WORLD TRADE ORGANIZATION

IP/C/W/706

23 October 2023

(23-7121)

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Council for Trade-Related Aspects of Intellectual Property Rights

COUNCIL FOR TRIPS

PARAGRAPH 8 OF THE MINISTERIAL DECISION ON THE TRIPS AGREEMENT

INFORMAL THEMATIC SESSION FOR EXTERNAL STAKEHOLDER INPUT

Report by the Chair

1. Under paragraph 8 of the Ministerial Decision on the TRIPS Agreement (document WT/L/1141), Members agreed to decide on an extension of the Decision to COVID-19 diagnostics and therapeutics within six months of adoption. Following the extension of this deadline by the General Council on 19 December 2022[1], Members have continued their discussion on this question in the Council for TRIPS in formal and informal settings. In order to support a fact and evidence-based discussion, the Council agreed at its meeting in June 2023, to invite international organizations, civil society, business representatives and academics to share facts, evidence and experiences relevant to Members' deliberations under paragraph 8 of the TRIPS Decision. This Informal Thematic Session for External Stakeholder Input was held on 28 September 2023 at the WTO premises in a hybrid format.

2. This was the first time that the Council organized a Thematic Session with outside speakers as part of its proceedings, and I would like to commend Members for having agreed to use this format for collecting views and information from outside the organization. With this approach we are following the example of Director-General Dr Ngozi Okonjo-Iwela, who is also championing a more direct engagement with stakeholders from the "real world", as was evidenced at this year's Public Forum. The programme for the Thematic Session was developed on the basis of suggestions received from Members. It aimed to provide a geographically and organizationally balanced cross-section of stakeholders in the hope that the broad spectrum of expertise and views represented will be helpful for Members – and the Council as a whole – to find common ground and develop a constructive path forward.

3. The Council heard interventions from 22 speakers from a wide range of perspectives, who kindly agreed to share facts, evidence and experiences from their respective areas of expertise. The rich and detailed interventions helped illuminate certain points and arguments of this long-standing debate in much more detail. The data and analysis illustrated in the first session provided up-to date perspectives on the market situation of therapeutics and diagnostics, while recognizing certain data gaps. The perspectives of our colleagues from international organizations in the second session highlighted their activities surrounding intellectual property in the context of pandemic response, and the Medicines Patent Pool provided first-hand experience of its licensing approach regarding COVID-19 treatments.

4. In the third session, civil society organizations explored the nature of the MC12 Decision in the context of TRIPS flexibilities and provided health-related experiences from the grass-roots in

[1] On 19 December 2022 the General Council agreed to the TRIPS Council's 16 December recommendation (document IP/C/95) to extend the six month deadline for deciding on an extension of the MC12 TRIPS Decision to diagnostics and therapeutics. The duration of such an extension remains before the General Council while substantive discussions continue in the Council for TRIPS.

developing countries. Business representatives from the pharmaceutical industry – both originator and generic companies from a range of countries – shared their experiences and their views on what made collaboration and diversified production possible, and what was needed to ensure this in the future. Finally, academics gave a detailed legal view on the nature and legal operation of the MC12 Decision, and some proposed a more proactive and institutionalised licensing approach to tackle this and future pandemics.

5. Feedback across the membership suggests that the Thematic Session was well received and considered useful, and I hope Member will consider using this or a similar format again in the future.

6. This report contains the programme of the event, the biographies of speakers, and summaries of the presentations that have been provided by the speakers themselves.[2]

[2] Speakers' presentations were made available to Members via an internal WTO webpage.

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Geneva, 28 September 2023 - Centre William Rappard, Room W
8.45 a.m. – 5.30 p.m.

Revised Programme	
8h45 – 9h00	**Opening** **H.E. Ambassador Pimchanok Pitfield** – Chair of the Council for TRIPS
9h00 – 10h00	**Data collection and analysis on vaccines, therapeutics and diagnostics** **[Ms Paulina Rivas Calderón**, Market Research Officer, United Nations Children's Fund (UNICEF), Operator of the COVID-19 Market Dashboard] **Mr Rasmus Bech Hansen**, Co-founder & CEO at Airfinity Ltd. **Dr Emma Hannay**, Chief Access Officer, FIND, Global Alliance for Innovation in Diagnostics, co-convener of the ACT Accelerator Diagnostics Pillar *Questions & Answers* (15 minutes)
10h00 – 11h30	**Intergovernmental organizations and international initiatives** **Prof. John Reeder**, Director, Research for Health Department and Director TDR, World Health Organization (WHO) **Ms Erika Dueñas Loayza**, Technical Officer, Department of Essential Medicines and Health Products, World Health Organization (WHO) **Mr Edward Kwakwa**, Assistant Director General, Global Challenges and Partnerships Sector, World Intellectual Property Organization (WIPO) **Ms Amy Dietterich**, Director, Global Challenges Division, World Intellectual Property Organization (WIPO) **Mr Nirmalya Syam**, Senior Program Officer, Health, Intellectual Property and Biodiversity Programme, South Centre **Mr Charles Gore**, Executive Director, Medicines Patent Pool (MPP) *Questions & Answers* (15 minutes)

Revised Programme	
11h30 – 13h00	**<u>Civil Society Organizations</u>** **Mr Tahir Amin**, CEO, Initiative for Medicines, Access & Knowledge (I-MAK), United States of America **Dr Ellen 't Hoen**, Director, Medicines Law and Policy, The Netherlands **Ms Sangeeta Shashikant**, Third World Network, Malaysia **Mr James Packard Love**, Director, Knowledge Ecology International, United States of America **Ms Fatima Hassan**, Director/Founder, Health Justice Initiative, South Africa **Ms Jennifer Brant**, Director, Innovation Council, Switzerland *Questions & Answers* (15 minutes)
13h00 – 14h30	**Lunch**
14h30 – 16h30	**<u>Business</u>** **Dr Julia Spencer**, Associate Vice President, Global Multilateral Engagement & Strategic Alliances, MSD **Ms Elsie Soto**, VP Supply Chain, Emerging Markets, Pfizer Global Supply **Mr Cheik Tidiane Diagne**, Head of Operations, DIA*TROPIX*, Institut Pasteur de Dakar, Senegal **Mr Osman Khalid Waheed**, CEO, Ferozsons Laboratories Ltd., Pakistan **Dr Morena Makhoana**, CEO, Biovac, South Africa **Mr Alejandro Gómez López**, Health Secretary of the District of Bogota, Speaker of BogotáBio, Colombian Public Enterprise for the local production of vaccines *Questions & Answers* (30 minutes)
16h30 – 17h15	**<u>Academics</u>** **Dr Daria Kim**, Max Planck Institute for Innovation and Competition, Munich, Germany **Prof. Dr Yangmu Huang**, Deputy Director, Department of Global Health, Research Professor, Beijing University, China **Prof. William Fisher**, Wilmer Hale Professor of Intellectual Property Law, Harvard University *Questions & Answers* (15 minutes)
17h15 – 17h30	**<u>Closing</u>** **H.E. Ambassador Pimchanok Pitfield** – Chair of the Council for TRIPS

BIOGRAPHIES OF SPEAKERS AND SUMMARIES OF THEIR INTERVENTIONS

1 DATA COLLECTION AND ANALYSIS ON VACCINES, THERAPEUTICS AND DIAGNOSTICS

1.1 Mr Rasmus Bech Hansen, CEO, Airfinity, Predictive Health Intelligence and Data Analytics

1. Rasmus is a globally recognised global health security expert and data entrepreneur. The first part of his career he worked as strategist and partner in various boutique advisory firms working for governments, UN entities, and corporates, in particular pharmaceuticals. He also had a regular column in a national newspaper and wrote a book on innovation. He founded Airfinity as a result of having personally experienced how better health data can or could have saved lives. For the last 8 years, he has, as CEO, spearheaded the company's development and driven its high impact predictive analysis.

2. He is often quoted in leading media outlets such as Financial Times, Bloomberg and CNN and is a regular key-note speaker at events such as the Rhodes Summit and the FT Pharma and Biotech Summit. He holds a B.Sc. in Political Science, a MPA from Harvard University and is a recipient of the Crown Prince Frederic award for excellent scholarship. He lives in London with his wife and two sons.

1.1.1 Summary of Intervention

3. Airfinity's proprietary data set on COVID-19 provides a unique insight into the landscape for treatments and the issues surrounding supply, access and demand. Airfinity's presentation to the TRIPs council aimed to explore whether intellectual property is a barrier to equitable supply and access.

4. The success rate of COVID-19 treatment development is low with less than 5% of candidates entering clinical trials reaching market to date. 900 candidates have begun preclinical development, 44 of which have been approved with only seven receiving WHO endorsements. WHO recommended treatments have widespread regulatory authorisations worldwide but there is low coverage for approvals across Africa.

5. Publicly available data on global supply agreements suggests nearly 80% of total oral antiviral supply has gone to high income countries (HICs), with 2.8% going up upper middle income countries (UMICs), 6% to lower middle income countries (LMICs) and 5% to low income countries (LICs).

6. Analysis on when licensing agreements were signed to improve access for poorer nations reveals many were signed shortly after regulatory approval and sometimes before so. The first voluntary license agreements (VLAs) for Remdesivir were announced 12 days after FDA approval. The first VLAs for Merck's Molnupiravir were signed 217 days before EUA approval. The first MPP agreements for Pfizer's Paxlovid were signed 50 days after FDA approval. There is a total of 107 MPP agreements and VLAs publicly announced. Nearly 47% of the global population is covered by all three of the Medicines Patent Pool (MPP) licencing agreements, with the majority residing in the global south.

7. There have been 185 industry collaborations on the production of COVID-19 treatments, of which 105 were specifically designed to increase access to LMICs.

8. Analysis comparing the industry's response to COVID-19 with that of HIV shows a roughly equal number of MPP licencing agreements. For COVID-19 treatments there has been 80 licencing agreements facilitated by the MPP in less than two years, this compares to 76 for HIV across four years.

9. The production and supply of COVID-19 treatments is of a drastically smaller scale than COVID-19 vaccines. To date over 16 billion COVID-19 vaccines have been produced while only

103 million treatments of antivirals and monoclonal antibodies (mAbs) have been produced. The trend is repeated in supply agreements with over 20 billion vaccine doses ordered in public supply agreements with only 75 million courses known to have been under contract for antivirals and mAbs.

10. There are still data holes in the global public health infrastructure which would help answer the question of equitable access. Improved data availability and sharing on disease prevalence, testing, rollout capacity and uptake would provide the industry and policy makers with a more holistic view on the dynamics involved.

1.2 Dr Emma Hannay, Chief Access Officer, FIND, Global Alliance for Innovation in Diagnostics

11. Emma is FIND's Chief Access Officer and recently led the ACT-Accelerator Diagnostics Partnership on behalf of FIND and The Global Fund. She is a public health doctor with a focus on global health strategy and delivery. Her work has been centred at a global level on organizational strategy in global health, and at a country level in implementing health systems reforms in complex operating environments.

12. In her previous role as Head of Health at Acasus, she was part of the team leading the Pakistan Health Reforms Roadmaps, which improved primary care for more than 150 million people, and the DRC's Mashako Plan to increase immunization coverage for children. Prior to joining Acasus she was the manager of the Market Dynamics Team at Unitaid in Geneva, and an Engagement Manager for McKinsey & Company based out of Dubai and Washington, DC. She holds a medical degree from the University of Auckland, New Zealand and a Master of Public Health from Harvard University.

1.2.1 Summary of Intervention

13. Following the waiver of certain patent-related Articles of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines, there have been ongoing discussions around a potential extension of this waiver to cover the production and supply of COVID-19 therapeutics and diagnostics. This statement summarizes FIND's position on these discussions.

14. **First**, most COVID-19 diagnostics are composed of biomarkers (which are not patentable), capture agents (which can be proprietary or non-proprietary), detection reagents (which are mostly generic commodities), and sensing technologies (the basis for most diagnostics patents). Many COVID-19 diagnostic tests were based on PCR and lateral flow, for which key patents are expired. As a result, access to COVID-19 diagnostics has not been limited by enforceable patents. Neither compulsory nor voluntary licenses on diagnostic technologies would have been likely to stimulate innovation or sufficient to enable local manufacturing of COVID-19 tests in middle-income countries. Nonetheless, patent-related waivers under the TRIPS Articles may one day be applicable to essential diagnostics or diagnostics for future pandemics, such as emerging sensing technologies.

15. **Second**, unlike therapeutics, competitive advantages in the diagnostics industry are often linked to engineering know-how, manufacturing technologies, and production costs. For low- and middle-income countries (LMICs), the lack of manufacturing 'know how' and the dearth of technology transfer programmes to support local manufacturing are one of the largest trade-related barriers to global access to diagnostics.

16. Consequently, TRIPS Articles concerning trade secrets and technology transfer are more relevant to equitable global diagnostics access than those relating to patents and waivers. Trade secrets are addressed in Article 39, Section 7 of the TRIPS Articles; technology transfer is addressed in Article 66, Section 66.2, which states: "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base". This statement has been reaffirmed in paragraph 7 of the Doha Declaration.

17. **Third**, given the importance of manufacturing technology and manufacturing know-how to equitable global diagnostics access, we believe that full application of the principles in Section 66.2 could have an important impact. We are therefore calling for Article 66 to be brought to the forefront of ongoing WTO discussions around equitable global access to healthcare products, to remind Members of their commitments to technology transfer, and to advocate for the establishment and use of meaningful incentive programmes to transfer diagnostic manufacturing know-how and technology to LMICs.

18. **Fourth**, we are calling for further WTO engagement beyond the scope of the TRIPS Agreement to address other trade-related barriers that adversely affect the availability of diagnostics in LMICs. These include barriers relating to import duties, product registration, and regulatory harmonization.

19. **In summary**, leveraging Article 66 of the TRIPS Agreement has the potential to yield a significant impact on access to diagnostics, even more so than an extended waiver of patent-related TRIPS Articles. We believe that this, along with initiatives to address other trade-related barriers, could represent an effective strategy to improve equitable global access to diagnostics.

2 INTERGOVERNMENTAL ORGANIZATIONS AND INTERNATIONAL INITIATIVES

2.1 Prof. John Reeder, Director Research for Health Department and Director of the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), World Health Organization, (WHO)

20. Professor John Reeder is Director of TDR, the Special Programme for Research and Training in Tropical Diseases (since 2012) and Director of the WHO Research for Health Department (since 2019). In these positions he has responsibility for co-ordinating an effective, strategic and well-harmonized research effort across the WHO.

21. Before joining WHO, he was most recently Co-Director of the Centre for Population Health at the Burnet Institute, Melbourne, Australia. Before this, he was Director of the Papua New Guinea Institute of Medical Research, where he worked on translating scientific findings from the field into policy for improved health.

22. John began his career in medical microbiology laboratories in the United Kingdom and then moved to health training as a development volunteer in the Highlands of Papua New Guinea, before joining the world-renowned malaria research team at the Walter and Eliza Hall Institute.

23. A naturalized Australian, born and educated in England, he received his PhD in medical microbiology at the University of Manchester. He has published around 200 scientific papers, that span basic laboratory research to large community-based field studies. Among a number of honours, Professor Reeder received the 2020 Mitchell Humanitarian Award for his contribution to end the debilitating disease onchocerciasis.

2.1.1 Summary of Intervention

24. As the COVID-19 pandemic is coming to an end, we are observing that new variants of the virus are still causing waves of infection, however, at much lower levels and with smaller health impact. This contrasts to the first months of the pandemic when countries struggling to respond to the largest public health emergency in recent history. The pandemic brought to the fore a substantive global inequity in terms of access to health technologies to fight the pandemic. For the case of vaccination rates, high-income countries achieved rates that were twice as high as in the rest of the world and, combined with better health systems, led to significantly lower excess mortality.

25. The reasons for the global vaccine inequity were multiple. One being that countries with the ability to manufacture vaccines, often stockpiled them, while countries with no vaccine manufacturing capacity were struggling to secure a sufficient supply of vaccines. This experience has changed the thinking of many governments about health security. WHO has received strong feedback from its Member States that they want to increase their domestic manufacturing and R&D capacity.

26. Increasing the effectiveness of R&D and innovation systems and developing technologies adapted to local context is an important part of work program of WHO's Science Division. For R&D systems to deliver new health technologies, several elements need to be in place: (i) an intellectual property regime (as discussed in-depth by other presenters during the meeting); (ii) sufficient human resource capacity for R&D; (iii) global supply chains that continue working during pandemic times; (iv) ethics committee and mature regulatory agencies; (v) national, regional and global R&D plans and networks; and finally (v) funding and financing opportunities for R&D.

27. WHO has been working on those elements for many years, starting even before the pandemic. Examples of some of those efforts by WHO include (i) technology transfer and local production programs (e.g., mRNA technology transfer program); (ii) regulatory system strengthening; (iii) workforce training (e.g., biomanufacturing workforce training hub); and (iv) the WHO Framework for Strengthening R&D and Innovation Systems.

28. The main lessons learned from the pandemic are the following: First, to ensure access to new health technologies, an entire eco-system needs to be in place, spanning from basic research, applied R&D to manufacturing. Second, there is a need for better coordination of R&D policies across different sectors, across countries and across regions. And finally, one needs to build R&D systems, infrastructure, and institutions in peacetime in order to be working and be ready for scale up during crises.

2.2 Ms Erika Dueñas Loayza, Technical Officer, Department of Essential Medicines and Health Products, World Health Organization (WHO)

29. Erika Dueñas leads the Intellectual Property Unit at WHO HQ/Access to Medicines and Health Products Division providing technical advice on issues related to innovation, access to health technologies, and Intellectual Property (IP). She also supports activities to build and strengthen national and regional capacities in the intersections between public health, trade and IP. Erika worked at the Medicines Patent Pool and has more than 20 years of experience in the field of access to medicines, innovation and IP. As a career diplomat, she worked many years for the Bolivian government. After her diplomatic mission at the Embassy in Washington as Chargée d'Affaires, she was Vice-Minister at the Ministry of Foreign Affairs in Bolivia. Erika holds a Master's degree in International Law and Economics (LLM) from the World Trade Institute/Universities of Bern, Fribourg & Neuchâtel – Bern, Switzerland.

2.2.1 Summary of Intervention

30. Erika Duenas reiterated the importance of the implementation of Paragraph "8. No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics." Bringing to the attention that WHO supports member States to use all the tools in their hands to promote timely global equitable access for all, as indicated by Dr. Tedros Adhanom Ghebreyesus, WHO Director General to The Guardian since the beginning of the Pandemic," boosting manufacturing won't happen by itself. We are living through an exceptional moment in history and must rise to the challenge. Whether it's dose sharing, tech transfer or voluntary licensing, as the WHO's own COVID-19 Technology Access Pool initiative encourages, or waiving intellectual property rights, as South Africa and India have suggested, we need to pull out all the stops."

31. The message from WHO is "Pandemic is not over". On 5 May 2023, more than three years into the pandemic, the WHO Emergency Committee on COVID-19 recommended to the Director-General, who accepted the recommendation, that given the disease was by now well-established and ongoing, it no longer fit the definition of a PHEIC. This does not mean the pandemic itself is over, but the global emergency it has caused is, for now. A Review Committee is developing long-term, standing recommendations for countries on how to manage COVID-19 on an ongoing basis.

32. She highlighted that WHO promotes and integrated approach for health: Prevention, detection and treatment are essential pillars and she provided examples with reasons why none of these pillars should be left behind to get find real solutions. Access to diagnostics and therapeutics remain a

challenge and she mentioned the WHO Living Guideline from 13 January 2023 that responds to emerging evidence on existing and new COVID-19 treatments, where in many cases the challenges related to availability and affordability remain.

33. Countries with manufacturing capacities are excluded from the geographical scope of existing licenses and affordable prices. She also presented a joint briefing recently published with UNITAID on improving access to novel COVID-19 treatments and how member States can navigate on interfaces between public health and intellectual property. https://www.who.int/publications/m/item/improving-accessto-novel-covid-19treatments.

34. In relation to the implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), she informed that the World Health Assembly decided 75(14) to extend the time frame for the implementation from 2022 to 2030. https://apps.who.int/gb/ebwha/pdf_files/WHA75-REC1/A75_REC1_Interactive_en.pdf#page=1. WHO member States agreed on the continuing relevance of the GSPA-PHI recommendations, reenforced by country experiences during the COVID-19 pandemic. The eight elements of the GSPA-PHI remain valid and well connected with the current discussions on a pandemic accord in WHO. https://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

35. Finally, she indicated that WHO-WIPO-WTO DGs agreed recently that Members should fully implement at domestic level the wide range of available options to secure timely and equitable access to health technologies. Trilateral cooperation should address these challenges by intensifying activities to provide support to Members, including through joint technical seminars for delegates handling health, trade and IP issues in Geneva.

2.3 Mr Edward Kwakwa, Assistant Director General, Global Challenges and Partnerships Sector, World Intellectual Property Organization (WIPO)

36. Edward Kwakwa is Assistant Director General, Global Challenges and Partnerships Sector, World Intellectual Property Organization (WIPO) in Geneva. He served as General Counsel at WIPO from 2004 until September 2016. Kwakwa holds an LL.B. degree from the University of Ghana, an LL.M. from Queen's University in Canada, and an LL.M. and a J.S.D. from Yale Law School in the U.S.A.

37. Before joining WIPO, Kwakwa practiced with the law firm of O'Melveny and Myers in Washington, D.C., worked as International Legal Adviser at the Commission on Global Governance in Geneva, as Senior Legal Adviser at the Office of the United Nations High Commissioner for Refugees (UNHCR), and as Legal Affairs Officer at the World Trade Organization (WTO).

2.4 Ms Amy Dietterich, Director, Global Challenges Division, World Intellectual Property Organization (WIPO)

38. Marion "Amy" Dietterich is the Director of the Global Challenges Division at the World Intellectual Property Organization (WIPO). In this role, she covers Intellectual Property (IP)-related global policy issues in the areas of Global Health, Climate Change, and Food Security.

39. Amy has twenty years of experience in the fields of public health, water & sanitation, and governance, spanning community-based organizations, international NGOs, global health partnerships, and United Nations institutions. Prior to joining WIPO in 2018, she worked with the International Federation of Red Cross and Red Crescent Societies (IFRC) to ensure stronger community engagement in health systems governance and service delivery, and with the Parliamentary Network on the World Bank and IMF to support parliamentary oversight of development cooperation and financing.

40. Ms. Dietterich earned her academic qualifications in Public Health, Biology, and French from the London School of Hygiene and Tropical Medicine (LSHTM) and Bucknell University in 2005 and 2000 respectively.

2.4.1 Summary of WIPO Intervention

41. WIPO continues to operationalize its commitment to universal, equitable access to COVID-19 vaccines, therapeutics, and diagnostics. WIPO sees intellectual property (IP) broadly as a powerful tool to achieve this objective. WIPO acknowledges the challenges in ensuring timely and equitable access to COVID-19 vaccines, therapeutics and diagnostics, however access and innovation determinants are multi-faceted reflecting the complex health, IP and trade ecosystem.[1] Factors impacting on innovation and access include regulatory hurdles, market demand, trade restrictions, supply chain disruptions, manufacturing capacity, health system resilience, and vaccine misinformation. It is crucial to use empirical evidence to understand the role of IP, and its relationship with other factors, in achieving public health objectives. Through the WIPO COVID-19 package and the WHO-WIPO-WTO Trilateral Cooperation, WIPO gathered evidence relevant to consideration of access and innovation determinants in relation to COVID-19 vaccines, therapeutics and diagnostics.

42. Drawing on this evidence and its experiences with member States and stakeholders such as the Medicines Patent Pool, WIPO presented three general findings to the Thematic Session on Paragraph 8 of the Ministerial Decision on the TRIPS Agreement: (1) IP tools may have different applications depending on the medical technology[2], (2) IP supported innovation and production of COVID-19 vaccines[3] and therapeutics by enabling funding, R&D collaboration agreements, purchasing and licensing[4], and, (3) IP is an enabler for access by supporting tailored licensing practices including public-health focused voluntary licensing, which may include clauses for alternate dispute resolution.[5] WIPO outlined its experience of the important role of technical assistance in developing domestic IP frameworks that are equipped to deliver public health-related policy objectives.[6] In this regard, WIPO has provided support to its member States for the development of innovation ecosystems and skills and capacity related to IP management and technology transfer for life sciences, for example. WIPO has also provided legislative assistance and advice including on the use of TRIPS flexibilities for public health. Future work by WIPO may support ongoing discussions on the role of the IP framework in supporting equitable access, including studies on voluntary licensing, the management of IP in publicly-funded R&D and the interplay between patents and trade secrets throughout the innovation process and product value chain in the field of medical technologies.[7]

43. WIPO stands ready to provide further facts, evidence and experience as requested by TRIPS Council Members in their deliberation on relevant matters.

[1] WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade, 2nd Edition (2020)

[2] WHO, WIPO, WTO, An Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic, 2nd Edition (2023)

[3] R.M. Conti, The Determinants of COVID-19 Vaccine Development Success (2021) and CEPR, EPO, KULeuven USPTO and WIPO, Global Innovation Responses to COVID-19 (2022)

[4] WIPO, COVID-19-related vaccines and therapeutics: Preliminary insights on related patenting activity during the pandemic (2022) and WIPO, COVID-19 vaccines and therapeutics: Insights into related patenting activity throughout the pandemic (2023)

[5] WIPO, WIPO Alternative Dispute Options for Life Science Disputes and Resolution, (2022)

[6] IP/C/R/TC/WIPO/4 Technical Cooperation Activities: Information from other Intergovernmental Organizations World Intellectual Property Organization (WIPO) (2023)

[7] WIPO discussion paper on the interplay between patents and trade secrets and how they interact with each other throughout the innovation process and product value chain in the field of medical technologies at the policy, law and practical levels to be launched on October 18, 2023.

2.5 Mr Nirmalya Syam, Senior Program Officer, The South Centre

44. Mr Syam has more than 10 years' experience on issues related to IPRs and access to medicines. He holds a bachelor's degree in law (LL.B) from the University of Calcutta and a master's degree (M.Phil.) in international law from Jawaharlal Nehru University, New Delhi.

2.5.1 Summary of Intervention

45. The discussion on extension of the MC12 decision should be seen in the context of the scope of the decision as applicable currently to vaccines, in terms of objective and duration. Paragraph 1 of the Decision makes it clear that the objective of the decision is to allow eligible Members to limit the rights provided for under article 28.1 of the TRIPS Agreement *to the extent necessary* to address the pandemic. In terms of duration, the Decision clearly states that it is for a duration of 5 years.

46. This implies that at the time of adopting this Decision, the negotiators had clearly envisaged that it may be necessary to allow eligible Members to limit the patent rights provided under article 28.1 for a duration of 5 years. Moreover, the Decision would also be applicable as long as it is force, to not only an existing COVID-19 pandemic but also to the potential re-emergence of the pandemic because of new variants. This approach is logical given the ebb and flow of the COVID-19 pandemic with emergence of new variants that spread rapidly from time to time.

47. The WHO also clearly recognizes that the virus which causes COVID-19, SaRS CoV 2, is a pathogen of pandemic potential, and new variants continue to emerge. In a span of 1 month from July-August 2023 over 1.4 million new COVID-19 cases and over 1800 deaths were reported to the WHO. According to the WHO, due to reduction in testing and reporting globally, the reported cases do not accurately reflect currently prevalent infection rates.

48. In August 2023 the WHO classified a new variant of COVID-19 - EG.5 - as a variant of interest, implying that countries should monitor this strain more closely because of mutations that could make it more contagious or severe. Recently the US CDC has authorized broad use of updated vaccines to target new variants.

49. What are the facts relating to patenting of COVID-19 therapeutics? According to the WIPO patent landscape report on COVID-19 related vaccines and therapeutics, patent applications on COVID-19 therapeutics are 4 times higher than vaccine patent applications. While voluntary licenses may enable access where the patentee consents to grant such license, often voluntary licenses have restrictive conditions and are limited in geographical scope, making them a sub-optimal solution for rapid access in fast spreading global pandemic.

50. This is exemplified by the limitation on access to nirmatrelvir-ritonavir (Paxlovid) - a drug that is recommended by WHO for patients with non-severe illness with highest risk of hospitalization. WHO has admitted that obstacles to access to this drug due to cost and availability could be formidable in low and middle income countries. Nevertheless, patent applications on the drug have been filed in more than 160 countries, with a broad range of claims on compounds, specific compositions (including with ritonavir) and use of the drug for treatment of COVID-19. At the same time, many developing countries (e.g., most Latin American countries) have been excluded from the voluntary license on the drug.

51. In view of the above circumstantial evidence, it is imperative that the TRIPS Decision is extended to therapeutics and diagnostics.

2.6 Mr Charles Gore, Executive Director, Medicines Patent Pool (MPP)

52. Charles Gore is the Executive Director of the Medicines Patent Pool (MPP). Following a career in patient representation and public health advocacy, he took up the post in July 2018 to guide MPP in its expansion into new areas covered by the WHO Essential Medicines List.

53. He was diagnosed with hepatitis C in 1995 and cirrhosis in 1998. In 2000 he set up The Hepatitis C Trust in the UK which he ran for 18 years. In 2002 he was treated and cured of the virus. He helped create the European Liver Patients Association and was its first President in 2004. In 2007 he established the World Hepatitis Alliance and was President until December 2017. As a result of advocacy by the Alliance, WHO adopted successive viral hepatitis resolutions in 2010, 2014 and 2016, culminating in endorsement of the goal of eliminating hepatitis B and C by 2030.

54. Charles has sat on a number of national and international advisory bodies including the WHO Director-General's HIV and Hepatitis STAC, various WHO regional STACs and up till 2019 was a member of all the WHO guideline development groups on testing and treating viral hepatitis.

2.6.1 Summary of Intervention

55. The Medicines Patent Pool (MPP) is a public health organization established by Unitaid in 2010 to accelerate access to innovative medicines and new health technologies in Low- and Middle-Income Countries (LMICs). MPP's mandate was initially focused on HIV, but its work has progressively expanded to include hepatitis C, tuberculosis, non-communicable diseases, COVID-19, and countermeasures to pandemics and other international health emergencies. See MPP's website for details about MPP's work and impact.

56. MPP operates through the voluntary licensing of intellectual property rights and technology transfer, based on the principles of public health, transparency, and market non-exclusivity. The process includes negotiating of licences on innovative medicines and health technologies with patent holders; sub-licensing the products to multiple manufacturers to ensure availability and affordability in LMICs through competition; facilitating technology transfer and providing support to sub-licensees on product development and regulatory filings; managing the implementation of sub-license agreements to ensure adherence to license terms; and supporting market entry and uptake. See this publication for additional information on MPP's approach.

57. During the COVID-19 pandemic, MPP secured licenses for three patent-protected COVID-19 therapeutics – molnupiravir, nirmatrelvir/ritonavir, and ensitrelvir from Merck, Sharp & Dohme (MSD), Pfizer, and Shionogi & Co., Ltd respectively. It signed sublicence agreements with generic manufacturers based in 16 countries across all continents: 27 companies to manufacture and supply molnupiravir in 106 LMICs; 36 companies for nirmatrelvir in 95 LMICs; and seven companies for ensitrelvir in 117 LMICs. The countries covered account for 56% of the world population. Prior WHO prequalification (PQ) was required for the sale of licensed products. All three products were royalty free during the period that COVID-19 was classified as a Public Health Emergency of International Concern (PHEIC). See here for a chronology of key activities and access the license agreements through this link.

58. **Lessons learnt:**

a. MPP-licensed COVID-19 therapeutics reached regulatory approval in record time. It took 1 year as against 3-4 years in pre-pandemic times. Yet, opportunities exist to further shorten timelines in future pandemics:

   i. Relevant access provisions in funding agreements on research and development (R&D) could push licensing and technology transfer to happen sooner.

   ii. Pre-selection of manufacturers, building on the existing network of manufacturers established in the context of COVID-19 as recently proposed by the G20 health ministers, removes the need for the process during a crisis.

   iii. The use of pre-agreed licence templates could reduce negotiating time.

   iv. Possible collaborative mechanism that could enable the sharing of starting materials and RLDs with generics even before innovator products are proven to be effective could be explored.

b. MPP-facilitated provision of innovator's technology transfer package permitted accelerated product development for manufacturers that needed it.

c. Although MPP's criteria enabled the selection of manufacturers from a broad geography, very few applications for licenses were received from certain regions of the world.

   i. To ensure more diversified manufacturing, stakeholders would need to provide necessary support to local/regional manufacturers from regions with less developed capacities.

d. Demand projections for therapeutics did not materialize and several sublicensees terminated their agreement with MPP or put development on hold.

   i. It would be critical to de-risk early development and manufacturing of generics in future health emergencies to stimulate manufacturer interest and investment.

e. Conditional waivers on regulatory requirements for molnupiravir enabled earlier access in India, before WHO-PQ

   i. Relevant global public health community could explore complementary regulatory pathways allowing for speed in a pandemic context while not compromising quality.

3 CIVIL SOCIETY ORGANIZATIONS

3.1 Mr Tahir Amin, Initiative for Medicines, Access & Knowledge ("I-MAK")

59. Tahir Amin, LL.B., Dip. LP., is a founder and executive director of the Initiative for Medicines, Access & Knowledge (I-MAK), a non-profit organisation working to address structural inequities in how medicines are developed and distributed. He has over 25 years of experience in intellectual property (IP) law, during which he has practised with two of the leading IP law firms in the United Kingdom and served as IP Counsel for multinational corporations. His work focuses on re-shaping IP laws and the related global political economy to better serve the public interest, by changing the structural power dynamics that allow health and economic inequities to persist.

60. He is a former Harvard Medical School Fellow in the Department of Global Health & Social Medicine. Amin has served as legal advisor/consultant to many international groups, including the European Patent Office, UNITAID and World Health Organization, and has testified before the U.S. Congress on intellectual property and unsustainable drug prices.

3.1.1 Summary of Intervention

61. The facts, evidence and experiences relevant to the production of, and access to vaccines, therapeutics and diagnostics and the case for extending the decision to such products need to be considered in the context of the history of how the WTO TRIPS Agreement was imposed on many of today's Member states that previously did not have IP regimes, and the impact it has had over the last 28 years when it comes to the lack of access to medicines and technology transfer. Without such context, the framing of the current debate is misleading and allows the Global North and its pharmaceutical manufacturers that hold the IP rights on many COVID-19 technologies to control the narrative and set the terms of the debate.

62. Even though the TRIPS Agreement provides Members with flexibilities to manage IP issues in public health emergencies, opposing political pressure from the United States, Europe and other Global North nations, as well as lobbying from their pharmaceutical manufacturers, has created a chilling effect. As a result, many countries that would benefit from utilising such flexibilities have refrained from doing so. Alongside the imposition of TRIPS, these constant trade threats have squeezed the sovereignty and policy space within which Global South members can serve their national needs – something wealthy Global North countries never had to face as they developed technologically.

63. This squeezing of the policy space through TRIPS and other free trade agreements has, by design, led to an increasing reliance on the voluntary measures of IP holders. These voluntary measures, such as licenses, not only undermine the flexibilities a country may want to use or have tried to use, they also manage the competition by heavily restricting the territories where Global South manufacturers can sell their products. For example, the voluntary licenses for Paxlovid that Pfizer entered into have excluded many middle and upper- middle income countries. This will be repeated for other products going forward. As such, voluntary measures around IP offered by pharmaceutical companies are not a solution that meets the global needs of COVID-19 or pandemic preparedness.

64. Finally, the argument that the proposal to suspend IP for therapeutics and diagnostics is outdated due to there no longer being any demand, misrepresents the current situation in Global South countries. With only approximately 20% of people in these nations fully vaccinated, treatments are the only way to limit hospitalisations, death and economic losses. Demand is very much linked to availability and affordability of treatments and diagnostics. The assessment of unmet need should reflect people's actual needs – based on infection rates and the target populations that would be treated – were testing and affordable treatments readily available.

65. In light of the COVID-19 treatments in the pipeline and the experiences of the past three years, it should be an open and shut case to extend the Ministerial Decision in order to get ahead of the limited supplies that will be swallowed up by the wealthier nations should there be an increase in demand due to another outbreak. In fact, given the manufacturing capability that exists in many Global South countries to produce therapeutics and diagnostics, the Ministerial Decision should have already been extended at the outset. Despite this undue delay, a decision now would not only meet the current moment, it would help prepare for future equitable pandemic preparedness.

3.2 Dr Ellen 't Hoen, Director, Medicines Law and Policy

66. Ellen 't Hoen (1960) is the director of Medicines Law & Policy (ML&P), a group of legal and policy experts offering advice to international organizations, NGOs and governments. ML&P regularly publishes briefing documents and commentaries on legal and policy developments in the field of medicines. ML&P also maintains apublic database of the use of TRIPS flexibilities for public health purposes. She is the founder and former executive director of the Medicines Patent Pool. She is also a Global Health Law Fellow at the law faculty of the University of Groningen.

67. She has published widely and is the author of several books. In 2017 she received the *Prix Prescrire* for her book *"Private Patents and Public Health: Changing intellectual property rules for public health."* In 2020, she was appointed Officer of the Order of Oranje-Nassau, a Dutch royal award given in recognition of her work on access to medicines. She has a master's degree in law from the University of Amsterdam and a PhD from the University of Groningen.

3.2.1 Summary of Intervention

68. Discussions at the World Trade Organization (WTO) on the TRIPS Agreement and COVID-19-19 have been taking place since India and South Africa tabled a proposal for a pandemic waiver in October 2020. On 17 June 2022, the Ministerial Decision on the TRIPS Agreement was adopted. The Decision is modest, limited to vaccines for one disease, limited in time, and mostly reiterates existing Members' rights to use TRIPS flexibilities. Paragraph 3(b) of the Decision is the one bright light, waiving the requirement that production under a compulsory licence (CL) must be predominantly for the domestic market without having to resort to TRIPS Article 31*bis*. See comments here.

69. Medicines Law & Policy (ML&P) has tracked the use of TRIPS flexibilities for health purposes since the adoption of the Doha Declaration on TRIPS and Public Health in 2001. Lessons from ML&P's TRIPS Flexibilities Databasemay be useful in the TRIPS Council deliberations. They include that **TRIPS Flexibilities have been more widely used than generally assumed**. The database currently documents 172 instances, of which 122 concern CLs. CLs have **proven to be useful in a**

pandemic. Since 2020, 10 instances of CLs concerned products needed to prevent or treat COVID-19. **High-income countries also use TRIPS flexibilities**. It would therefore be sensible for them to opt back into the Article 31(bis) mechanism. Further, CLs can be useful **for countries excluded from the Medicines Patent Pool licences**. For details see: Presentation slides and submission to the USITC.

70. The Decision focuses on CLs. CLs can be effective to secure access to certain technologies for which access to patents alone is sufficient, such as small molecule medicines and certain diagnostic tools. But a CL may not be sufficient for more complex technologies such as mRNA vaccines, monoclonal antibodies and other biologics or complex diagnostics which require access to trade secrets/knowhow that remain outside the reach of a CL.

71. Ironically, the Decision covers only vaccines, for which it is least useful, and excludes technologies such as therapeutics and diagnostics that would likely benefit from its provisions. The answer to the question whether the Decision should be extended to therapeutics and diagnostics is therefore an easy one: it would be the most logical step to take.

72. Access to trade secrets/knowhow may be essential for certain technologies. The issue of trade secrets is not addressed in the Decision. It is also not addressed in any of the drafts of the WHO Pandemic Accord that are publicly available. It would be important to provide for measures to ensure the possibility to compel the sharing of trade secrets. This can be done in a manner compliant with the TRIPS Agreement and operationalised in WHO Pandemic Accord. Here is a proposal for a trade secrets provision.

73. Regardless of decisions taken at the WTO or WHO, the efficacy of TRIPS flexibilities generally depends on implementation in national and regional law. These include, easy to use compulsory licensing/ government use provisions as well as waivers of data exclusivity to enable registration of products produced under a CL. The European Commission has embarked on such implementation for the EU.

74. Finally, compulsory measures may not be necessary where voluntary measures are effective. However, considering the reluctance by certain rights holders to enter into voluntary agreements during the COVID-19 pandemic it seems prudent to ensure effective non-voluntary mechanisms are in place.

3.3 Ms Sangeeta Shashikant, Third World Network, Malaysia

75. Sangeeta Shashikant is the coordinator of Third World Network's Development and IP programme. She has Bachelor of Laws (University of Malaya); Masters Degree in Public International Law (University College London), and has practiced as an advocate and solicitor with the Malaysian Bar. She has 19 years of research and advocacy experience in intellectual property and public policy matters in particular access to medicines. She has collaborated with regional and international organizations and advised governments on intellectual property and access to medicines. She has authored and contributed towards numerous publications including "Negotiating a 'Development Agenda' for the World Intellectual Property Organisation"; "Intellectual Property and Technology Transfer Issues in the Context of Climate Change"; "The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines" and the "Pandemic Preparedness: Creating a Fair and Equitable Influenza Virus and Benefit Sharing System".

3.3.1 Summary of Intervention

76. Experts warn "there remains uncertainty about how the virus will behave, the path of its mutations and COVID-19's long-term effects" adding that "the unknowns could have public-health

consequences in the years ahead".[8] Recognizing this, the **WTO must proactively take measures to safeguard public health interests in the face of such a formidable adversary**.[9]

77. Throughout the pandemic, developing countries struggled to obtain timely affordable access to needed medical tools. Shortages and prohibitively high prices were seen across all medical products including diagnostics and therapeutics recommended by WHO[10], a primary factor driving transmission of COVID-19.

78. A key conclusion reached by expert reviews of COVID-19 response is that **manufacturing is too concentrated, the need for diversified production, expanding supply options** to meet the needs of developing countries.[11]

79. **Voluntary licenses (VL) are inadequate and are not a substitute for compulsory license (CL)**. By its very nature, VLs are not guaranteed. VL terms are determined by the patent holder, often delay access, are anti-competitive, as well as exclude many developing countries from being supplied by the licensees.[12] For e.g. the MPP- Pfizer Paxlovid VL prohibits the licensee from supplying many developing countries including most Latin American countries even as patents in all of these countries will last until at least 2041.[13] This same VL contains troubling conditions preventing R&D on combination regimens, co- formulation, and even co-packaging that may be helpful to treat COVID-19.[14]

80. **VLs also do not provide the prompt affordable access that is needed in times of health emergency**. It generally takes more than a year before affordable generics enters the market. Meanwhile, there is no access to affordable treatment. Generic supply only became available in December 2022, one year after the MPP- Pfizer VL was signed, and that as well only from one generic company to supply a limited number of countries.

81. In contrast, CLs allow governments to take immediate action to facilitate access, and has demonstrated to improve timely access.[15] Extension of the TRIPS Decision will make available to developing countries an important flexibility to facilitate timely affordable access to therapeutics and diagnostics. In particular, **waiving the limitation on exports contained in Article 31(f) of TRIPS will allow manufacturers to achieve economies of scale, and to supply developing countries with insufficient manufacturing capacity** with much needed affordable therapeutics and diagnostics.

82. **Claims that CLs discourage R&D and profits are baseless**. In fact, CLs played a significant role in COVID-19 response as several countries enacted progressive CL provisions to make it easier to use CL, while others have actually issued CL to address shortages of COVID-19 therapeutics. These instances have not adversely impacted pharmaceutical profits or R&D as evidenced by the thriving R&D pipeline for COVID-19 therapeutics and record-breaking profits of the pharmaceutical companies.

83. **The Decision should apply to existing and future COVID-19 diagnostics and therapeutics**. WHO itself maintains a "Therapeutics and COVID-19 living guideline" with recommendations that changes multiple times every year as new variants circulate and evidence emerges. National treatment guidelines may follow WHO or may vary.

84. **Concerns about extending the TRIPS Decision are unjustified**. The Decision is limited, narrow in scope as in COVID-19, time-bound as well as only applicable to 'developing countries". It

[8] https://www.wsj.com/articles/what-do-we-actually-know-about-covid-19-not-enough-ec1dcafe
[9] See Articles 7 and 8 of TRIPS Agreement
[10] See for e.g. https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1
[11] https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics?utm_source=substack&utm_medium=email
[12] See https://msfaccess.org/voluntary-licenses-access-medicines
[13] https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments
[14] See https://healthgap.org/pfizerletter/ and https://infojustice.org/archives/44914
[15] See Country experiences in using TRIPS safeguards: Part 1, WHO at Country-experiences-TRIPS-Part1.pdf (who.int)

does not waive all IP, as often erroneously claimed by pharmaceutical companies. Nor does it not affect the sales of pharmaceutical companies which tends to be in developed country markets.

85. Further resources:

a. See TWN's Detailed Submissions to the USITC Investigation rebutting concerns and arguments raised by those opposing extension of the TRIPS Decision to diagnostics and therapeutics. https://www.twn.my/title2/intellectual_property/TWNSubmissionstoUSITC.htm

b. See Voluntary Licenses and Access to Medicines, MSF Technical Briefing Document available at https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf

3.4 Mr James Love, Director, Knowledge Ecology International (KEI), United States of America

86. James Love is Director of Knowledge Ecology International. His training is in economics and finance, and work focuses on the production, management and access to knowledge resources, as well as aspects of competition policy.

87. The current focus is on the financing of research and development, intellectual property rights, prices for and access to new drugs, vaccines and other medical technologies, as well as related topics for other knowledge goods, including data, software, other information protected by copyright or related rights, and proposals to expand the production of knowledge as a public good. James Love holds a Master of Public Administration from Harvard University's Kennedy School of Government and a Master in Public Affairs from Princeton's Woodrow Wilson School of Public and International Affairs.

3.4.1 Summary of Intervention

88. The June 17, 2022 decision on the TRIPS Agreement and COVID-19 vaccines was very narrow. It was a temporary, conditional waiver of Article 31.f of the TRIPS Agreement, which provided additional but limited flexibility on exports under a non-voluntary authorization to use patented inventions. The decision only applied to one virus, only to vaccines, is temporary, and attached conditions.

89. In the decision, the WTO limited eligibility to developing countries, for both importing and exporting, subject to further opt-outs. This condition limits the ability of vaccine manufacturers to benefit from economies of scale and importers' ability to engage with many potential suppliers. There were some clarifications issued regarding the decision, but in the nature of restating existing flexibilities in the TRIPS Agreement. The decision did not address IP or investment provisions in bilateral or plurilateral agreements, nor did it deal with access to know-how protected in Article 39.2 of TRIPS. The decision has not been used by WTO Members.

90. Despite its limitations, the decision does have some potential value, particularly for therapeutics, where the regulatory pathway is less challenging than is the case for vaccines, and where there is a robust and promising pipeline, including both new and repurposed drugs. Negotiators should also consider that for example, in HIV, HCV, and other diseases often combination treatments are more effective. There can be patent challenges even for testing combination products given the terms of some voluntary licensing agreements, such as the Pfizer license for Paxlovid.

91. Negotiators should also reflect on the contrasts between the narrow and limited 17 June 2022 decision and what measures high-income countries enacted in their domestic legislation in 2020 and 2021, and are continuing to do today. In the Spring of 2020, Canada and Germany created very broad exceptions to patent rights for emergencies, exceptions that were not limited to vaccines. The United States of America issued dozens of contracts with FAR 52.227-1 authorization and consent clauses, giving Merck, Sanofi, Lilly, Moderna, Novavax, Siemens, Philips, Quidel, and others the

freedom to use any US government-issued patents, to make and sell a very diverse set of countermeasures.

92. Today the European Commission has proposed legislation for exceptions to intellectual property rights that include multi-country compulsory licenses, exceptions to rights in test data, a cap on royalties of four percent of the generic price and the ability to compel the sharing of manufacturing know-how or other complementary measures. The EU's proposed exceptions will be permanent, not limited to particular diseases or viruses, and will apply to all countermeasures.

93. As an alternative to extending the extremely limited 17 June 2022 decision, WTO Members should consider new exceptions and other measures more in line with the ambitions of the current European Commission's proposal on compulsory licensing.

94. Links and references:

a. COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006.

b. FAR 52.227-1 Authorization and Consent. https://www.acquisition.gov/far/52.227-1

c. German Government Plans Possibilities to Limit Patents In View of Corona Pandemic Thomas Musmann (Rospatt Osten Pross)/March 24, 2020. https://patentblog.kluweriplaw.com/2020/03/24/german-government-plans-possibilities-to-limit-patents-in-view-of-corona-pandemic/

d. Governmental Use of Patented Inventions during a Pandemic: A Global Survey, April 16, 2020. Norton Rose Fullbright. https://www.nortonrosefulbright.com/-/media/files/nrf/nrfweb/knowledge-pdfs/governmental-use-of-patented-inventions-during-a-pandemic.pdf

e. KEI Briefing Note 2022:3: Selected differences between Article 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions.

f. KEI Research Note 2023:2. Examples of US agency uses of FAR 52.227-1.

g. BIO COVID-19 Therapeutic Development Tracker, https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

3.5 Ms Fatima Hassan, Health Justice Initiative, South Africa

95. Fatima Hassan is a human rights lawyer and social justice activist and the founder of the HJI. She is the recipient of the 2022 Calgary Peace Prize and is a 2023 Echoing Green Fellow. She has dedicated her professional life to defending and promoting human rights in South Africa, especially in the field of HIV/AIDS. She has worked as a Ministerial Advisor, and in philanthropy as well as the not-for-profit sector.

96. She has served on several NFP boards and is the recipient of several awards, and often writes for local and international media publications. She is currently a Board member of Global Witness and serves on the Advisory Group for Resolve to Save Lives.

3.5.1 Summary of Intervention

97. The world has lived through vaccine nationalism since 2020. Hoarding of life saving vaccine supplies was accompanied by knowledge hoarding and racism. The WHO estimates at least 14.9 million direct and indirect deaths from COVID-19 in 2020-2021. But right now, the tests and treatments to track and manage COVID-19 infections are out of reach for many of us in the Global South. At the beginning of COVID-19, we were promised solidarity. But, when it mattered the most, we were not beneficiaries of that solidarity. What we experienced was pernicious bullying by

manufacturers and delayed negotiations at the WTO. Even the SA President likened our terrible experience to being a 'beggar'.

98. And the reason we were 'beggars' is simple: The market failed us. It was unregulated and used its power to distort equity norms while benefiting from public funding and trial participation of our people. That, coupled with no restrictions on excessive IP protection during a global health crisis and the absence of a timely and time bound *IP waiver* meant that we were left with concentrated manufacturing; high prices, refusal of broad knowledge sharing; limited generic entrants; bullying, one-sided demands including contractual secrecy and minimal transparency in respect of material elements of pandemic contracting.

99. This cannot be repeated: There is a pipeline of treatments for COVID-19, dozens of which are in late-stage clinical trials and many could even be more effective than Paxlovid. But we are unlikely to benefit in a timely and affordable manner. We cannot access affordable and widespread testing kits including test consumables either, because decisions regarding access, timing and price are not prioritised and manufacturing (test consumables especially) remain highly concentrated with very few countries being able to alter that on their own. That is the crux of the issue here: the drugs and treatments in the pipeline. Without easing limits to enable wider production and export of generic versions and easier access we cannot manage to contain COVID-19, treat it, or even diagnose it in an optimal manner.

100. I live in one of the most unequal countries in the world, with an apartheid based, two-tier, unequal health system. Yet, SA is often regarded as 'middle income', a classification that often excludes SA from licensing deals for our *entire* health sector. For about 2 years, we challenged the secrecy that companies demanded of SA and others elsewhere in the procurement of COVID-19 vaccines (paid for by public funds). On 17 August 2023 the HJI won an important, precedent setting case when the High Court ordered the public and unredacted disclosure of all vaccine procurement contracts. When we initiated the case, we were told that even the contracting parties' details were a ''secret''. Our analysis of the four unredacted contracts show one-sided, onerous terms and conditions as well as worrying, 'bullying' behaviour from certain pharmaceutical companies. Since the disclosure, government officials have publicly admitted that they were 'bullied' in 'take it or leave it' negotiations. The now opened contracts indeed tell a disturbing story.

101. The market has let us down before: Alone, it cannot secure equity; timely access; affordability. We need proper countermeasures. We therefore urge Members to make a final decision on extending Para 8 for therapeutics and diagnostics. Further delays will risk making the WTO increasingly unhelpful and irrelevant for people in the Global South.

3.6 Ms Jennifer Brant, Director, Innovation Council, Switzerland

102. Jennifer Brant runs a consulting business called Innovation Insights, based in Geneva, Switzerland. She works with companies, NGOs, governments, and international organizations on policy issues related to intellectual property (IP) and innovation, technology transfer, international trade, and public health. She is committed to gender parity, leading global advocacy campaigns to tackle IP diversity gaps and serving as member of the International Gender Champion network.

103. As part of her consulting work, Jen leads a cross-sectoral innovators' group called Innovation Council. This global organization connects policymakers to organizations that are bringing technology solutions to society. Jennifer is trained in international law, development, and economics. She has authored and co-authored many reports and articles, including Unprecedented (2022), which analyses the role of intellectual property in the COVID-19 innovation response, and Biomanufacturing Resilience (2023), which endorses action by governments and companies to reinforce biologics supply chains.

3.6.1 Summary of Intervention

104. **Jennifer Brant** presented recent interview-based research projects, the findings of which were published in reports entitled *Unprecedented* (2021, co-authored with Prof. Mark Schultz),

Making Biologics (2022), and *Biomanufacturing Resilience* (2023). She noted that the topic of the Special Session – extension of the 2022 TRIPS decision – is really about ensuring adequate health products supply and extending biomanufacturing capacity, for health security. The three reports touch on these issues.

105. As documented in ***Unprecedented***, IP played an enabling role at all stages of the COVID-19 innovation response:

106. *Development of relevant background IP*. Existing technologies and know-how were quickly leveraged for the pandemic response. These were the result of past R&D, enabled by IP within the biopharma innovation ecosystem. In some cases, public research outcomes were moving to market via hand-off to companies. COVID technologies were "overnight successes years in the making".

a. *Development of COVID technologies.* Collaboration was crucial to developing and repurposing COVID technologies in record time, and for developing and optimizing the manufacturing processes for them. Nobody could develop and deliver products at the scale needed on their own. IP made it less risky to work with others.

b. *Scaling manufacturing for a pandemic response.* Collaboration was essential to establish the necessary global manufacturing networks; in-house capacity was inadequate for a pandemic response. Capable partners were identified (not an easy task) then innovators shared technology and know-how with them, also helping them to set up supply chains and clear regulatory hurdles.

c. *Investments for the pandemic response*. IP enabled investments in a highly uncertain environment. Companies produced at risk, redirected resources to COVID-19, made commitments to suppliers, set up voluntary licensing arrangements, and upgraded manufacturing capacity – even before receiving regulatory approval. Government action helped to de-risk such activities.

107. Industry leaders interviewed for *Unprecedented* said that, had there not been IP protection, their companies would have supported the pandemic response but with less collaboration; sharing tech and know-how would have been unduly risky. This would have resulted in a slower, and perhaps very different, pandemic response. Without collaboration, manufacturing at the scale needed to fight COVID-19 would not have been possible.

108. By mid-2021 there were already 300 vaccine partnerships (more than 230 involving tech transfer). Technology and know-how *were* shared during the pandemic response. IP was managed to maximize global supply.

109. ***Making Biologics*** and ***Biomanufacturing Resilience***, focus on promising practices for building resilient biomanufacturing capacity globally.

110. *Making Biologics* identifies four key pathways for building capacity, based on historic evidence and insights from biologics industry leaders. All the pathways require collaboration and tech transfer, along with legally certain business environments that include IP protection. One approach for building vaccine production capacity is "backwards integration"; companies start with activities like fill and finish, then work side-by-side with tech transfer partners over many years to gain expertise and move up the value chain, ultimately performing R&D and activities like bulk antigen production. A backwards integration success story is Biovac (South Africa).

111. *Biomanufacturing Resilience* suggests actions for governments and companies to reinforce biopharma supply chains and thus improve healthcare delivery and pandemic preparedness. The report highlights the significant, IP-driven innovation in the upstream part of these value chains, where companies deliver manufacturing equipment, consumables, and services like facility design and workforce training. Such innovation is facilitating the establishment of efficient, flexible biopharma production in more regions. Upstream companies are often global tech transfer partners for regional manufacturers, with IP facilitating technology and knowledge exchange. The report suggests that governments contribute to resilience by tackling trade barriers, improving regulatory systems and regulatory coordination, and providing financial and other support for local producers.

It cites the range of factors – including workforce, procurement and demand, and access to raw materials – that influence success when extending biomanufacturing capacity.

112. Conclusions:

a. IP played an important enabling role in the COVID-19 response and would undoubtedly support rapid pandemic innovation in the future as well.

b. IP continues to facilitate tech transfer and other collaborations that build global biomanufacturing capacity across regions, contributing to health security.

c. Work at the WTO is needed to ensure trade policies align with public health goals; for example, export restraints were problematic during the pandemic and their use should be disciplined.

113. Jennifer spoke in her personal capacity.

4 BUSINESS

4.1 Dr Julia Spencer, AVP, Global Multilateral Engagement, Strategic Alliances, and International Relations, MerkSD

114. Julia Spencer serves as the lead for MSD's engagement with key global multilateral organizations, embassies, consulates, and missions in Washington, DC, New York, and Geneva, and is based in Geneva, Switzerland. She is also the focal point for and coordinates the company's participation in international industry trade associations and business groups and directs the multilateral and strategic alliance policy agenda focused on UN and international health, trade, and innovation organizations; G7/G20 and other global government alliances; health security organizations, and economic and financing institutions.

115. Prior to taking on this role, Julia served for 5 years as the Associate Vice President, Global Vaccines Public Policy, Partnerships, and Government Affairs, during which time she led global policy and advocacy efforts to expand and sustain access to MSD's vaccines and to strengthen the immunization systems delivering our products. Julia also served as the Chair of the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Vaccine Committee from 2021-2022.

116. Prior to joining Merck, Julia served for 15 years as a senior health official in the US Department of Health and Human Services (HHS). Her tenure at HHS included service as the Science Policy Director within the HHS Secretary's policy, planning, and evaluation office (ASPE) where she was responsible for policy analysis, coordination, planning, and legislative development focused on the HHS science agencies – Centers for Disease Control and Prevention, Food & Drug Administration, National Institutes of Health, and Office of the Assistant Secretary for Preparedness and Response.

117. During the decade she worked in ASPE, she led the creation of two 5-year HHS Strategic Plans, the first HHS Global Health Strategy and the Health System Measurement Project; developed a new HHS-wide evaluation capacity development initiative; and served on assignment in the US CDC Rwanda Office.

118. Prior to joining ASPE, Julia spent six years working on tobacco policy and substance abuse prevention efforts with HHS's Substance Abuse and Mental Health Services Administration. Julia holds a Doctor of Philosophy degree in public health, Master of Science in public health, and Bachelor's degrees in psychology and health education

4.1.1 Summary of Intervention

119. MSD is co-developer and manufacturer of molnupiravir, an investigational oral COVID-19 antiviral approved or authorized in more than 25 countries. In response to the COVID-19 pandemic,

MSD pursued R&D partnerships for 4 vaccine and treatment candidates, with substantial investments in manufacturing scale up in parallel to clinical development. Due to the high-risk nature of R&D, only one candidate, molnupiravir, advanced through early clinical development and MSD prioritized its rapid and equitable global access through a proactive, three-pronged strategy:

a. Manufacturing at scale during clinical development to ensure ample supply at authorization and entering into advance supply agreements with approximately 40 governments for rapid availability.

b. Engaging early with generic manufacturers to facilitate affordable access in low- and middle-income countries ("LMICs"), through bilateral voluntary licenses and with the Medicines Patent Pool, which issued sublicenses to 27 generic manufacturers from 10 countries. MSD's voluntary licensed territory and local manufacturing partnerships cover approximately 90% of the population in LMICs.

c. Reserving supply of MSD-manufactured product for global health programs. MSD made up to 5 million courses (more than 30% of our global supply) available to UNICEF and USAID at our best access price for distribution in 107 LMICs eligible for donor-supported funding; MSD donated 100,000 courses to Direct Relief for refugee programs.

120. Through MSD and our generic partners, more molnupiravir courses were available to LMICs (5.5M) during Q1 2022 than were supplied to high-income countries (5M). Despite MSD's efforts to ensure equitable molnupiravir access, procurement and distribution by governments and global health organizations have been slow or nonexistent for reasons unrelated to availability or price.

a. Global health organizations have distributed few courses. UNICEF had access to 3 million molnupiravir courses in January 2022, but shipped only 60,478 courses to just 10 countries through September 2023.

b. Outside of Asia-Pacific, demand from many governments and public health programs has been limited. Despite proactive MSD engagement, many governments, including Colombia, Mexico, South Africa, India, and Brazil, have not prioritized the purchase or recommended the use of COVID-19 antivirals as part of their pandemic response.

c. Governments have been slow to implement and scale-up test-and-treat programs to identify individuals eligible for oral antiviral treatment within 5 days of symptom onset and help raise awareness of antiviral availability among health care providers.

121. There have been no supply barriers for molnupiravir and no shortages of funding for therapeutic procurement through ACT-A partners. Extending the TRIPS waiver to COVID-19 therapeutics would not improve global access to this treatment. Rather, an extension may have an adverse impact on global health and access to medicines by weakening incentives for research-based companies to continue investing in future innovations. Therapeutics regularly have multiple uses, so it would be impossible to constrain the impact of a TRIPS waiver to a product's COVID-19 use only, putting at risk investments underway to evaluate the potential of current COVID-19 therapeutics as medicines against other viral threats.

122. Without IP protections, MSD likely could not have justified investment in the development of molnupiravir as a COVID-19 treatment, which we did without external funding, and would be disincentivized to continue evaluating it against other diseases. MSD urges the Council to not support an extension of the TRIPS waiver to COVID-19 therapeutics and diagnostics, and instead to work to address the real barriers to access.

123. Additional References:

a. MSD, *U.S. International Trade Commission Written Comments to the Docket* (May 2023) https://www.usitc.gov/press_room/news_release/2023/er0201_63483.htm. Note, In February 2023, The U.S. International Trade Commission (USITC) launched a factfinding investigation into extending the TRIPS Waiver to COVID-19 diagnostics and therapeutics. MSD submitted detailed comments to the docket, which can be found through the USITC

Electronic Document Information System link above (please note free registration is required)

b. International Federation of Pharmaceutical Manufacturers and Associations, *How Different Partnership Models Supported the Response against COVID-19* (June 2023), https://www.ifpma.org/news/first-of-its-kind-event-brings-together-10-companies-that-partnered-to-deliver-vaccines-and-treatments-in-response-to-covid-19/

c. Center for Global Development, *Lessons from Expanding Access to COVID-19 Treatments in LMICs through Voluntary Licsensing (*Dec 2022), https://www.cgdev.org/publication/lessons-expanding-access-covid-19-treatments-lmics-through-voluntary-licensing

d. International Federation of Pharmaceutical Manufacturers and Associations, *Impact of a Waiver of Intellectual Property Rights for COVID-19 Therapeutics* (Dec 2022), https://www.ifpma.org/resources/impact-of-a-waiver-of-intellectual-property-rights-for-covid-19-therapeutics/

e. Brant, J. & Schultz, M.P., *Unprecedented: How Intellectual Property Rights Helped the Pandemic Response* (Nov 2021), https://www.unpackingip.org/

4.2 Ms Elsie Soto, VP Supply Chain, Emerging Markets & China, Pfizer Global Supply

124. Elsie initiated her career in Pfizer Puerto Rico in 1993. Elsie assumed positions of increased responsibility at the Vega Baja and Fajardo sites, and then internationally in Spain, Korea, the US and Hong Kong. Elsie was honoured in 2011 with the National Hispanics Corporate Achievers Award for her career accomplishments as a corporate leader at Pfizer. In 2013, Elsie was appointed Vice President Product Portfolio Management (PPM) for Pfizer's Established Business.

125. In 2016 she assumed the role of VP PPM for the Innovative Business. In 2019 she was appointed to her current role as VP Supply Chain Emerging Markets and China overseeing the supply strategic aspects and commercial interface of those areas. During the Pandemic, Elsie co-led Pfizer's COVID-19 Manufacturing taskforce. Elsie is also currently leading the Manufacturing & Supply Chain activities related to the Accord for Healthier World. Elsie holds a bachelor's degree in Industrial Engineering from the University of Puerto Rico at Mayaguez. She brings 30 years of site, market, and centre experience in the areas of Procurement, Product Transfers, New Product Launches, Site Production Planning, Logistics, PGS Market Leadership, Business Development, Portfolio Strategy and Supply Chain Management in both Established and Innovative Businesses to her role.

4.2.1 Summary of Intervention

126. Collaboration has been hardwired into Pfizer's work in supporting the pandemic response, be it our partnership with BioNTech for our COVID-19 vaccine, or with manufacturers globally to scale up at risk and at pace for both our vaccine (with more than 20 partners) and our therapeutic (with more than 30 partners).

127. Producing vaccines and therapeutics at pace requires trust and partnership. The intellectual property (IP) system provided the framework that enabled the long-term risk-taking, collaboration and investments necessary to develop these products. It facilitated the transfer of information by providing the legal certainty needed to allow for tech transfer and information exchanges between companies.

128. As of September 2023, Pfizer and BioNTech have distributed more than 4.6 billion COVID-19 vaccine doses to patients in 181 countries and territories worldwide; this includes over 1.8 billion doses to low-and middle-income countries. For our COVID-19 therapeutic, as of 30 June 2023, we have shipped approximately 53 million courses to 79 countries globally.

129. Equitable distribution is Pfizer's North Star. Since day one we helped enable broad and equitable access to our COVID-19 therapeutic through, for example, tiered pricing, a voluntary license agreement with the Medicines Patent Pool (MPP)our therapeutic or a generic version through one or more of these pathways[16], supply agreements with UNICEF and Global Fund, and other initiatives. Altogether, with the MPP, UNICEF, and Global Fund agreements, every low and middle-income country in the world, except China, now has the potential to access.[17]

130. Despite these efforts, the principal access challenges for COVID-19 therapeutics are well documented.[18] They include, for example, pandemic fatigue, healthcare professional education, testing capacity, and sustained overall pandemic response financing. In some countries our COVID-19 antiviral has still not been approved. Demand has been another significant challenge. Pfizer initially allocated a significantly higher percentage of our total supply via the Global Fund and UNICEF, however, as of May 2023, of the 2.1 million units offered, just over 140,000 units - or 6% - were requested by the 59 low-and-lower-middle-income countries that opted in. And so far, we are aware of three sub-licensees for the MPP deciding to terminate their agreements, with two publicly citing commercial viability or considerably decreased usage as reasons for terminating.[19]

131. Weakening IP rules will not solve any of these challenges. In addition to not addressing the root causes of access challenges, any expansion of the June 2022 TRIPS Decision would introduce additional risks. It lacks clear guardrails for safety, post-market surveillance and equitable distribution found in voluntary licenses.

132. There is no factual basis for expanding the TRIPS Decision. Further weakening IP protections will undermine the ability of companies to invest in the type of innovation and partnerships that helped us confront the COVID-19 pandemic, and it will potentially stifle the ability to respond to future pandemics.

133. WTO Members should instead focus on strengthening and maintaining health infrastructure to deliver therapeutics; increasing access to testing; implementing public information campaigns to increase awareness and acceptance of therapeutics; and, importantly, removing trade barriers.

134. More information on Pfizer's efforts towards equitable access, including our forward-looking work through 'An Accord for a Healthier World', can also be found here:

a. https://www.pfizer.com/TradeEquitableAccess

b. https://www.pfizer.com/Therapeutics-Equitable-Access

c. https://www.pfizer.com/about/responsibility/global-impact/accord

4.3 Dr Cheikh Tidiane Diagne, Head of Operations, DIATROPIX, Institute Pasteur, Dakar, Senegal

135. Dr Cheikh Tidiane Diagne trained at the Centre National de la Recherche Scientifique and at the University of Toulouse (France) where he graduated in 2013 with a PhD in Structural and Functional Biology. His PhD research was focused on the dynamic analysis and assembly of site-specific DNA recombination machineries using single molecule techniques. From 2014 to 2016, he worked at the Electronics Department (LETI) of the French Commission for Atomic Energy and Alternative Energies (CEA) in Grenoble (France) as a postdoctoral researcher. There, his research efforts were focused on bio-inspired technologies for molecular electronics.

136. Dr Diagne joined the virology department and the WHO collaborating for arboviruses and haemorrhagic fever viruses of the Pasteur Institute of Dakar in Senegal in 2016. His primary interests

[16] Pfizer's MPP agreement covers 95 low- and middle-income countries, covering 53% of the world's population.

[17] Pfizer has other agreements in place to help facilitate access in China.

[18] https://www.ifpma.org/insights/is-an-extension-of-the-trips-waiver-needed-for-covid-19-tools/

[19] https://medicinespatentpool.org/licence-post/pf-07321332 (See section "Additional information")

were centred on innovation for Global Health, particularly on the development and evaluation of point-of-care diagnostic tools, digital health for biosample transportation and banking and rapid extraction method for nucleic acid amplification. Since March 2020, he has been leading the DIATROPIX laboratory, a social venture founded by the Institut Pasteur de Dakar (Senegal), the Merieux Foundation (France), the Foundation for Innovative New Diagnostic (Geneva) and the Institut de Recherche et de Développement (France). DIATROPIX focuses on local manufacturing of rapid diagnostic tests for neglected and epidemic diseases in Africa.

4.3.1 Summary of Intervention

137. Institut Pasteur de Dakar is a public health institution in Senegal that collaborates with the Ministry of Health to monitor and combat outbreak-prone diseases in every region of the country. They also provide diagnostic support for infectious diseases in various African nations.

138. In 2019, the World Bank reported that countries with the lowest GDP per capita, mostly in Africa, had the highest burden of communicable diseases, revealing the fragmentation and lack of accurate diagnostics in Africa's healthcare system. Despite attempts to allocate 15% of government GDP to health, Africa spends significantly less per capita on healthcare than high-income countries, leading to a reliance on imported medical tools and a shortage of diagnostics during crises like the COVID-19 pandemic.

139. DIATROPIX aims to address these challenges by focusing on local manufacturing and a new business model. However, limited investment in research and development (R&D) in Africa has hindered the development of healthcare manufacturing capabilities on the continent.

140. During the COVID-19 pandemic, DIATROPIX collaborated with FIND and UNITAID to produce COVID-19 products, expanding its manufacturing capacity. The transition from Bionote to DIATROPIX manufacturing presented challenges related to equipment, assembly line capacity, and personnel training. Due to the urgency of the pandemic, they initially focused on the packaging step. Product launch involved collaboration with local regulators and the West African Health Organization for safety and conformity assessments, and regulatory harmonization in the ECOWAS region.

141. As COVID-19 demand for diagnostics decreased, DIATROPIX is updating its business model to focus on Neglected Tropical Diseases while working also on high volume products such as HIV and malaria. It plans to expand its product portfolio with support from FIND and UNITAID and increase manufacturing capacity to reduce product costs, although this requires premium payment support to expedite the process.

4.4 Mr Osman Khalid Waheed, CEO, Ferozsons Laboratories Ltd., Pakistan

142. Osman Khalid Waheed joined Ferozsons Laboratories Limited, a publicly listed pharmaceutical company in 1993 after obtaining his undergraduate degree from Harvard. During his tenure as CEO since 1998, the company has forged alliances with international partners including the Boston Scientific Corporation and Gilead Sciences Inc. to expand access in disease areas including heart disease, viral hepatitis, HIV and COVID-19. In 2019, Ferozsons became one of 9 international producers selected to manufacture and supply its therapeutic remdesivir to 127 low and middle-income countries under a voluntary license from Gilead. Mr. Waheed serves as a trustee of LUMS, Pakistan's premier multi-disciplinary university, and was the founding chairman of the Lahore Biennale Foundation, a non-profit dedicated to public art.

4.4.1 Summary of Intervention

143. Ferozsons has worked with Gilead as a Voluntary Licensee since 2016, enabling access to viral hepatitis treatments to patients in Pakistan. Our VL collaboration, which includes local manufacturing, has helped us reach over 250,000 HCV patients at a treatment cost that is among the world's lowest.

144. At the start of the COVID-19 pandemic, in line with its VL-driven access model, Gilead swiftly authorized 9 manufacturers from its VL network across India, Pakistan and Egypt to produce remdesivir for 127 LLMIC's, within weeks of FDA's EUA for the drug.

145. Gilead granted its licensee producers access to a complete technology transfer package to manufacture remdesivir in line with Gilead's specifications. A dedicated team, headed by Elizabeth Murray, was available round-the-clock to help licensees meet technology, regulatory and supply chain challenges, particularly important for an injectable like Remdesivir. Ferozsons began production within 12 weeks of its agreement. The direct nature of the VL, coupled with Gilead's pre-existing relationships with its licensees, allowed for an exceptionally agile and proactive manufacturing response.

146. On day one of Covid operations, the Ferozsons team pledged that we would respond to every request for remdesivir, no matter how small or distant. This pledge was tested early on, when we received an emergency mail from an ER Doctor in Costa Rica requesting treatment for one patient (11 vials). We were able to get the treatment across to the patient in one week, and to this day, we receive letters from the patient's family expressing their appreciation for being there in their time of need.

147. Through the course of the pandemic, we were privileged to supply remdesivir to patients in 24 countries, and collectively among the licensees, I believe that all requests for remdesivir were met. I am proud to report that despite the incredibly difficult relationship between India and Pakistan at the state level, we were able to work with Indian licensees to supply product to countries they were unable to reach during India's delta surge and the resulting export ban imposed by their government.

148. Owing to its competitive nature (licensees were free to compete across all access countries), the VL model also helped drive down product costs dramatically. As manufacturing scaled up, robust competition among licensees ensured that the resulting economies were passed on to governments and patients in LLMIC's.

149. Gilead's VL model has also helped expand local capacity in LLMIC countries through knowledge-sharing and technology transfer. As an example, on the back of our track record of producing remdesivir, we were able to raise financing in Pakistan during COVID-19 to undertake a USD 25 million expansion in our manufacturing lines, increasing our capacity to formulate specialty lyophilized and liquid therapeutics, and potentially vaccines, by 11 times.

150. Gilead's experience across two global emergencies (HIV and HCV) and the COVID-19 pandemic, clearly demonstrates that compared to IP waivers, Voluntary Licensing through multiple licensees provides a significantly more robust model for ensuring equitable access to life-saving medicines and vaccines across all parts of the globe. I would also suggest, based on experience, that for *quality assurance and standardization*, it is important to ring-fence voluntary licensing with IP-enforcement. During COVID-19, unlicensed versions of product created, in some instances, serious quality concerns, particularly in countries that lacked capacities to ascertain product safety and quality in the midst of a pandemic.

4.5 Dr Morena Makhoana, CEO, Biovac, South Africa

151. Dr Morena Makhoana joined Biovac in 2004 and holds the role of Chief Executive Officer. He is a member of the Board and the Biovac Executive team. Prior to his CEO role at Biovac he held the role of Deputy CEO and prior to that of Medical Affairs Director for Biovac.

152. His mandate is to realise the objective of building vaccine manufacturing capacity in Southern Africa. During his tenure Biovac has attracted three successful technology transfers with global pharmaceutical companies such as Sanofi and Pfizer that has allowed the company to grow its staff complement from 24 to over 400. Biovac's next phase is to enter strengthen its product development as well as its drug substance capability in order for Biovac and Africa to have end to end manufacture.

153. Morena is a medical graduate from the University of Cape Town (UCT) in South Africa. He has participated in numerous executive and business courses at both Harvard and Stanford Universities.

4.5.1 Summary of Intervention

154. Biovac was established in 2003, making us exactly 20 years old as a company. As an African manufacturer, with very limited means, we have been building our capacity slowly and gradually. We began operations with sales and marketing, moved on to packaging and labelling and then to very specialized area of fill-finish. However, as we did not have our own products, we recognized the need to learn, hence, partnered with companies that had the products and technical know-how. We partnered with a French-based company, Sanofi in localizing a modern 6-in-1 combination vaccine for children through fill and finish.

155. We then entered into another partnership with Pfizer on the pneumococcal conjugate vaccine (a 13-valent vaccine). This one included formulation of the vaccine that was a further step towards end-to-end manufacturing. As a result, when COVID-19 hit, we had those two experiences to build on and enough experience to act quickly.

156. Biovac always had the ambition to be an to end vaccine manufacturer therefore it invested from the beginning in a small product development team of about 30 to 40 scientists. This enabled us to develop our skills in other areas, starting with bacterial fermentation and conjugation platforms, albeit slowly.

157. **Paragraph 8:** Our ability to intervene in Africa during the COVID-19 pandemic was a result of our past relationships with our multinational partners. With our existing partnerships we could engage these companies for further collaboration.

158. Biovac, thus entered into a second technology transfer agreement with Pfizer to produce the COVID-19 vaccine which had been developed together with BioNTech. Our past experiences empowered us to negotiate and conclude a technology transfer agreement quicker, in the wake of the pandemic. For context, our first tech transfer with Sanofi took 7 years to execute; the one with Pfizer on the pneumococcal conjugate vaccine also took about 5 years. However, with the COVID-19 vaccine agreement, as we had gotten better at this, it took 15 months to execute.

159. Consequently, Biovac was able to establish between 75 and 100 million doses of vaccines capability through the COVID-19 programme which were to be made available not only to South Africa but to the rest of the African continent as well. However, Africa as we know, does not have the most needed drug substance capability. We hope that with time and experience, developing countries would be able to respond better to pandemics through building drug substance capability for routine vaccines. A few initiatives have been established since the pandemic.

a. **The WHO's mRNA Vaccine Technology Transfer Hub:**

   i. This programme, hosted in South Africa by Afrigen, is responsible for developing the technology from scratch. The programme is aimed at sharing mRNA technology with others. This will hopefully get other African companies to engage in end-to-end manufacturing on platforms like the mRNA technology. Biovac will be the first recipient of this technology. There were indeed some challenges in the mRNA technology. Initially, it was not clear whether Moderna would waive their patent rights as Afrigen, being part of the hub, was using technology similar to Moderna's. Eventually, we learnt that Moderna waived those rights during the pandemic.

   ii. We are unable to predict what would happen going forward in the post-pandemic period, and whether the patent rights would then be enforced, since there is indeed some risk that the technology that was previously developed would then have limited use. Our interest in patents is in their impact and whether those patent rights are enforceable even after the pandemic.

b. **Extension of waiver to therapeutics and diagnostics:**

i. We need to acknowledge that progress has been made in Africa. This is because in 2009 when the pandemic potential of the H1N1 flu was contained, many African countries did not have any capacity to produce vaccines. As a result of routine vaccines and partnerships that we have had, companies like Biovac were now able to contribute during the COVID-19 pandemic our fill-and-finish operations, albeit with limited resources. Our aim, not only as a company but as the African continent, led by the African Union and Africa CDC, is to ensure that many African manufacturers have the capacity for pandemic response to be able to do end-to-end manufacturing.

160. **Biovac's position on Paragraph 8:** The question to ask ourselves is whether some of these waivers should be extended to therapeutics and diagnostics. Our position is that the waivers have been granted to vaccines as one therapeutic category, but there ought to be standardization. It is important to remember that while vaccines were the most impactful medical intervention during the recent pandemic, vaccines may not be as effective another time. It is possible that therapeutics would rather be needed in addition to diagnostics which are always required because of the need to test. This is why we need to develop a more holistic approach regardless of what term it gives them. For us, it is about accessibility. If we make all options (therapeutics, diagnostics and vaccines) accessible through these licences or patent waivers we will be able to save the world.

4.6 Mr Alejandro Gómez López, Health Secretary of the District of Bogota, Speaker of BogotáBio, Colombian Public Enterprise for the local production of vaccines

161. Medical Doctor. Specialist in Health Auditing and Finance. Master in Political and International Studies. He has more than 20 years of experience in the health sector, holding positions in all areas: delivery, insurance and government. He was National Director of Nutrition for the Colombian Institute of Family Welfare (ICBF) and Director of Public Health for the Mayor's Office of Medellín.

4.6.1 Summary of Intervention

162. *BogotáBio* is a brand-new public initiative for the production of vaccines and other biologicals, guided by public health needs. It contemplates a novel, complete technology transfer scheme to build a plant that allows for the local production, from start to finish, including the antigen, of the following vaccines: COVID-19, hepatitis A, chickenpox and polio. It is a medium-term project that will be completed in the next 8 years, whose construction and equipment are fully financed with the public budget of the city of Bogotá.

163. With *BogotáBio*, Colombia will resume its public vaccine production capacities, abandoned in the early 2000s. Indeed, many Latin American countries, and also some developed countries, stopped producing vaccines as public goods, to make way for a market logic in which vaccines were produced by private companies and free trade between countries was promised. The pandemic showed that this promise was failed. The need is now recognized for the production of certain valuable goods, such as health technologies, to be deconcentrated and plans are designed for the repatriation of production.

164. Regarding the technology transfer model, Bogotá chose the figure of a mixed company as a model of collaboration with the private sector. The city deliberately avoided a 'customary' voluntary license agreement. These schemes have a very limited scope (generally only for certain segments of the manufacturing process, such as fill and finish), a limited duration, very narrow obligations for the private party and very strict conditions for the party receiving the technology. As the company that transfers the technology develops certain specific activities and complies with the schedule, the contracts will be deemed to have been executed, regardless of the result or its impacts. Under these figures, the private company may not guarantee that the technology transfer effectively results in a viable product. This has led to many voluntary licensing initiatives not being successful in the medium term or taking much longer than initially planned to deliver pharmaceutical products suitable for human consumption. Finally, the customary voluntary licenses are subject to very strong confidentiality issues, which do not adequately account for the needs of public production schemes such as this one.

165. Bogotá then looked for a private strategic partner that was willing i) to form a partnership with the government, ii) to be a minority partner in that partnership, and iii) to make a complete

technological transfer that, beyond the filling and finishing of the vaccines, would allow the antigen to be learned and manufactured locally. Bogotá made a very broad call and a diplomatic effort for potential partners. No Western company was willing to follow a business model like the one proposed -with real technology transfer and learning, and not simple manufacturing processes-.

166. SINOVAC will be the partner of *BogotáBio*. The Chinese company will share with the public sector the benefits (represented in company dividends), but also the risks. Furthermore, since it is a partnership, there is a vocation for permanence with no specific term. This implies that SINOVAC will have incentives so that technology transfer is successful and translates into products that benefit Colombians.

167. This shows that there are viable models for real and impactful technology transfers, far superior to the simple voluntary licenses usually known and used.

5 ACADEMICS

5.1 Dr Daria Kim, Max Planck Institute for Innovation and Competition

168. Daria Kim is a Senior Research Fellow at the Max Planck Institute for Competition and Innovation (Munich). She holds MA (Indiana University of Pennsylvania), LLM (Munich Intellectual Property Law Center), and Dr iur. (University of Augsburg) degrees.

169. Her research focuses on topics at the intersection of law, technology, and society, which include intellectual property law, governance frameworks for medical and genomic research, marketing authorisation regulations, and access to data within the context of the data economy. https://www.ip.mpg.de/en/persons/kim-daria.html

5.2 Summary of Intervention

170. The question of whether the Ministerial Decision on the TRIPS Agreement, adopted on 17 June 2022 [Decision], should be extended to include therapeutics and diagnostics, is a matter of assessing its potential consequences. Ultimately, at issue is whether the Decision can improve the availability and accessibility of medicinal products, especially for new COVID-19 variants.

171. From a legal perspective, the Decision primarily clarifies the application of the existing flexibilities under the TRIPS Agreement, with only one requirement under Article 31(f) TRIPS being waived for the eligible Members. Hence, the extension of the Decision will not substantially change the legal status quo. This is not to diminish the importance of such clarifications, as they enhance legal certainty and can provide interpretative guidance, especially concerning the instruments for issuing a compulsory licence or the interaction between test data protection and limitations on patents. This can be helpful, particularly for countries that might be hesitant to apply limitations on patent rights or other TRIPS flexibilities where they are needed.

172. While the Decision refers to the exceptional circumstances of COVID-19, it is worth emphasising that clarifications of the TRIPS provisions cannot and should not be tied to the unique circumstances of this pandemic. The application of the clarifications made by the Decision does not need to be justified by the exceptional circumstances of COVID-19, and the same applies to their duration.

173. The practical impact of the extension on access to affordable therapeutic and diagnostic products for COVID-19 would depend on the actual use of provisions under the Decision. Since the Decision was adopted, we have not witnessed a significant increase in the utilisation of TRIPS flexibilities, including for vaccine exports. However, the case of therapeutics and diagnostics might be different due to the distinct nature of these products.

174. Concerns regarding the offsetting effect on innovation incentives, often raised in opposition to extending the Decision, might be misplaced. In general, the impact of the Decision on innovation incentives should not be greater than the impact of the existing TRIPS flexibilities. The potential

effect of waiving the 31(f) TRIPS requirement on innovation incentives is speculative, especially given the low likelihood of it being routinely invoked in practice.

175. Overall, the extension of the Decision can be viewed as part of an effort to enhance and streamline the national implementation and application of TRIPS flexibilities. The motivation behind limiting the Decision to the production and supply of COVID-19 vaccines, while postponing its extension to therapeutics and diagnostics, was not clear from the outset. Ensuring access to therapeutics and diagnostics has been no less critical than ensuring access to vaccines. There is hardly any justification for not applying the same measures and flexibilities to all medicinal products in the context of the COVID-19 pandemic and public health protection more broadly.

5.3 Prof. Dr Yangmu Huang, Deputy Director, Department of Global Health, Research Professor, Beijing University, China

176. Yangmu Huang is deputy director, research professor and doctoral supervisor in the Department of Global Health, School of Public Health, Peking University. Her research focuses on global health governance, R&D and public health, and health emergency, which mainly aims at the vulnerable population. She has hosted and participated in tens of national and international research projects supported by National Natural Science Foundation of China, World Health Organization (WHO), etc. She has published over 60 articles in peer reviewed journals, such as the Lancet. As the senior consultant of the China's Delegation, she has been invited to attend the World Health Assemble, WHO Executive Board annually. She has also provided consultation for China's national ministries and commissions, such as the National Health Commission, UN agencies, etc. Due to her contribution and achievements, she was awarded as Health Young Physician Leaders (ranked 1st in 2019) by the InterAcademy Partnership.

5.3.1 Summary of Intervention

177. Beginning in the late 1970s, China's in vitro diagnostics (IVD) and modern therapeutic industries has seen significant growth, thriving into the complete supply chain ecosystem with improving R&D capacity and fast-growing markets, and moving from foreign company dominance to a scenario where domestic products command significant market share, especially in the mid and low-end market segments.

178. During the past decade, China has issued a number of policies on regulatory and approval, R&D incentives, manufacturing and distribution, and technical standards to accelerate the high-quality development of diagnostics and therapeutics. With all these supporting environments, very diverse disease types and technologies were developed for IVDs, with immunological, molecular and biochemical diagnostic share nearly 75% of market. However, there are still many challenges for IVD industry in China. For example, in the upstream, imported raw material products dominate the IVD market, with an average of 87%; in the midstream, domestic products dominate enzyme immunoassay, molecular diagnostics and biochemical diagnostics market, but in the more advanced high-end NGs, POCT, etc. are still dominated by imported products.

179. For therapeutics, the number of biologics and chemical drugs approved in China is increasing. By 2021, China becomes the world's second largest pharmaceutical market. However, the proportion of biologics manufacturers that rely on innovation is relatively small. As for traditional Chinese medicines, China has actively promoted scientific research on traditional Chinese medicines, with an upward trend of clinical trials, and has built a strong cooperative network with more than 20 countries.

180. In response to the COVID-19 pandemic, almost all the relevant departments in China have quickly issued a number of policies on regulatory and approval, R&D incentives, and technical standards, with the foundation of previous regulations and capacity strengthening of the system. China's series of actions to promote COVID-19 vaccine innovation, accessibility and knowledge protection are consistent with the relevant regulations and purposes of international organizations. With all these supports, the number of patent applications for COVID-19 diagnostics reached the peak after four months since the outbreak. The State Intellectual Property Office (SIPO) has specially

opened a green channel (or fast-track examination) for relevant patent applications. More than half of the patents have an examination length of 1 to 6 months, which is significantly shorter than the average review time (18.5 months). Between 2020 and 2021, production capacity for diagnostics grows 21-fold, largely represented by nucleic acid and antibody tests. The IVD exports reach RMB 34.9 billion in 2020 and RMB 84.6 billion in 2021. Lianhua Qingwen, the representative of proprietary Chinese medicine, has obtained regulatory approvals and/or import licenses in approximately 30 countries and regions.

181. With all these facts from China, we can see that strong and timely policy and regulatory supports are essential for promoting innovation and access, only if the upfront domestic capacity building has been long-term constructed. Stimulating innovation and accelerating patent approvals can better promote access to pharmaceutical products, in the basis of R&D. Considering advanced technology R&D takes a long time, one-time policy support is insufficient to promote rapid technological development. Cooperative R&D and technology transfer can better leverage the advantages of different countries to achieve health and equity. As for China, we have very strong policy support, complete supply chain, extensive product technology pipeline, and adequate production capacity. However, China's advantage of production capacity cannot be fully used to better serve global health unless with the support of new technology and innovation.

182. Together, let's be a strong supporter and guarantor to meet the challenges of emerging infectious diseases.

5.4 Prof. William Fisher, William Fisher, Wilmer Hale Professor of Intellectual Property Law, Harvard University

183. William Fisher received his undergraduate degree (in American Studies) from Amherst College and his graduate degrees (J.D. and Ph.D. in the History of American Civilization) from Harvard University. Between 1982 and 1984, he served as a law clerk, first to Judge Harry T. Edwards of the US Court of Appeals for the D.C. Circuit and then to Justice Thurgood Marshall of the US Supreme Court. Since 1984, he has taught at Harvard Law School, where he is now the Wilmer Hale Professor of Intellectual Property Law. In 2013, he created the CopyrightX online course, which is now offered annually to approximately 1000 students worldwide. In 2011 he and Professor Ruth Okediji created a similar course on Patent Law and Global Public Health, which is now offered semi-annually in collaboration with the World Intellectual Property Organization. He is currently a director of Global Access in Action, a non-profit organization, based at Harvard Law School, whose primary mission is improving public health in low and middle-income countries.

5.4.1 Summary of Intervention

184. The following seven points combine my own views on the issue confronting the TRIPS Council with a distillation of the most salient arguments made by other speakers during the thematic session.

a. The decision that the Council is considering is narrow. The existing waiver represents a modest extension, limited to COVID-19 vaccines, of the general compulsory-licensing flexibilities that already exist under TRIPS. At issue is a possible extension of those flexibilities to COVID-19 diagnostics and therapeutics. This should not be characterized as a general "weakening" of IP protection.

b. Despite the narrowness of the issue, the decision taken by the Council will have a precedential effect. Determination of the scope of the COVID-19 waiver will affect not only the patterns of innovation and distribution of COVID-19 products, but also those patterns with respect to products aimed at future pandemics. This is not necessarily an argument against proposed extension, but a recognition of its impact on our responses to future crises.

c. Many contributors to the thematic session have argued that more extensive use of voluntary licensing would be superior to extension of the existing waiver to therapeutics and diagnostics. The plausibility of that claim is enhanced if the characteristics of the

voluntary licenses are specified. What might be described as "access-oriented voluntary licenses" ("AVLs") have the following characteristics:

i. Nominal royalties (typically 5-10% of generics' revenues from finished products);

ii. Broad geographic field-of-use provisions;

iii. Mechanisms to ensure that the prices of the licensed generic products remain low (such as competition among generics and the maintenance in LMIC markets of low-priced branded versions of the drugs at issue);

iv. Provisions mandating the transfer of technology from licensors to licensees;

v. Quality-control mechanisms (including licensees' obligation to seek WHO prequalification, EMA approval, or tentative FDA approval – and integrated mechanisms for post-market surveillance);

vi. Transparency

(Additional detail concerning the merits of licenses of this sort are available at https://ipxcourses.org/GAiA/VLAM_Report_v1.1.pdf.)

d. AVLs do indeed have significant advantages over compulsory licenses within the zones to which they apply. Those advantages include: (a) Technology transfer makes possible more efficient and rapid manufacturing and distribution of the generic products than is possible through compulsory licensing. (b) AVLs make it easier for the licensor to ensure adequate markets for generic manufacturers in LMICs – and thus to accelerate capacity building. (c) Judicious selection of licensees and the establishment of long-term partnerships enhances quality control and thus both reduces the incidence of substandard or falsified medicines in LMICs and protects the reputation of licensors. (d) Finally, to maintain a valuable relationship with the licensor, the licensees have an incentive to respect anti-diversion restrictions. Major examples of these benefits include the radical reduction in HIV deaths in sub-Saharan Africa and the near elimination of Hepatitis C in Egypt – both of which were made possible by the pioneering use of AVLs by Gilead Sciences.

e. However, AVLs have thus far failed to address fully the health needs of LMICs. Examples of failures properly emphasized by other contributors to the thematic session include: Moderna's long-standing resistance to use of AVLs for its COVID-19 vaccine; the high prices and sharp field-of-use limitations that have thus far limited the benefit of AVLs with respect to COVID-19 therapeutics; and the limited use of AVLs with respect to monoclonal antibodies aimed at diseases other than COVID-19 (the subject of a recent conference organized by the MPP). AVLs thus should not be considered a panacea.

f. The extension of the existing waiver to COVID-19 Diagnostics and Therapeutics could help alleviate COVID-19 and future pandemics in two ways: (a) It would enable LMIC governments to use compulsory licenses to fill the gaps when IP holders refuse to use AVLs; (b) Equally important, the power of LMIC governments to use compulsory licenses as a last resort would increase incentives for innovators to use AVLs.

g. If possible, the Council should also consider other ways of encouraging innovators to make greater use of AVLs. Such alternative strategies include:

i. Educational programs to augment awareness of all of the so-called "TRIPS flexibilities" already available to LMICs – thereby increasing the leverage of LMIC governments when negotiating or catalyzing AVLs;

ii. forbidding retaliation (either by the governments of upper-income countries or by innovator pharmaceutical firms) against LMIC governments that employ those flexibilities.

iii. Providing institutional support for apprenticeship programs, which have proven to be the most efficient mechanism for technology transfer – and thus reduce the administrative burdens that AVLs impose on licensors.