to echo the proposal by South Africa.

### 13.66 Singapore

435. I want just to make three brief points. First, it is not fair to accuse you of trying to rush things. I think you have put in tremendous efforts, and we actually appreciate what you have done and what you are trying to do. Second, you have put forward a clear path that can take us forward and that is to use the draft that you have put on the table, and which is acceptable to the majority – large number – of Members. And three, Chair, there is a suggestion that we can work over the weekend. My delegation is committed to do it, provided that there is sincerity, a real flexibility, not just saying "I am flexible", but not really moving anything. So, Chair, if that is the understanding my delegation is prepared to work, although our preference clearly is to use the path that you have given to us, and to use the draft that you have put on the table.

### 13.67 Chair

436. We have to end this meeting today. My feeling is that it will be difficult to reach *consensus* on all these new amendments, and that there is some bad faith on the part of some Members accusing me of being the one – and not them – causing a delay in decision. But here is my challenge: I will give until 12 noon tomorrow – and if all these elements can be worked out by then we can have a brief Council meeting to adopt it formally. Such a communication, that there is a *consensus* text that has been agreed bilaterally between the co-sponsors and other Members can be sent to the Secretariat. I will then convene a meeting for maybe half an hour, and we adopt it. Otherwise, if we do not have that, I will have to report under my own responsibility. Some delegations have so many other things to do, and you can blame me all you want – it is fine. Next time you probably have to do more vetting of chairs. Thank you all and I hope we do get something from you by noon tomorrow so that we can convene a quick meeting.

### 13.68 Egypt

437. If you can, please, call for a meeting tomorrow at 10 o'clock so we can discuss or reach a consensus on a report. Otherwise, if we only come together tomorrow at 12 noon to find a way, where would we do this and when? So if there is a meeting, an informal meeting, even on the level of experts to discuss the report even for one or two hours and then we can come up to adopt this report, that would be great.

### 13.69 Chair

438. I disagree.

### 13.70 South Africa

439. I think we need to avoid coming up with new procedures not normally done for other issues. That is one point. Two, I agree with you that consensus will be reached if we engage as Members, and that should be encouraged. But this new procedure, to say the meeting will be called only if there is a consensus document – we disagree with that because I have not seen that in other negotiations whatsoever. So I think the best way forward would be to say you encourage Members to speak with each other so that we can have a way forward. Then we can set a time within which we need to meet as Members to see where we are and of course hopefully we will be close to each other, to have a short meeting. But again, I think it is pre-emptive to say "only 30 minutes" because new ideas may come as we engage with each other. And so, I propose that we show that flexibility

to agree on the time to meet, and of course all of us attempt to engage with each other towards finding a common ground.

**13.71 Chair**

440. I meant to say that, if you can have a conversation and reach a consensus, then we can meet and adopt it. But we are not going to meet again to have a long conversation with new elements who have to be introduced - that it is not going to happen. I am sorry. So, we can certainly circulate something to have a meeting sometime tomorrow to make a final decision. But it is just not productive to bring in new elements at the last minutes when we are really there to adopt a draft document that has gone around for such a long time.

**13.72 Egypt**

441. I am reiterating my call for a meeting tomorrow, an informal meeting of the Council in the morning to meet together and just see a way forward on the report.

**13.73 Chair**

442. This is not decided on the spot. There are a lot of other issues. In any case, a formal report to the General Council is not mandatory. It is not as important as reaching consensus on extending the decision under paragraph 8. This is simply a report, a factual report reflecting on our work. So, it shouldn't be this difficult. Comparing it to MC12 it is not a true comparison. So, if you can meet at 10 o'clock - I will be not there – hopefully there will be interaction between the co-sponsors and others and a new document can be brought to the Secretariat. Then we will convene a meeting and see how we can adopt it. We are open to that, but I am not going to be chairing another informal meeting.

**13.74 Sri Lanka**

443. I think we should not be repeating a practice that many facilitators and chairs actually adopted during MC12. Some facilitators actually left the Members even to each other. We fortunately did not end up like that in the end. But, Chair, as the Chair of this Council I think you should be there to lead these Members to arrive at some consensus. That is a responsibility of a chair, because you cannot say "these countries do not agree, therefore I cannot report". You know Chair, I think you should make all the attempts - we have to really use all options available, because this is an important issue, and this is the first of the Ministerial outcomes on that we are supposed to deliver something. If we fail in this particular first kind of mandate that Ministers have just given us, if we fail to deliver something, it will reflect very badly on other outcomes and other engagements, and to arrive to such outcomes also will be in jeopardy. So, how do we really believe in a system, if within 6 months we fail to even agree on a report? So, as the Chair of this Council I think you should be making all your efforts. Maybe you do not have the magic wand to really get everyone on board, but at least you must make all your efforts to bring Members together and create a platform for Members to arrive at consensual language so that you have your report. So therefore, we like you to chair the meeting which Egypt has very kindly requested you to convene.

444. Now, this is a normal formal committee. If the Secretariat has logistical challenges with resources, then I am puzzled as we were assured in the Committee on Budget, Finance and Administration (CBFA) that formal committees can be conducted uninterruptedly. This is precisely what I have been raising in the CBFA. They are allocating a lot of money on other non-mandated committees and meetings, but they do not have logistical capacity and resources to convene a meeting, which multilateral ministers have mandated us to work on. So, I try to understand what kind of logistical hurdles there are. We will be raising this again in the General Council. If the Secretariat is experiencing logistical hurdles to conduct these meetings, where does this money and other capacity go?

**13.75 Chair**

445. Thank you. You cannot make the Secretariat the focus on this conversation. The time is not right, there are a lot of other issues, other commitments, other logistical issues. It is not the Secretariat saying that – it is me. Number two, you are confusing the categories. The important

decision here would have been to extend paragraph 8. Agreeing on a report is not the important decision. It is not. So, let's not confuse all these categories, please. Egypt has made a good suggestion, but I will not be chairing a meeting. You can ask the Secretariat to organize a room and you can have this conversation, and if a consensus can be reached, we can meet again at a set time and adopt the report. The report is not important, it is not mandatory. It would be nice to have, but if it is not here it is not a tragic event.

### 13.76 South Africa

446. I feel you are now abandoning the Members, because I cannot understand why – when the Members are asking for a meeting – the Chair says, I am not there. It is a bit of a challenge. We humbly request, Chair, that you reconsider because I think it will set a seriously wrong precedent for the Chair to say, "meet on your own". Then what's the point of having chairs if we can meet on our own. Of course, we will meet on our own in terms of lobbying each other to come to a common ground, but a platform has to be provided for Members to engage. Because we probably will meet in different configurations, because we know what the challenge is of the European Union with regards to the World Health Organization. So, if we have to discuss about World Heath Organization we need to engage the European Union. On other issues, with need to engage the United States of America, on other issue we need to engage Switzerland and the United Kingdom. But for everyone to have an appreciation on where the consensus is emerging among those Members that have different positions, a platform is required. We also disagree with you, Chair, that this report is not important. This report is important, that is why we spent time as Members. Otherwise, if it was not important, we would not even have engaged. The reason it is important is because if you are able to have emerging consensus here, you are not out of the discussion at the General Council. So, it is important in that regard. So, as I said Chair, we ask you to reconsider your position because we do believe this is an important issue that affects peoples' lives and we cannot take it for granted.

### 13.77 Chair

447. A formal meeting can be called, which I would chair, to adopt whatever it is you may be able to agree. I know that most constructive work can be done when you talk to each other.

### 13.78 South Africa

448. Engaging in this process, you know the dynamics. You had to convene us in informal and formal mode to try to get us to a common ground. That is what it is going to get us forward. So again, I am asking humbly that you reconsider your position because we need a platform, both informal and formal mode, and to do whatever it takes to get us to a way forward.

### 13.79 Chair

449. I still encourage you to have that kind of informal conversation among yourself and see if something can be hammered out. I did not say, by the way, that the report is not important. I drafted it because I know it is important – but it is not mandatory. There is a difference in emphasis. All these new different elements, newly introduced, mean that there is some bad faith on the part of some Members, I regret to say. If you are accusing me of all sorts of things, I think you should also take responsibility for the lack of consensus.

### 13.80 Egypt

450. I am requesting that our call for an informal meeting, that has been rejected twice, be added to your report to the General Council under your own responsibility. This is a formal request to call for an informal meeting and it has been rejected twice from many Members.

### 13.81 Chair

451. If I report under my own responsibility, I will decide myself what goes into that report. Not Members. So, I am hoping some kind of meeting can take place and I will call a formal meeting if there is agreement, and then we can meet to adopt that report. I thank you all for the very constructive engagement today. The formal meeting of the Council for TRIPS is closed. The Council

for TRIPS takes note of the statements made today and this brings us to the end of today's resumed meeting. The meeting is suspended.

Resumption of the Council for TRIPS on 16 December 2022

### 13.82 Switzerland

452. Just a brief statement from Switzerland. We did not oppose the consensus on this report to the General Council although we must say that some elements contained in it remain a little bit unclear to us. So, what I would like to be put on the record, to be very clear, is that we have noted in the past that there have been different understandings of the meaning of paragraph 8 of the Ministerial Decision on the TRIPS Agreement. Switzerland has made its views and its understanding of the meaning quite clear in the past, as have others. I just would like to confirm that our understanding of this paragraph 8 will not change, or is not changed, by us joining the consensus of this draft report.

## 14 INTELLECTUAL PROPERTY AND INNOVATION: ROLE OF IP TO RAISE FINANCE FOR START-UPS

### 14.1 Switzerland

453. My delegation has the honour to briefly introduce, on behalf of the group of the 'Friends of IP and Innovation (FOII)', the communication contained in document IP/C/W/692, titled "Intellectual property and innovation – Role of IP to raise finance for start-ups". The submission is co-sponsored by the delegations of Australia, Canada, Chile, the European Union, Japan, Singapore, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, the United Kingdom and the United States of America.

454. During the Council's lunch break yesterday, the Friends of IP and Innovation organized an event with panellist from WIPO, from WTO delegations and the private sector. It that focused on IP and finance, with a focus on start-ups and MSMEs many questions were posed, and we had a lively debate.

455. For start-ups it is a particular challenge to raise enough capital to be able to grow and to reach their full potential. IP financing can help in this challenge. In our submission, the following six types of IP financing are being examined more closely:

1. IP-based equity financing - when partners invest their own money in the company.

2. IP-backed venture debt - a newer form of financing for young firms in which IP serves as collateral.

3. Revenue from IP licenses - the classic method of generating cash flow from IP rights such as patents, trademarks or designs. The purchase of a license allows the buyer to use the company's IP.

4. Royalty securitisation - in which the IP owner sells an income stream associated with the IP for a specified period of time in exchange for an upfront payment. An example from the area of copyright are artists selling rights to future income from their songs or photographs.

5. IP sale-leaseback - here, IPRs are sold by the right holder to an investor and then leased back from it. For start-ups, this type of IP financing has the advantage of providing immediate liquidity.

6. Finally - IP insurance - in which a third party provides upfront capital to the IP owner to fund potential IP infringement disputes.

456. I will now introduce our own country experience with regard to the use of these types of IP financing. Switzerland has fared well over the past years in WIPO's Global Innovation Index when it comes to its innovation environment and performance. This said, WIPO's report points us to areas

where we can further improve. For example, in the category of "Venture capital received". On this background, Switzerland recently conducted a country study on IP financing[19], in partnership with WIPO. The study brought several insights to light: in order to convince investors, such as business angels or venture capitalists, start-ups should present a compelling business case.

457. A promising IP portfolio can be one way of doing this or at least an important part of such a strategy. In Switzerland, IP financing is focused on Venture Capital funding. Especially patents are frequently used to signal that there is qualitative substance in a young company. This is particularly so in the life science sector, but also for clean-tech and ICT start-ups. By contrast, IP is rarely used as collateral in classical debt finance in Switzerland, although the Venture Debt market has grown in significance more recently. Even more of a niche in Switzerland's innovation environment are the financing methods of IP insurance and IP sale-leasebacks.

458. Let me now present a real-life example of how patents can help in the financing process: The Swiss start-up Oxara[20] has developed a cement-free admixture-technology that converts waste into cement-free concrete and non-fired bricks. Compared to conventional concrete, the production of so-called "Cleancrete" or "Cleanbrick" (both are registered trademarks of Oxara) leads to significantly lower CO2 emissions. For the future, Oxara plans to expand its portfolio with new products and patents. Oxara has won several grants and awards for its patented technologies. According to Oxara, its patent portfolio and IP strategy has been key to attract financing from investors, enabling Oxara to take off fast, hopefully into a promising future.

459. In order to encourage the use of IP for financing purposes, it can be helpful to support start-ups and MSMEs in establishing an IP strategy. One such support in Switzerland is through coaching programs in which start-ups receive expert advice, for example, in relation to setting up their own IP management. The Innosuisse Start-Up Coaching program[21] offers packages for high-tech start-ups where they get advice from fellow entrepreneurs and coaches that are experts in relevant business areas like finance, commercial law and, not least, of course, IP.

460. Before concluding, I would like to draw delegations' attention to a high-level conversation organized by WIPO entitled "Unlocking Intangible Asset Finance". This conversation will take place in three weeks' time, on 1 of November. The event will highlight the potential of intangible assets for financing to a wider audience from both the public and private sector.

461. As for today, my delegation is looking forward to a fruitful exchange among Members. We encourage others to share experiences they have made with IP financing, challenges encountered, lessons they have learned and to pose questions they may have.

### 14.2 Japan

462. Thank you, Mr Chair and colleagues, for giving us the opportunity to share our experiences and national policies regarding this agenda item. First of all, the delegation of Japan would like to thank the Swiss delegation for introducing our concept paper. Also, we have prepared copies of today's presentation[22] materials at the entrance please feel free to pick them if you like. As today's theme suggests, we consider IP financing as critically important for start-ups. Today, we would like to introduce Japan's initiatives on IP financing.

463. The term "IP financing" usually refers to methods or techniques, such as attaching security interest in IP or collecting royalties under license agreements on IP rights, which take advantage of the value of IP rights themselves in the hopes of monetizing them. In Japan, however, those techniques have not become the mainstream in financing IP. One of the major reasons for this situation is that lenders, including banks, hesitate to make loans using IP rights as collateral, since traditional asset evaluation methods that emphasize tangible assets have taken deep root in banks - who consequently tend to find less value in intangible assets than they actually are worth.

464. Many start-ups in Japan obtain the needed funds through loan financing from banks. Difficulties in collateralizing IP rights could bring hurdles for start-ups that do not have substantial

[19] See WIPO and IPI (2022 – to be published).
[20] https://oxara.ch/technology/
[21] https://www.innosuisse.ch/inno/en/home/support-for-start-ups/startup-coaching.html
[22] Circulated as dcument RD/IP/50

tangible assets - particularly IT start-ups - in terms of obtaining smooth funding. Under such circumstances, the Japanese government has shifted its strategy on IP financing from simply measuring the value of the IP rights alone, to evaluating what additional value such IP rights bring to the business: in other words, evaluating the IP rights in combination with the entire business.

465. Given that start-ups do not always have substantial tangible assets, we hope that this presentation will be useful for other Members - especially where IP rights have not been sufficiently utilized as financial assets, due to the difficulties in evaluating intangible assets.

466. The Japanese Government's initiatives on IP financing consist of two pillars. The first is that of the efforts to ensure proper evaluation of companies' business value by investors and companies themselves. These efforts include the revision of Japan's Corporate Governance Code in 2021, which required businesses to disclose information on IP investment strategies.

467. The second pillar consists of efforts to introduce a securitization system that allows the entire business value of a company, including IP, to be collateralized. We will not mention this today, but the overview is shown in the last page. This is also an initiative based on the idea of understanding the value of IP rights as part of the value of the entire business. Please feel free to contact us for further information in this regard.

468. Today, I would like to introduce the Japan Patent Office's initiatives, which are part of the first pillar, in terms of facilitating the proper evaluation of corporate value by investors and companies. Many banks in Japan have conducted business feasibility assessments. The purpose is not limited to financing, but also includes aspects of business and management support for companies.

469. The Japan Patent Office's primary initiative, "IP Financing Business", helps banks to properly assess the business value and the feasibility of their client companies by offering the perspective of the IP side, so that banks understand the actual financial state of their clients. Incorporating an evaluation from the perspective of IP will enable both investors and companies to understand a company's genuine business value and its strengths - thereby promoting the utilization of IP. This will especially help start-ups that do not have many tangible assets, but do have technological strengths, in terms of achieving smooth financing and expediting their growth.

470. Proper value assessment can indicate a company's room for growth in terms of new businesses or new markets, for example, where financing will ultimately be necessary to realize such potential. In other words, the idea is that banks actively create their own financing opportunities. Most of the financing results in Japan have been indirectly linked to such financing. There is one barrier to including a technological perspective such as IP, especially patents, in a bank's business feasibility assessment. Generally, banks are good at understanding a company's value or status based on financial information - but they may not necessarily have such an understanding of its technological capabilities. In fact, there are very few technical personnel in Japan's banks.

471. In order for banks to provide effective business and management support to client companies, it is essential that they understand their clients' technological capabilities which serve as the source of sales, including IP. In Japan, small and medium-sized enterprises (SMEs), including most start-ups, account for more than 99% of all businesses. There are many manufacturing companies with excellent technological capabilities, but at the same time, many among them have not fully made use of their skills in terms of calling for further investments. It is necessary for banks to have a proper understanding of the excellent technological capabilities of manufacturing companies.

472. Based on this background, the IP Financing Business initiative put the focus on SMEs. Under this initiative, the Japan Patent Office provides IP business assessment reports and IP business proposals for banks and their client SMEs. These reports provide business feasibility evaluations from a technical perspective. This is done in order to complement the evaluation methods used by banks that have difficulty in understanding corporate IP activities, such as technology and know-how. It is expected that these reports and existing evaluation methods will complement each other, so that stakeholders can understand and evaluate corporate activities more accurately.

473. IP Business Assessment Reports cover target companies that assess the relationship between that company's entire business and its IP, such as technology and brand power, which are the sources of SME management power. This report is prepared by a research company and experts,

such as patent attorneys and management consultants, who can appraise technical and brand power. IP Business Assessment reports are crafted in order to help banks properly understand the content and value of IP. The IP Business Proposal is a report on a target company. In addition to IP Business Assessment Reports, such proposals analyse the business issues and growth potential of that company, while also proposing recommended actions for the SME. Such recommended actions usually must be accompanied by management and financial support from the lender.

474. Next, I would like to introduce an example, in the form of an actual case study, to show how the IP Business Assessment Report can actually be utilized. There was an SME that was considering starting a new business using its technological capabilities. Its bank knew that the company was seeking to develop a new business but did not fully understand the relationship between the strengths of the company's technology and its business. Therefore, the bank asked for an IP Business Assessment Report.

475. The report from the Japan Patent Office revealed the relevance of the company's strengths and its business. In addition, through interviews conducted by experts with companies in the same industry, the report made it clear that although the basic technology was being established, there was still no prospect of commercialization. Therefore, the bank proposed that the company proceed with joint development through industry-academia collaboration with the research institution that the company was collaborating with for some time.

476. As a result of the joint development proposed by the bank, the company was able to complete the new product and successfully launch a new business. During this period, financial institutions also provided financing for joint development. In this case the IP business assessment report played a key role in promoting financial institutions understanding other companies' business with the intent a proposal industry-academia collaboration and further support through financing.

477. The IP Financing Business initiative has been conducted since 2014, and the results are shown on the slide. There are 216 financial institutions that have utilized the IP Business Assessment Report at least once during the 8 years from 2014 to 2021. Since there are approximately 500 regional financial institutions in Japan, this means that about 40% of regional financial institutions have used the IP Financing Business initiative. A total of 2,188 people attended IP Financing Business seminars and symposiums. In the past few years, we have not been able to hold large-scale events due to the COVID-19 pandemic—but such meetings are planned to be held this year.

478. The IP Business Assessment Reports have led to financing 88 institutions in 189 cases, totalling approximately YEN 9.32 billion. To avoid confusion, this amount does not include direct IP financing. Although this number of cases is not considerable, we believe that the positive effect for SMEs including start-ups were greater than mere monetary figures, since in most cases, financing for the companies was provided in combination with management support from financial institutions. This brings me to the end of this presentation. We hope that today's introduction will be useful to other Members. In addition, the delegation of Japan is looking forward to other Members sharing their own experiences.

### 14.3 United States of America

479. The United States of America extends our thanks to the Friends of IP and Innovation and to Switzerland for the discussion paper on IP financing and start-ups. I would also like to thank everyone who came to the side event yesterday. We had some excellent panel speakers who provided different perspectives on IP and financing. It was fascinating to hear from a start-up who could provide a first-hand account from small business perspective. Thanks to everyone for your great questions during that event.

480. New businesses in the United States rely on external debt (including trade credit and bank loans) for more than 60% of their initial funding. The leading sources of start-up equity investment are self-financing, friends and family, angel investors, and venture capital.[23]

481. While venture capital is the dominant source of start-up investment, only about one third of venture capital investment goes to seed and early-stage ventures. In addition to federal programs,

[23] SEC.gov | What are the differences in friends and family, angel investors, and venture capital funds?

state governments also provide significant support to start-ups, with state-level funds that can exceed USD 1 billion supporting a variety of grants, loans, and other forms of financing.

482. There is very limited data on the use of IP financing and a lack of research in this area. However, venture capital is the largest source of start-up financing and is highly responsive to start-ups' patent holdings. Surveys of high-technology entrepreneurs suggest that less than 40% of start-ups hold any patents, but over 80% of venture-backed firms hold at least one patent.[24]

483. IP valuation is a service provided by accounting firms and other smaller boutique firms in the private sector. They pitch these services to both IP holders (including start-ups) and to potential investors. They also pitch these services to entities involved in litigation surrounding IP. Education of start-ups and investors and banks about IP financing opportunities takes a variety of forms in the United States of America. There are many varieties of decentralized programs organized and run by educational institutions, technology transfer organizations and associations, the US Federal Government, and private sector firms. The USPTO's hub for start-up resources can help address the IP challenges specific to start-ups, including securing funding.[25]

484. In addition, the US Small Business Administration (SBA) works with innovative small businesses and start-ups to empower them to succeed with access to capital, valuable resources, business know-how, and the right expertise for each stage of their business lifecycle. As part of its counselling resources, SBA educates small businesses on the importance of and steps to take to protect their intellectual property both in the United States and globally. SBA also works to support small businesses through a variety of access to capital programs. Small businesses can explore microloans and bank financing, such as loans backed by the US Small Business Administration.[26] In addition, it provides education on other funding for small businesses including venture capital and crowdfunding.

485. Recognizing that we can always do better to support our innovative small businesses and start-ups, the Small Business Administration recently created two new advisory committees – the Invention, Innovation, and Entrepreneurship Advisory Committee (IIEAC) and the Investment Capital Advisory Committee (ICAC) – to accelerate support for start-ups driving critical innovation across the US and increase small businesses' access to capital.[27]

486. A challenge is to expand participation in IP, particularly among start-ups. IP holdings provide benefits such as adding credibility to start-up business plans that facilitate access to financing; however, a relatively small fraction of start-ups hold IP, particularly patents. Another challenge is to monetize IP once obtained. Beyond the classic model in which a start-up becomes a fully integrated firm that invents, develops, and sells products and services, other avenues to obtain financing from IP such as selling or licensing the IP are understudied and underdeveloped.

487. Increasing knowledge and awareness about start-ups and financing opportunities could be helpful, as could further research into the needs of start-ups when it comes to IP financing and awareness. Becoming familiar with its own IP assets may be a critical step for start-up seeking to use IP-backed finance.[28] To that end, one resource is a joint tool called The IP Awareness Assessment, developed under the joint efforts of United States Patent and Trademark Office (USPTO) and National Institute of Standards and Technology which provides the user an assessment of IP awareness, which may be a starting point for an individual or business trying to assess its IP assets. The USPTO also notes on its website the comprehensive information provided by WIPO on IP valuation and IP-backed financing.

[24] Graham, S. J., Merges, R. P., Samuelson, P., & Sichelman, T. (2009). High technology entrepreneurs and the patent system: Results of the 2008 Berkeley patent survey. Berkeley Technology Law Journal, 1255-1327. https://www.jstor.org/stable/24120583

[25] https://www.uspto.gov/learning-and-resources/startup-resources

[26] https://www.sba.gov/business-guide/plan-your-business/fund-your-business

[27] https://www.sba.gov/article/2022/jul/29/sba-administrator-guzman-announces-two-federal-advisory-committees-accelerate-american-innovation

[28] https://ipassessment.uspto.gov/start.html

### 14.4 Australia

488. Australia welcomes communication IP/C/W/692 and is pleased to co-sponsor the paper with the friends of IP and innovation. We support the sharing of information on the role IP can play in raising finance for start-ups. This communication provides a useful overview of the many different ways IP can be used to help start-ups access much-needed capital. It highlights key institutional considerations that can facilitate (or, if they are absent, prevent) the development of a well-functioning financial IP market.

489. As an innovative economy, Australia recognises the important role that start-ups play as catalysts for growth and acknowledge the challenges that start-ups face in accessing finance, particularly in the early stages. Start-ups in Australia face some of the specific challenges in accessing financing that are identified in communication IP/C/W/692.

490. A 2016 report into IP financing in Australia commissioned by Australia's IP office (IP Australia) found that there were no specific innovation-based or IP-based financing products available in Australia at the time. In Australia, start-ups often require funding from multiple sources – funding rarely occurs as a single-lump sum. We have found that equity investment is an important vehicle for financing new and innovative high-risk ventures. This can occur either through professional venture capital firms or 'business angels' which have niche interests.

491. Australia has several policies and programmes to support the commercialisation of innovation and technology. Australia has a dedicated debt venture fund which aims to grow companies commercialising technological innovation. The Government also encourages venture capital investment and angel investment in early-stage companies through tax incentives for investors

492. The National Reconstruction Fund (NRF) is a $AUD15 billion investment to diversify and transform Australia's industry and economy and includes support to make it easier to commercialise innovation and technology by providing loans, guarantees and equities to drive investments and develop capability in the area.

493. We look forward to further exchanges with Members on their experiences of IP financing for start-ups in particular, on the different sources of financing for start-ups seeking to commercialise their innovation; and ways we can help both start-ups and venture capital to better understand the opportunities IP offers as part of a business' business plan and as collateral for accessing finance.

### 14.5 Canada

494. Canada would like to thank Switzerland for drafting the communication for this item as well as other Members that are sharing their views and information on this topic today. Canada sees clear connections between the development and protection of IPRs by MSMEs and the ability to secure investment and financing, enhance their growth, facilitate additional innovation, and expand further into domestic and international markets. Canada has also identified some opportunities to facilitate the capacity of businesses in this area, particularly MSMEs, and will present on several related initiatives today.

495. As noted at a past meeting of the TRIPS Council, as part of its IP Awareness and Education program, the Canadian Intellectual Property Office has launched an online IP Academy, featuring a suite of information materials and interactive learning resources for businesses and entrepreneurs. The IP Academy includes a recently-developed "massive open online course" developed by the Canada-based Centre for International Governance Innovation on "Foundations of IP Strategy" that offers particular value for MSMEs. The IP Academy also includes an online self-assessment IP strategy tool for MSMEs which generates a tailored guide with information on what to consider when developing their IP strategies.

496. One of many areas covered by this resource is IP-based financing, an area of growing importance and potential for innovative companies. As noted in the tool, IP-based financing strategies include IP-backed loans, IP royalty securitization, which involves the pooling and selling of future IP-related income streams in exchange for immediate financing, and IP sale and license-back arrangements which can involve the sale of IP assets in exchange for immediate financing, while retaining the option of using the IP assets through a license-back arrangement and potential

option of to buy back the ownership of the IP assets at a fixed price at the end of the license period. The IP Academy materials are available online should any other Member wish to consult them, share with their own stakeholders, or have questions or feedback to share with Canada.

497. Additionally, in 2020 the Business Development Bank of Canada, that is to say a federal government corporation that supports Canadian businesses through financing advisory services and capital with focus on SMEs launched an IP-backed financing programme for businesses - the first of its kind in Canada to provide capital to high-potential companies in knowledge-based industries, particularly those who have monetized their IP portfolios through product commercialization or licensing arrangements, or both. If other Members with similar programmes – or with an interest in pursuing similar programmes – have an interest in further discussions with Canada on this programme, we would be pleased to follow up and arrange conversations involving our respective authorities in this area, in the spirit of continuing to leverage the TRIPS Council as a venue for collective policy exchange and learning.

### 14.6 Chinese Taipei

498. First, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu would like to thank the United States of America, Japan and the Swiss for organizing the side event yesterday, the discussion was very informative and also shows how IP and finance could assist start-ups and SMEs. Returning to today's agenda item we would like to thank Switzerland for preparing the paper. We are happy to co-sponsor the paper. According to the Global Competitiveness Report 2019 compiled by the World Economic Forum, our jurisdiction ranked 4th in the world in terms of innovation capability. While the innovative energy of start-ups is undoubtedly the driving force behind a nation's economic prosperity, start-ups are often faced with a shortage of capital. Technology innovation requires long-term capital investment; therefore, our government is working to assist start-ups in utilizing their intellectual property rights to obtain funds and address their capital needs at different stages of business operations.

499. The main factors that hinder the development of our IP financing market are the lack of a vibrant IP trading market and a credible authority that can undertake the valuation and disposition of IP assets for banks. In order to help start-ups secure financing with their IP assets, the Industrial Development Bureau of the Ministry of Economic Affairs has been actively promoting the registration and management of intangible asset appraisers and institutions, as well as facilitating intangible asset financing.

500. The government facilitated a tripartite cooperation between 26 financial institutions, Small and Medium Enterprise Credit Guarantee Fund, and Industrial Technology Research Institute in 2019 to increase the guarantee coverage of credit guarantee funds so as to lower financial risks that impact financial institutions, which has so far led to many successful cases of intangible asset financing, covering key industries such as biotechnology, medicine, green energy, smart machinery, and information technology.

501. Ways to effectively assist start-ups in obtaining funds through IP financing to maintain business operations and continuous R&D are matters that we must give thought to. We welcome Members to share their measures and experiences related to said matters.

### 14.7 Singapore

502. Singapore thanks the friends of IP and innovation and Switzerland for preparing the discussion paper which has been insightful for us. 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. Singapore's business environment enables innovative enterprises to seek and secure equity investment from angel investors and venture capital firms. In 2019, venture investments rose to more than USD 9.8 billion, representing a year-on-year increase of 36%.

503. The Intellectual Property Office of Singapore International recently launched a new "IP Start" programme for accelerators and early-stage start-ups in September this year. This programme will provide free IP advice, training, and resources to start-ups through start-up accelerators and incubators based in Singapore, and to support the integration of IP management into the early stages of their business.

504. This programme will also complement existing efforts by IPOS to overcome the key challenge of the lack of IP awareness among start-ups and MSMEs. As shared in previous sessions, IPOS has worked with the Singapore Business Federation to provide support to companies in improving their IP literacy and management. IP clinics were also offered to help businesses understand how to protect their IP portfolio through the development of an IP strategy. In closing, IP financing for start-ups is an often-overlooked area of work and we are happy that this is being discussed at the WTO. We look forward to hearing from other Members experiences.

### 14.8 European Union

505. The European Union is pleased to co-sponsor this agenda item together with the other delegations. We thank Switzerland, in particular, for the concept paper which was high quality and for its active role in the drafting of this document with the other delegations. We also thank, as usual, the United States for their full involvement in the coordination of the group and the organization also of the side event yesterday.

506. Intellectual property rights (IPRs) play an increasingly important role in corporate strategy and the intangible assets created through innovation represent a major share of the value of today's businesses. The IPRs associated with intangible assets are the legal guarantee for potential returns on investment in innovation and a means to get funding, notably in start-ups and early-stage companies. The use of IPRs to gain finance is considered an important aspect given that SMEs and start-ups encounter difficulties in raising funds from bank loans due to the risks involved, while venture capitals ask for a large equity interest.

507. According to certain surveys that we monitor in the European Union the EUIPO SME scoreboard 2019, and the most recent one in 2022, only 13% of SMEs owning IP rights tried to use intangible assets to obtain finance: 9% successfully and 4% unsuccessfully. Additionally, only 25% of SMEs IPR owners have professionally valued their intangible assets, and this drops to 20% for small and micro-sized IPR owners.

508. According to the most recent study 2022 Intellectual Property SME Scoreboard, 15% of SME owners of registered IP rights reported that they had suffered from infringement of an IP right that they own. In light of these figures, I have already mentioned this year, and in light of the information, the European Union has developed programmes supporting young entrepreneurs coming from the universities favouring the financing of the SMEs or innovative start-ups, most of the time these start-ups are created by PhD students.

509. The main programme, for PhD student in Europe or elsewhere, there is no discrimination, is the Marie Curie Actions. The newest programme, Marie Skłodowska, it is her name, (MSCA Doctoral Networks 2022 deadline next 15 November 2022) implements doctoral programmes, creating partnerships between universities, research institutions and research infrastructures, businesses including start-ups of course, and other socio-economic actors from different countries across Europe and beyond.

510. This action offers training in research-related domains, as well as transferable skills and competences relevant for innovation and long-term employability such as IPR but also entrepreneurship, commercialisation of results, communication. Through industrial doctorates, doctoral candidates may step outside academia and develop skills in industry and business by being jointly supervised by academic and non-academic organisations, both of which can be established in the same EU Member State or Horizon Europe Associated Country.

511. A start-up can also receive support of a technology transfer office in the university. Such offices accompany start-ups and provide the necessary initial guidance and resources, including designing the intellectual property strategy and providing help for IP registration. The technology transfer offices are organized at EU level within the European TTO circle | JRC Science Hub Communities, it is really easy to find on the net.

512. A PhD student with a good business idea would be eligible to apply for Erasmus for Young Entrepreneurs. This is a cross-border exchange programme which gives new or aspiring entrepreneurs the chance to learn from experienced entrepreneurs running small businesses in other participating countries. The exchange of experience takes place during a stay with the experienced

entrepreneur, which helps the new entrepreneur acquire the skills needed to run a small firm, in particular as regards the IP strategy. The host benefits from fresh perspectives on his/her business and gets the opportunities to cooperate with foreign partners or learn about new markets.

513. Furthermore, both the European Union and its Member States have a number of general programmes to support access to finance, in particular for micro, small and medium companies. Under the Single Digital Gateway, such young entrepreneurs can find a number of access to finance programmes: Access to finance/Your Europe.

514. As regards the EU, the Commission launched in November 2020 the Intellectual Property Action Plan to support the EU's recovery and resilience. The IP Action Plan identified a number of priorities, among which one was to promote an effective use and deployment of IP, in particular by SMEs and start-ups. To achieve this priority, the Commission committed to offer financial support for SMEs impacted by the COVID-19 crisis, helping them to manage their IP portfolios as well as helping them move towards green and digital technologies which are our priorities in the European Union.

515. In the framework of this general Action Plan, the Commission and the EUIPO launched the new EU SME Fund on Intellectual Property in 2022, which offers intellectual property vouchers for EU-based SMEs for post-COVID-19 recovery and green and digital transitions for the next three years (2022-2024). The new EU SME Fund, with its budget of EUR 47 million, offers a great variety of services: partial reimbursements of various national fees or costs for instance. Start-ups need a flexible IP toolbox and quick financing to protect their innovations. Hence, for the first time the new EU SME fund is now also covering patents. The European Commission's financial contribution, which can amount up to EUR 2 million, will be dedicated fully to the patent related services.

516. This action, the EU SME Fund, is implemented by the EUIPO through calls for proposals. The applications are examined and evaluated based on a first in first out criterion. SMEs with no experience in the area of intellectual property are encouraged to apply first for an IP Scan service and only subsequently to the other services. The IP Scan service will provide a broad assessment of the IP needs of the applicant SME, taking into account the innovative potential of its intangible assets.

### 14.9 United Kingdom

517. The United Kingdom would like to thank Switzerland for their interesting and informative paper on IP financing for start-ups. We also thank Members for helpful information shared so far. The United Kingdom believes that businesses' ability to access the right type of finance at each stage of development is critical to allowing innovators to develop their ideas and enabling businesses to grow.

518. Innovation is a key driver of economic growth, and finances affect every stage of the innovation cycle: from idea creation to commercialisation, expansion, and long-term business sustainability. Businesses' innovation finance journeys typically involve progression from the founder's own resources, grant funding, seed equity and later venture, institutional capital, and ultimately debt finance.

519. However, IP-rich companies with substantial intangible assets can find it difficult to secure debt finance. A key challenge for innovative businesses is the financial services sector's understanding of the role that IP plays in generating cashflow. To address this challenge, since 2018 the UK has been working and engaging with banks, lenders, investors, accountants, and insurers to:

a. Explore the challenges faced by the financial sector and businesses in using IP as a collateral for lending;

b. Explore the barriers financial institutions face in recognising IP as an asset, and how businesses can use their IP as leverage to access finance.

520. We also want innovative, IP intensive businesses to understand how to use their IP to gain access to funding.

521. To improve awareness amongst start-up businesses of how IP can be used to unlock access to finance, the UK offers a range of resources to help new businesses understand and identify their IP and incorporate it into their business planning. For example, the 'IP for Investment' digital toolkit was developed to prepare IP-rich businesses looking for equity finance to grow. The toolkit helps them to identify and assess their IP assets as part of their overall business strategy and provides guidance on their investor readiness.

522. The UK also offers a range of other digital resources to help businesses with managing, using and commercialising their IP. This includes the IP health check diagnostic tool kit for businesses to undertake an initial audit of their IP assets to identify how to maximise their value, and the Business Lifecycle Framework, which provides information aimed at pre-start-up and start-up businesses, such as how IP assets can be used for seeking finance. As a part of our commitment to improving understanding of IP, the UK is developing a specialist module on IP valuation as part of its IP awareness and education work. This will set out some of the key methods for IP valuation, sitting alongside a broader package of education resources on topics such as IP management, IP commercialisation, and IP in contracts, to improve understanding of the value of IP assets.

523. The United Kingdom has also worked with regional business services on IP and access to finance, as well as working with financial institutions directly. For example, by including IP within regional programmes aimed at supporting early-stage SMEs acquiring equity finance and working with finance providers to ensure they direct businesses to relevant IP information and support.

524. Financial support is also available to SMEs to help them to better manage, protect and commercialise their IP. The IP Audit scheme provides eligible, innovative high-growth potential businesses with funding towards an audit carried out by an IP professional. This in-depth analysis of the business's IP helps new businesses to identify how they can make their IP work for them as they grow, so they can unlock the value of their IP. Funding is also available to businesses to implement the recommendations in their audit report - such as engaging professional services to support IP management and commercialisation, including IP insurance and valuation of IP. I hope this information has illustrated how the United Kingdom sees IP as a way of unlocking finance for start-ups, and our commitment to ensuring that it can be fully used by such businesses.

### 14.10 Chile

525. Firstly, our delegation would like to thank the co-sponsors for placing this interesting matter on this Council's agenda. Our delegation considers that access to financing through intellectual property is crucial for SMEs. Many of the innovators taking their first steps do not have the financial track record or collateral needed to access financing via the traditional routes. This is precisely the reason why intellectual property assets can represent a powerful tool available to innovators who are seeking to take the next step in their projects.

526. Chile has been establishing itself as a business hub for start-ups through a drive by the State and collaboration with the private sector. These projects use a variety of sources to access financing. In terms of grants, we would like to highlight the existence of seed capital programmes and the "Start-up Chile" accelerator. Innovators may also access services and capital provided by incubators in the earliest stages of their projects' development. In both initiatives, the provision of grants and the incubators, the public sector plays a fundamental role in creating connections and enabling innovative projects to become a reality.

527. Accelerators are also increasingly present in later stages of the project, with recent years seeing the entry of new actors, which has led to the diversification of the offer in this area. Venture capital and angel investors may also be accessed. In this connection, some actors have decided to focus their investment on projects that are particularly strong in terms of intellectual property assets. This may be the case in the creative industries sector or for those products associated with commercial patents and/or trademarks that are strong or have potential.

528. Nevertheless, the valuation of intellectual property assets remains a significant challenge. The difficulties associated with this process mean that there is still potential that has not yet been fully exploited in terms of access to financing, whether it involves using these assets as collateral or other alternatives that take initiatives to the next level. Our delegation considers that it is highly important to identify potential shared challenges in this area.

### 14.11 Hong Kong, China

529. We would like to put on record our appreciation to the co-sponsors for the submission as well as for organising the side event yesterday. Yesterday, we indeed had a lively debate where we explored the difficulties faced by start-ups in securing capital due to the lack of hard assets, as well as what governments and international organisations could do to promote IP-backed finance. For example, raising IP awareness among start-ups and financial institutions, standardisation of IP valuation, review of financial reporting on intangible assets, as well as information sharing. Today, we continued to listen with great interest the different experiences and best practices around the world. We will reflect on these and see how we can create a sustainable ecosystem in Hong Kong, China to promote IP financing.

### 14.12 Uruguay

530. First of all, we welcome the drafting and submission of document IP/C/W/692, which was drawn up by Switzerland and endorsed by a number of other Members that are very active in this area. My Ambassador, as Coordinator of the Informal Working Group on MSMEs, had the honour and pleasure of presenting the issue of start-up financing based on intellectual property asset capitalization, from the public policy standpoint, at yesterday's lunchtime event moderated by the United States. There, we were joined by WIPO and an innovative enterprise from the food sector, both of which shared their views regarding technical aspects and the real challenges on the ground.

531. After attending yesterday's event and hearing about some Members' experiences, it is clear that the developing world still has a long way to go until the financial system recognizes intellectual property assets in a way that is effective from the point of view of risk and potential market gains. While some financial institutions are clearly already pioneers in this area, the vast majority continue to operate in a traditional and conservative manner. This is where States need to make an additional effort to ensure dialogue between MSMEs and entities with capital available for investment, and to perhaps amend domestic regulations at the central bank level. In this regard, we have found that financial regulations promote conservatism when it comes to providing high-risk capital, and this is detrimental in situations where an entrepreneur submits a business plan that is based, in many cases, on a patent, an industrial design or a trademark. The regulatory machinery should be used to ensure that central banks have the assurance they need that credit providers can conduct business safely, but without this stifling innovation or the possibility of financing projects that on the surface appear high-stakes.

532. In Uruguay, the National Innovation and Research Agency finances and supports business projects from their inception and the development of business plans. It provides financing and helps businesses to find other sources of capital in the public and private sectors. It is our understanding that public policies should provide the initial impetus to encourage central banks, financial institutions and, above all, entrepreneurs, so that this issue is not a taboo.

533. We suggest that this item remain on the Council's agenda on a permanent basis, so that the issue can continue to inspire Members. We also suggest that this issue continue to be discussed in the Informal Working Group on MSMEs. Lastly, we invite everyone to participate in the event to be held by WIPO on 1 November, which has already been mentioned by my Swiss colleagues.

### 14.13 Mexico

534. Mexico would like to thank the Friends of Intellectual Property and Innovation for including this item on the agenda, for the document IP/C/W/692, for yesterday's event and for their very interesting presentations. Mexico recognizes and concurs on the importance of protecting intellectual property rights as a key element in enabling start-ups to obtain financing. At present, Mexico does not have any similar government programmes owing to a lack of resources and because, outside of intellectual property related departments, there is a lack of awareness of the benefits that protecting intellectual property rights can bring to the wider economy.

535. However, the Mexican Institute of Intellectual Property (IMPI) provides advice to the general public, on a personal and individual basis. Appointments can be requested on the Institute's web page. Moreover, the IMPI carries out campaigns to encourage companies to protect their intellectual property rights through tariff reductions, up to 90% for micro-, small- and medium sized enterprises.

### 14.14 Uruguay

536. In that sense we understand that this agenda item has been proven to be very fruitful and it has engaged a lot of Members the side event and the level of attendance that the organizer had it was very interesting indeed and it is a dynamic issue that help us to apply IP policies on the field in our cases. So, it would be our understanding that there is some appetite for this kind of discussions, regularly, in this Council and we would like to suggest that we can have this agenda item permanently in our agenda, sometimes with a wider scope sometimes with a more discrete approach but the idea of linking IP policy and MSMEs I think that it is very useful for our daily work in this Organization.

### 14.15 Switzerland

537. We would certainly agree in fact that I think we have seen in this Council and in past Council meetings under this *ad hoc* agenda item IP and Innovation much interest by Members and we had very rich and useful discussions. I think it does cover a potentially very broad policy area and I think useful information and sharing exercise can be very useful so my delegation would certainly agree to having an agenda item IP and Innovation permanently on the agenda. Let me take this opportunity also to thank all those delegations in fact which have today taken the floor and shared their experience. I think we had a very useful discussion and it demonstrated that IP is in fact not a means in itself, but in fact a means to an end and an important end – I would say – particularly from the prospective of start-ups and MSMEs.

### 14.16 South Africa

538. We thank the co-sponsor of document IP/C/W/692 for the submission. Our delegation has consulted with stakeholders about this submission. The feedback we received is as follows:

539. It is important to interrogate the factual scenario in order to provide a realistic reflection of what is to follow. Therefore, the following 8 comments are submitted from a South African perspective:

a. Imagine that a young PhD student at a technical faculty of a renowned university comes up with a promising invention. Comment as follow - if that is the case the university's intellectual property policy would apply and the university rather than the student, would be the owner of both invention and resulting intellectual property, she would merely be named as inventor and have a share of the profits

b. Comment two: thanks to university modules she attended on how to deal with intellectual property (IP), she applies for and is granted a patent for her invention. Comment to the follows: the university's technology transfer office would do the application. She would never be the one applying. Only a patent attorney can file a final patent specification.

c. Comment three: now, together with the university technology transfer office, she would like to bring the invention to market. The comment to the follows: again, quite simplistic, the technology transfer office would do this probably through a spin-off company.

d. Comment four: when writing a business plan, she soon realises that the funds she needs greatly exceed her family's and her university's financial capacity. The comment to the follows: a technical university would have access to the necessary funds and if not, some state entity would assist - in South Africa the technology innovation agency would assist – one example is the Durban University of Technology which has a University Technology Fund which would fund this scenario}.

e. Comment five: where can she find funding? The comment to the follows: the question should be, where would the university find such funding? That would be the real question.

f. Comment six: various studies show that young companies that have an active and a well-managed IP portfolio to show to potential investors to obtain more funds and grow faster than those without. The comment to the follows: how has she morphed into a young company? Again, the applicant would be the university or its spin-off.

g. Comment seven: so, if the PhD student from our example seeks IP protection for her invention, she will stand a much better chance of finding the necessary funds to turn her idea into a business. The comment is she would not own the IP.

h. Comment eight: in addition to protecting intellectual assets from free riders, intellectual property rights are a potentially useful means of raising money, especially for start-ups. In the above example, IP is used as a signal to investors that there is considerable substance in the young company. Furthermore, IP can be used as leverage or collateral for borrowing, or for sale to prospective buyers through sale-leaseback transactions. The comment to the follows: in theory, it would be good if a start-up could protect its inventions/creations with IP. This indeed would give them the opportunity to raise funds, set collaborations etc. In our context, the financial services sector is very risk averse and as a result, use of IP as security is very uncommon, particularly in relation to MSMEs). Furthermore, it would be good to investigate, whether IP protection (of larger companies) can actually prevent start-ups from exploiting their inventions. In some industries, such as complex technologies, the number of patents is so high that it is very difficult to get through patent thickets of thousands of patents for a small start-up (e.g., mobile industry). To actually get something to the market, a company would need to have a portfolio of hundreds of patents to be able to negotiate cross-licences. So yes, the nice picture of a PhD student inventing something, patenting it, and then developing a successful business sounds like a very good example. But the reality may be more complicated.

540. The scenario would benefit from taking into account, the reality of university intellectual property policies, Bayh-Dole type legislation and the actual practice at universities. That concludes the statement.

541. With regard to the request that you are deliberating upon we would certainly need time to consult but one element that would be taken into consideration in our consultation would be over the inclusion of a mandated issue such as the Work Programme on E-commerce and the 1998 mandate we have and the contribution of this particular Council. Some delegations may be of the view that we should take those into consideration before bringing a new permanent item.

### 14.17 India

542. Thanks to the proponents for bringing this agenda item up here and thank you very much for your comprehensive presentation and statements and also for hosting yesterday's event. It was quite useful, thank you very much for that. Just to support South Africa's last comment here that today we are also not in the position to be able to say yes or no. We will still need more time to consult, whether to make this issue as a permanent standing agenda item.

### 14.18 China

543. China would like to thank the co-sponsors for their consistent efforts in pushing forward the discussion on IP and innovation. We have fully recognized the challenges faced by start-ups due to their limitation in scale, assets and other aspects. The discussion on this topic would contribute to the exchanges among Members. China would like to share our practices as well.

544. First of all, China has been continually improving the IP-related financing legal system, in particular, for example, the stipulations and provisions on the pledge of IPRs by the Civil Code of the People's Republic of China; and the measures for the Registration of Pledge of Patent Rights, etc. All these regulations have formed a solid legal and institutional basis for IP financing to facilitate the commercialization of IPs.

545. The second is about IP insurance. China National Intellectual Property Administration has carried out wide cooperation with insurance institutions in optimizing IP insurance products, services

and business models. By now, there have been 4 categories of insurance, namely liability insurance, guarantee insurance, credit insurance and expense compensation insurance, covering patent, trademark and other IP types. Moreover, China is seeking to widen the financing channels of start-ups through a new method called 'direct investment of insurance capital', so as to support their innovation and development.

546. The third is our efforts in strengthening IP assessment services. With Asset Appraisal Law of the People's Republic of China as the legal basis, China has established an evaluation system of IP intangible assets, which includes basic standards and specific standards for asset appraisal, as well as guidelines for IP asset appraisal. In this manner, the reliability of IP asset appraisal could be further improved.

547. There are a large number of MEMEs in China, lots of them being starts-up. The guiding questions raised by the co-sponsors point out a direction for in-depth research and discussion. We would like to listen to Members' experiences so as to further the discussion in the future.

### 14.19 Indonesia

548. Indonesia would also like to thank the proponents for their presentations to today, as well as the submissions, and also the side event that was held yesterday, we found it very useful and very informative as well. We note the importance of this issue, as well as its complexities. We also note that IP and Innovation is also an issue that is very much the focus of many discussions at Word Intellectual Property Organization. As such, noting the evolving nature of the issue, as well as taking lessons from yesterday in which we have many standing agenda where there were further interventions from Members. We are not ready at the moment to agree to the standing agenda of this issue at the TRIPS Council.

## 15 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

### 15.1 WTO Secretariat

549. 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. Since our last report during the TRIPS Council Meeting in July, the Trade Policy of Republic of Moldova and Mexico took place. 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. Enforcement, online and at the border; and

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

550. 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. The reports will be circulated in November.

## 16 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

551. No statements were made under this agenda item.

## 17 ANNUAL REPORT

552. No statements were made under this agenda item.

## 18 OTHER BUSINESS

553. No statements were made under this agenda item.