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January 31, 2024

PUBLIC DOCUMENT

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Written Comment Re: Implications of Access and Benefit Sharing (ABS) Commitments/ Regimes and Other Proposed Commitments in the WHO Pandemic Agreement[1]

Dear Principal Deputy Assistant Secretary Kim,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we hereby submit our written comments on the proposed commitments in the draft World Health Organization (WHO) Pandemic Agreement. While comments have been requested on the October 30, 2023 Negotiating Text of the WHO Pandemic Agreement, PhRMA would be pleased to provide additional comments as the Negotiating Text evolves.

PhRMA member companies are devoted to inventing, manufacturing and distributing valuable therapeutics and vaccines that enable people to live longer, healthier and more productive lives. PhRMA and its members strongly support and share the goal of international cooperation to make the world safer and better prepared to face a future pandemic. This can be facilitated through an agreement that promotes the development of treatments and vaccines for future pandemics, improves equitable access to future pandemic-related products and better anticipates and mitigates the access-systemic weaknesses that we saw during the COVID-19 pandemic. The Negotiating Text contains many positive elements that support our shared goal, including the following:

- a recognition of the "important" role of intellectual property (IP) and biopharmaceutical innovation "for the development of new medical products" (*Preamble, paragraph 10*);

- commitments for pandemic prevention and improved public health surveillance (*Article 4*);

[1] Submitted in response to Notice and Request for Comments on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments Being Considered Under a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response, 88 Fed. Reg. 88637 (Dec. 22, 2023) and Extension of Comment Period, 89 Fed. Reg. 4319 (Jan. 23, 2024).

- commitments to promote and implement a One Health approach for pandemic prevention, preparedness and response (PPPR) (*Article 5*);

- commitments for strengthened pandemic preparedness, readiness and resilience (*Article 6*);

- commitments to strengthen countries' health care workforces (*Article 7*);

- commitments to develop, monitor and review national PPPR strategies (*Article 8*);

- commitments for regulatory systems strengthening (*Article 14*). A recent conference organized by the African Union Development Agency-NEPAD, WHO and the African Medicines Regulatory Harmonization program found that some "70 % of countries globally have weak national medicines regulatory systems" and that "stronger regulatory systems can increase equitable access to life-saving medicines";[2]

- measures for increased international collaboration and cooperation to formulate cost-effective PPPR measures, procedures and guidelines (*Article 16*); and

- commitments to improve communication and public awareness, including public health and pandemic literacy in the population (*Article 18*).

The world has emerged from the COVID-19 pandemic, thanks in large part to U.S. leadership and the medical innovations of the U.S.-based research-intensive biopharmaceutical industry. In negotiating such an agreement, it is critical to ensure U.S. research remains at the forefront of innovation and to preserve the existing innovation ecosystem which is founded on time-limited IP protection and unrestricted access to pathogens. Many of the more positive proposals around these elements could go further to hold countries accountable for what they should be doing for their own populations and as a commitment to the world.

It is essential that no actions are taken that would undermine the research, development and deployment of future pandemic-related products, including innovative vaccines and therapeutics. Unfortunately, the Negotiating Text contains several proposed commitments that would do that, including longstanding ideological calls to waive all IP rights that were rejected during the COVID-19 pandemic and should be rejected now. These elements are predominantly contained in Article 9 (research and development); Article 10 (sustainable production); Article 11 (transfer of technology and know-how); Article 12 (access and benefit sharing (ABS)); and Article 13 (global supply chain and logistics).

PhRMA urges the Administration to keep the following principles in mind while negotiating any PPPR agreement under the auspices of the WHO:

- The goal should not be equitable *manufacturing*, but rather ensuring equitable *access*. The pharmaceutical industry relies upon a broad and geographically diverse global

[2] Jessica Ahedor, *Regulatory Collaboration Can Strengthen Medicines Access – African Scientific Conference*, HEALTH POLICY WATCH (Jan. 4, 2023), *available at* https://healthpolicy-watch.news/regulatory-collaboration-can-strengthen-medicines-access-african-scientific-conference/.

supply chain, which depends on the free movement of goods and supply across borders, including raw materials. Trade bottlenecks and disjointed requirements for localized manufacturing can add uncertainty, cost and delays in manufacturing and patient access. While geographical diversity is certainly an important factor that biopharmaceutical companies consider when seeking to ensure supply resilience, capacity is created with specific considerations in mind, ensuring that manufacturing is sustainable in the pre- and post-pandemic period. On their own, regional and local manufacturing cannot effectively address access barriers and their root causes.

- Prior to and during the COVID-19 pandemic, IP protections enabled longstanding and new R&D partnerships to develop medical countermeasures in record time and facilitated hundreds of partnerships around the world to manufacture vaccines and treatments at scale. For reasons explained in more detail, below, compromising IP protections in the WHO Pandemic Agreement will hinder, complicate and stall industry's response in a future pandemic when time is of the essence.

- Technology transfer supports medical innovation and robust manufacturing only when it is accomplished through voluntary initiatives. This is because voluntary initiatives frequently address more than just patents and usually facilitate access to the licensor's technology and know-how. Technology transfer requires significant resources (financial, human and time) from all parties to ensure viability and success of the agreed upon technology. Companies identify and partner with other manufacturers with the appropriate expertise, technical capabilities and facilities to produce safe, effective and high-quality products. The innovative U.S. biopharmaceutical industry must retain the ability to decide with whom and under what conditions it will share proprietary technology and know-how for pandemic-related product development.

- Pursuant to its constitution, it is the mandate of the WHO to "act as the directing and coordinating authority on international health work."[3] The organization is well-positioned to collect public health data, analyze global indicators of pandemic preparedness, monitor the development and deployment of pandemic-related products, and make recommendations on population prioritization during a pandemic. The WHO is ***not*** designed to: control the sharing of pathogens and their sequence information, prescribe conditions on national government funding for R&D, determine IP rights, regulate the disclosure of confidential commercial information or interfere with the approval, manufacturing, supply or pricing of pandemic-related products. These responsibilities exceed the WHO's mandate, expertise and funding. Any efforts to vest the WHO with these powers through the Pandemic Agreement should be rejected.

- The Convention on Biological Diversity's (CBD) ABS model – which links access to biological resources with the provision of monetary and non-monetary benefits to the resources' original stewards – is inappropriate and unhelpful to apply to pathogens and pandemic-related pathogens and their genetic sequence data (GSD). To ensure pandemic readiness, the global scientific community, including the U.S. innovative

[3] Constitution of the World Health Organization, art. 2(a), *entered into force* Apr. 7, 1948 (as amended through May 31, 2019), *available at* https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=6.

biopharmaceutical industry, must have prompt, unburdened access to pathogens and their GSD. Subjecting such access to demanding logistical barriers and benefit sharing conditions will have catastrophic effects on infectious disease research and hinder the development of pandemic-related products, ultimately jeopardizing lives.

With regard to U.S. implementation of any resulting treaty, it is our understanding that the Administration plans to pursue a sole executive agreement that does not require congressional approval. As such, it will be critical to ensure that none of the provisions in the agreement, including those related to protection of IP, are inconsistent with or require changes to existing U.S. law.

In addition, as is true of any international agreement, the U.S. negotiating position will be subject to the bounds of the U.S. Constitution.[4] To that end, the United States could not accede to an agreement that allows the government to compel holders of U.S. biopharmaceutical IP rights to license their patents or share trade secrets without providing those rights holders with just compensation.[5] Specifically, the U.S. negotiating position is constrained by the Takings Clause, which prohibits the government from interfering with U.S. property rights in a manner that wholly or very significantly deprives the property owner of the expected value of their property.[6] There is substantial case law indicating that the subject matter of patents, as well as trade secrets, are protected by the Takings Clause.[7] Compulsory licenses (CLs) or waivers on U.S. biopharmaceutical patents – which would seriously damage the value of those patents[8] – would violate the Takings Clause if granted without just compensation.

Mandates to share undisclosed information, including trade secrets, pose even greater constitutional risks. Trade secrets are valuable precisely because they are secret and thereby give their owners a competitive commercial advantage.[9] As soon as the government compels a trade secret owner to share its undisclosed, proprietary information with another party, that other party

[4] *See Reid v. Covert*, 354 U.S. 1, 17 (1957) ("This Court has regularly and uniformly recognized the supremacy of the Constitution over a treaty.").

[5] U.S. CONST. amend. V. Compulsory patent licenses without adequate compensation would also violate the United States' obligations under the TRIPS Agreement. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(h), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (hereinafter "TRIPS Agreement") (providing that compulsory licenses for patents, including licenses to the government, must ensure that "the right holder [is] paid adequate remuneration in the circumstances of each case, taking into account the economic value of the [license].").

[6] *See* ADAM VANN, CONG. RSCH. SERV., THE TAKINGS CLAUSE AND EMINENT DOMAIN: AN OVERVIEW OF SUPREME COURT JURISPRUDENCE 1, 6-7 (2023), *available at* https://sgp.fas.org/crs/misc/R47562.pdf.

[7] *See generally* James Flynn, *What's Mine is Not Yours to Give Me—Nor To Take Without Just Compensation: A New Jersey's Reaction To Sovereign Immunity, Intellectual Property, & Takings*, INT'L L. NETWORK (Jan. 5, 2022), *available at* https://casetext.com/case/james-v-campbell-4/analysis?sort=relevance&citingPage=1&sortCiting=date-ascending (summarizing case law).

[8] *See* Eric Solovy, *The TRIPS Waiver for COVID-19 Vaccines, and Its Potential Expansion: Assessing the Impact on Global IP Protection and Public Health*, CENTER FOR INTELLECTUAL PROPERTY X INNOVATION POLICY 7 (Dec. 2022), *available at* https://cip2.gmu.edu/wp-content/uploads/sites/31/2022/12/GMU-C-IP2-Solovy-PolicyBrief-TRIPS.pdf (hereinafter, "Solovy TRIPS Waiver Article").

[9] *See Ruckelhaus v. Monsanto Co.*, 467 U.S. 986, 1012 (1984).

will permanently "know . . . and be in lawful possession of that information."[10] As a result, the trade secret holder's competitive advantage – i.e., the cornerstone of its value – will be destroyed.[11] Notwithstanding the impracticability of monitoring the second party use of trade secrets, the ability of a second party to exploit the trade secret for varied commercial uses in perpetuity – and the substantial risk that this initial disclosure will result in additional parties acquiring the trade secret – destroys a trade secret's value to its owner so extensively as to result in a taking.[12]

Below, PhRMA provides additional detail on the specific questions raised in the Federal Register notice.

* * *

Article 9, Research and Development

- **What approaches or incentives might be provided to governments, research institutions, or the private sector to encourage participation of relevant stakeholders to, as proposed in the Negotiating Text, "accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential"?**

PhRMA comment: PhRMA members are already engaged in pre-R&D and clinical research to address emerging pathogens. The most recent example is the industry's response to COVID-19. Building on decades of significant research into coronaviruses and the development of new technology platforms, biopharmaceutical innovators were able to develop COVID-19 vaccines and therapeutics at an accelerated pace while upholding robust safety and efficacy standards. As a result, the first vaccine against SARS-CoV2 was available within twelve months from when the genetic sequence of SARS-CoV2 was published.[13] Those efforts were underpinned by the existing robust IP ecosystem with both industry-to-industry partnerships and public private partnerships. 531 unique active compounds were under development – 173 vaccines, 190 treatments and 168 antivirals.[14] While the vaccine development process typically takes ten years, due to the swift and open pathogen sharing, rapid funding availability (including huge at risk investments in R&D driven by supportive IP protections), regulatory agilities and the freedom to

[10] Eric M. Solovy & Deepak Raju, *Compulsory Licensing of Trade Secrets: Illegality Under International and Domestic Laws*, 55 INT'L L. 221, 230-231 (2022).

[11] *Ruckelhaus*, 467 U.S. at 1012 ("The economic value of [a trade secret] lies in the competitive advantage over others that [its owner] enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge.").

[12] *See Ruckelhaus*, 467 U.S. at 1000-1014 (holding that trade secrets are protected by the Takings Clause and that the EPA's disclosure of certain trade secrets submitted by pesticide registration applicants, under certain circumstances, would amount to a taking).

[13] *See*, *e.g.*, MILKEN INSTITUTE, COVID-19 TREATMENT AND VACCINE TRACKER – THE RACE FOR THE VACCINE VISUALIZED (last updated Sept. 2, 2020, 10:16 PM PST), *available at* https://www.covid-19vaccinetracker.org/.

[14] *See* BIO, BIO COVID-19 Therapeutic Development Tracker, *available at* https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker, as listed in the World Trade Organization's Inventory of COVID-19 information resources, *available at* https://www.wto.org/english/tratop_e/covid19_e/inventory_resources_e.htm.

select high-quality, experienced partners and contract manufacturers to rapidly increase supply, millions of patient lives were saved.

Similarly, PhRMA members are engaged in an ongoing, wide range of collaborations and partnerships for a range of infectious diseases, from R&D, manufacturing and distribution, to partnerships aimed at improving access and surveillance.[15] During the COVID-19 pandemic, PhRMA members joined forces with hundreds of key health stakeholders at both domestic and international levels, to address challenges ranging from ramping-up production capacity to partnering with community organizations to address health disparities exacerbated by the pandemic.[16]

Bearing in mind the need for continued – and sustainable – manufacturing efficiency, companies continue to identify and partner with other manufacturers with the appropriate expertise, technical capabilities and facilities. Collaborations are created with specific considerations in mind and are often focused on a single step or stage of the overall manufacturing process that needs to be optimized. These collaborations need to be voluntary to ensure they take place with trusted and capable partners. Notably, during COVID-19 this included entering into manufacturing and other partnerships with direct competitors to maximize production capacity.

Early in the pandemic, there were limited opportunities for clinicians, researchers, policymakers and medicine developers to share real-time scientific insights, disease understanding and policy obstacles. Traditionally used platforms such as scientific publications and formal regulatory guidance development were not rapid enough to inform the development of initial diagnostics, therapeutics and vaccines, which began within weeks of the declaration of a global pandemic. Additionally, there was a lack of a shared understanding about available and emerging technologies. As a result, confusion and lack of alignment about the best treatment options, clinical development priorities and advice from global regulators on the amount and types of data needed to support regulatory 'emergency use' approvals slowed early progress.

Yet accelerating R&D and expanding collaborations alone is not enough. To ensure that products resulting from biopharmaceutical R&D reach patients, long-term changes to the clinical trial process have the potential to lead to a more streamlined and accessible approach to developing new pandemic-related products. Efforts during the pandemic – such as U.S. FDA's timely and updated clinical trial guidance, and advances in information technology and data science – have provided the foundation for potential long-term changes, including: a comprehensive strategy for data modernization and regulatory processes to move to a more virtual environment; increasing the use of digital health technology tools in drug development; decentralizing clinical trials; and advancing the use of real world evidence/real world data. Ultimately, these improvements will

[15] *See* PhRMA, OVERVIEW OF SELECTED COLLABORATIONS, *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/Reservoir-PhRMA-Partnership-Research-Design-Support_Full-Appendix_march222021.pdf. For a more general overview, *see* PhRMA, THE POWER AND PROMISE OF A COLLABORATIVE BIOPHARMACEUTICAL ECOSYSTEM (March 2021), *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/PhRMA_EcosystemMarch-Report_FINAL.pdf.

[16] For an illustrative list of examples, *see* PhRMA, PHRMA MEMBER COMPANY EFFORTS TO FIGHT COVID-19, *available at* https://phrma.org/Coronavirus/PhRMA-Member-Efforts.

lead to more timely access to innovative, safe and effective pandemic-related products for patients.

- **What voluntary steps could Research & Development (R&D) stakeholders take that would build capacities and promote more inclusive research collaborations and participation from basic science through advanced development and clinical research, addressing the global calls for equity and inclusion?**

PhRMA comment: PhRMA members engage in a wide range of voluntary collaborations and partnerships, including research and development, building health care worker capacity to conduct clinical trials and care for patients, strengthening health systems, increasing health literacy and community awareness, openly sharing surveillance data on infectious diseases with healthcare professionals and public health bodies so that they have up-to-date country-specific resistance levels,[17] promoting the development and diffusion of technologies, and ramping up production capacity.[18]

- **What national policies might be developed that (as proposed in the Negotiating Text), "support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications"?**

PhRMA comment: ClinicalTrials.gov is good example of such a national policy. It publicly shares information about clinical trials and their results. For example, it describes the disease or health problem studied, who and how many participants can join the clinical trial, and what researchers learned from the study.

PhRMA members remain committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with safeguarding the privacy of patients, respecting the integrity of national regulatory systems and maintaining incentives for investment in biomedical research. Together with its European sister association – EFPIA – PhRMA developed "Joint Principles for Responsible Clinical Trial Data Sharing."[19] As part of these principles, PhRMA members are committed to make publicly available, "at a minimum, the synopses of clinical study reports (CSRs) for clinical trials in patients submitted to the Food and Drug Administration (FDA), European Medicines Agency (EMA) or national competent authorities of EU Member States. Companies will make this information available consistent with the need to protect patient privacy, publication rights and confidential commercial information through appropriate redaction. Companies will make available technical results or CSR synopses for studies filed with regulators on or after January 1, 2014".

[17] https://www.amrindustryalliance.org/case-study/gsks-survey-of-antibiotic-resistance-soar/

[18] *See*, e.g., *supra* n. 15 and IFPMA, *Advancing Universal Health Coverage in Africa*, (May 22, 2023), available at https://www.ifpma.org/resources/advancing-universal-health-coverage-in-africa/.

[19] EFPIA & PhRMA, PRINCIPLES FOR RESPONSIBLE CLINICAL TRIAL DATA SHARING (updated Jun. 21, 2023), *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMAEFPIAPrinciplesForResponsibleDataSharing2023.pdf.

- **What are respective pros and cons of, the following proposed language in the Negotiating Text: "in accordance with national laws and considering the extent of public funding provided, publish[ing] the terms of government-funded research and development agreements for pandemic-related products, including information on: (a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability and reusability principles; (b) the pricing of end-products, or pricing policies for end-products; (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic"? In your view, are there alternative recommended actions or commitments that could be considered?**

PhRMA comment:

PhRMA has significant concerns with any requirements to share contractual terms of actual agreements that typically include business sensitive and/or confidential information, with respect to technical (research inputs, processes, etc.) and financial (pricing) arrangements. Technical information and pricing policies are subject to trade secret protection; and information on pricing policies, markets, etc. is subject to antitrust laws. Maintaining the confidentiality of such information is not only required by national law (whose application can extend extraterritorially[20]), but compromising confidentiality and trade secret protections will also hinder, complicate and stall industry response during pandemic when time is of the essence.

The proposed transparency requirements would not improve equitable access but would instead infuse legal uncertainty in the contract negotiating process. The European Commission has aptly summarized this, in the context of negotiating the bloc's COVID-19 vaccine contracts:

> Contracts are protected for confidentiality reasons, which is warranted by the highly competitive nature of this global market. All companies require that such sensitive business information remains confidential between the signatories of the contract. This is in order to protect sensitive negotiations as well as business-related information, such as financial information and development and production plans.
>
> Disclosing sensitive business information would also undermine the tendering process and have potentially far-reaching consequences for the ability of the Commission to carry out its tasks, as set out in the legal instruments that form the basis of the negotiations.[21]

As an **alternative recommended action**, WHO Member States could adopt a similar approach to the United States' ClinicalTrials.gov. About 50% of clinical trials go unreported, since the

[20] *See* Michelle Freeman, David Hickerson & William McCaughey, *Prepare for Extraterritorial Enforcement of US Antitrust Law*, LAW360 (Mar. 30, 2023), *available at* https://www.foley.com/wp-content/uploads/imported/82c52fbb494c46b5a92077fb11c3a5c8.pdf.

[21] Press Release, European Commission, Questions & Answers on Vaccine Negotiations (Jan. 8, 2021), *available at* https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_48.

vast majority of Member States do not have transparency provisions in place.[22] The inaccessibility of clinical trial data prevents physicians from making an informed decision with regards to patient care, thus hindering patients from accessing potentially life-saving medical products. Seeking to raise WHO Members' commitments to the level of ClinicalTrials.gov and create a transparent, level playing field would be preferable over trying to supplant an effective model that already exists in the United States.

- **What is the appropriate role for WHO in facilitating the R&D process in areas focusing on infectious diseases?**

PhRMA comment: Pursuant to its constitution, the mandate of the WHO includes "act[ing] as the directing and coordinating authority on international health work" and "assist[ing] Governments … in strengthening health services".[23] With respect to infectious diseases, the WHO is fulfilling its mandate, including through: activating the R&D Blueprint for pathogens of pandemic potential, which aims to improve coordination and allows for the rapid activation of R&D activities during pandemics;[24] coordinated two key documents to help guide the allocation and prioritization of populations to receive COVID-19 vaccines;[25] and publishing routine updates on the status of COVID-19 vaccines within the WHO Emergency Use Listing Procedure /Prequalification evaluation process.[26] WHO manages the Global Influenza Surveillance and Response System (GISRS) network effectively and efficiently to collect comprehensive influenza data in a timely manner, to ensure that the best matched seasonal vaccines are developed and to also rapidly detect the emergence of any pandemic influenza strain.

The WHO should not: prescribe conditions of R&D funding; prescribe or mandate the financing of WHO priorities (which may not align with individual Members' R&D priorities); participate in or intervene in the Member States's review of R&D results; participate in the review of R&D results in scientific journals; interfere in the rapid and transparent sharing of pathogens; be involved in the rapid funding of developers and manufacturing capabilities, participate in or intervene in manufacturing or supply chain decisions on products; be involved in setting prices; or pursue workstreams on IP which undermine R&D and innovation. These responsibilities exceed WHO's constitutional mandate, its expertise and its funding.

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[22] Press Release, WHO, Joint Statement on Public Disclosure of Results from Clinical Trials (May 18, 2017), *available at* https://www.who.int/news/item/18-05-2017-joint-statement-on-registration.

[23] *See supra* n. 3.

[24] *See* WHO, R&D BLUEPRINT AND COVID-19, *available at* https://www.who.int/teams/blueprint/covid-19. For additional background on the R&D Blueprint, *see* https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/who-r-d-blueprint/background.

[25] *See* WHO, WHO SAGE VALUES FRAMEWORK FOR THE ALLOCATION AND PRIORITIZATION OF COVID-19 VACCINATION (Sept. 13, 2020), *available at* https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination and WHO, WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES (Nov. 10, 2023), *available at* https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2023.1.

[26] *See* WHO, REGULATION AND PREQUALIFICATION, *available at* https://www.who.int/teams/regulation-prequalification/eul/covid-19.

Article 10, Sustainable Production

- **What approaches or incentives might be used to encourage manufacturers and others "to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licenses to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries"?**

PhRMA comment: Voluntary licenses (VLs) can be one of several tools that help expand access to medical products and scale up production and security of supply. VLs are more feasible to implement when products are in a therapy area where there are limited suitable alternative products available; policies and funding are in place to support the purchase of the licensed products at volumes that are attractive and sustainable for generic producers; products are easy to manufacture and administer and do not require complex, capital-intensive facilities; and clear demand forecasts are available to support generic and third-party investments to build appropriate manufacturing capacity and ensure sustainability.

Enforceable IP rights enable innovators to manage and share (i.e., voluntarily license) their product designs, manufacturing technologies and know-how with others – including, as shown during the COVID-19 pandemic, potential competitors – with the assurance that they can seek remedies if those parties misappropriate the innovator's IP.[27] In this sense, IP rights engender trust among collaborators and create opportunities for innovative partnerships.[28]

In addition to incentivizing R&D and the necessary investment to bring new medical products into existence, IP protection enables the rapid manufacture and distribution of pandemic-related products. As companies seek to scale up production – particularly in the event of a pandemic – they identify trusted partners who have the appropriate expertise, technical capabilities and facilities to produce safe, effective and high-quality products. Each manufacturer is best positioned to identify such partners, underscoring the importance of ensuring that such collaborations are voluntary.

The pharmaceutical industry relies upon a broad and geographically diverse global supply chain, which depends on the free movement of goods and supply across borders, including raw materials. Trade bottlenecks and disjointed requirements for localized manufacturing can add uncertainty, cost and delays in manufacturing and patient access. While geographical diversity is certainly an important factor that biopharmaceutical companies consider when seeking to build capacity, capacity is created with specific considerations in mind, often focused on a single step or stage of the overall manufacturing process (e.g., production of specific ingredients or fill and finish), ensuring that manufacturing is sustainable in the pre- and post-pandemic period.

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[27] *See generally*, Jennifer Brant & Mark F. Schultz, UNPRECEDENTED: THE RAPID INNOVATION RESPONSE TO COVID-19 AND THE ROLE OF INTELLECTUAL PROPERTY (Nov. 2021), *available at* https://www.unpackingip.org/ (hereinafter, "Brant & Schultz").

[28] *See* Eric M. Solovy, *The Doha Declaration at Twenty: Interpretation, Implementation, and Lessons Learned on the Relationship Between the TRIPS Agreement and Global Health*, 42 NW. J. INT'L L. & BUS. 253, 292 (2022).

Ultimately, the goal should not necessarily be equitable *manufacturing* or *local manufacturing*, but rather ensuring equitable *access* to the authorized product. The COVID-19 experience includes lessons from African biopharmaceutical manufacturers that were unable to sustainably manufacture and sell vaccines due to a variety of factors, including fluctuating/waning demand and a lack of timely regulatory authorizations to export product throughout the continent.[29] It is natural that many emerging markets seek to expand local production, but attracting foreign direct investment in local manufacturing depends on a number of enabling factors. Promoting those factors is beyond the mandate, capacity and resources of the WHO, and as such the WHO Pandemic Agreement should not be the conduit for those discussions.

In addition to bilateral partnerships and VLs, another way to facilitate equitable access in developing countries to new medical products is through voluntary patent pools, which allow third party manufacturers to acquire non-exclusive licenses for the IP needed to produce the products. One such example is the Medicines Patent Pool (MPP). Past experience shows that the MPP has helped increase access to several life-saving medicines for low- and lower-middle-income countries. During the COVID-19 pandemic, innovators worked with MPP to issue licenses for their therapeutics to generic manufacturers to meet the needs of more than 100 low- and lower-middle-income countries. Yet more could be done to make the MPP more attractive as a mechanism during pandemic times to help facilitate non-exclusive VLs. One of the major shortcomings of the MPP has been the significant (greater than 6 months') delays in finalizing agreements with generic manufacturers once the innovator company had signed the VL with the MPP. This shortcoming could be addressed through administrative changes, such as: increasing staff numbers, in particular contract/IP lawyers, and updating the MPP's IT system. Additionally, a key issue identified in lessons learned has been delays with WHO prequalification of sublicensees, which significantly affected the ability of sublicensees to enter markets fast.

- **How helpful or harmful would the following proposed obligations for governments be for public health, business, and innovation interests generally:**
    - **(a) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;**

PhRMA comment: During the COVID-19 pandemic, many PhRMA members voluntarily offered preferential royalty payment schemes to licensees for their pandemic-related products during the Public Health Emergency of International Concern (PHEIC). For example, Gilead's and Merck's bilateral VLs covering their COVID-19 therapeutics provided grace periods during which licensees would not owe any royalties (and the Gilead licenses remain royalty-free as of October 2023).[30] In its VL agreement with the MPP covering nirmatrelvir (+ ritonavir), Pfizer waived royalties on all sales in low-income countries and waived "royalties on sales in all countries covered by the [license] agreement while COVID-19 remain[ed] classified as a Public

[29] *See*, *e.g.*, Kerry Cullinan, *Important Lessons From the African Vaccine Manufacturer That Could Not Sell a Single Dose*, HEALTH POLICY WATCH (Nov. 5, 2023), *available at* https://healthpolicy-watch.news/important-lessons-from-the-african-vaccine-producer-that-never-sold-a-single-dose/.

[30] *See* ITC Report, at 175-176, 240.

Health Emergency of International Concern by the World Health Organization" (i.e., until May 2023).[31] Merck and Shionogi & Co. also waived royalty payments until May 2023 in the MPP VLs covering their COVID-19 therapeutics.[32]

It is critical that such arrangements are made on mutually agreed terms and take into account contractual and other relevant obligations.

PhRMA opposes any provisions in the WHO Pandemic Agreement that impose higher burdens on companies receiving public funding to assist in the development of pandemic-related products than solely privately-funded companies. Such disparate treatment of companies receiving any public funding – particularly when such funding is likely to be only a portion of that needed to develop an innovative medicines – would disincentivize manufacturers of pandemic-related products from accepting government funding and inhibit public private partnerships. Conditions on the receipt of U.S. public funding should be governed by U.S. law and left to the U.S. government and manufacturers to decide, by contract, on a case-by-case basis. The WHO is not an appropriate regulator of U.S. government funding conditions.

- **(b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products; and**

PhRMA comment: Please see our response above related to proposed transparency provisions in Article 9.

- **(c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks."**

PhRMA comment: As shown during the COVID-19 pandemic, the U.S. innovative biopharmaceutical industry has pursued a variety of bilateral and multilateral mechanisms to prioritize global access to affordable COVID-19 therapeutics.[33] In many cases, this involved entering into royalty-free agreements for the voluntary licensing of technologies, sometimes even before marketing authorization had been granted by any regulatory authority.

Recognizing the far-reaching benefits of working with multilateral institutions, PhRMA member companies partnered with the MPP, Global Fund, UNICEF and others to help expand access. For example, leveraging its existing network, Gilead signed VLs with foreign generic manufacturers – including in Egypt, India and Pakistan – to expand access to remdesivir, an antiviral medication to treat COVID-19, in 127 countries, most of which are low-income or lower-middle-

[31] Press Release, Pfizer, Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries (Nov. 16, 2021), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing.

[32] *See* ITC Report, at 180.

[33] *See* Megan Van Etten, *Partnerships are driving global COVID-19 treatment access*, PHRMA (Sept. 22, 2022), *available at* https://phrma.org/Blog/Partnerships-are-driving-global-COVID-19-treatment-access.

income and have populations with limited access to health care. Each of Gilead's licensees maintain contracts with Gilead that involve technology transfer and information sharing.[34] Together, these partnerships treated more than 13 million patients globally, including eight million in low and lower-middle-income countries,[35] an accomplishment that was appropriately recognized by the U.S. Patent and Trademark Office in 2022 with a "Patents for Humanity" award.[36]

Merck signed an agreement with the MPP that further diversified the manufacturing base for quality-assured molnupiravir across Asia, Africa, Europe and North America and helped create access pathways for generic molnupiravir in more than 100 low- and middle-income countries following appropriate regulatory approvals.[37] Pfizer signed similar agreements with the MPP for PAXLOVID™ that enabled qualified sub-licensees to supply countries comprising approximately 53 percent of the world's population, including all low- and lower-middle-income countries and some upper-middle-income countries, and by March 2022, over 35 generic manufacturers had signed agreements with the MPP to produce generic versions of the product.[38] In March 2022, just three months after receiving FDA EUA, Pfizer signed a supply agreement with UNICEF for up to 4 million treatment courses of its oral COVID-19 treatment for distribution to 137 low- and middle-income-countries, subject to local regulatory authorization or approval.[39] As part of a September 2022 agreement, Pfizer also agreed to supply the Global Fund with up to 6 million treatment courses of its oral COVID-19 treatment for supply to 132 Global Fund-eligible low- and middle-income countries in all regions of the world, subject to local regulatory authorization or approval.[40] Merck & Co., Inc. (Merck), also signed an agreement

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[34] Gilead, Access Partnerships, *available at* https://www.gilead.com/purpose/medication-access/global-access/access-partnerships.

[35] Mike Boyd, *Gilead's Path to Equitable Global COVID-19 Treatment Access* (Oct. 4, 2022), *available at* https://stories.gilead.com/articles/gilead-path-to-equitable-global-covid-19-treatment-access.

[36] *See* USPTO, PATENTS FOR HUMANITY: COVID-19 CATEGORY AWARD RECIPIENTS, available at https://www.uspto.gov/ip-policy/patent-policy/patents-humanity/patents-humanity-covid-19-category-award-recipients.

[37] Press Release, Merck, The Medicines Patent Pool (MPP) and Merck Enter Into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries (Oct. 27, 2021), *available at* https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countri/#:~:text=KENILWORTH%2C%20N.J.%2D%2D(BUSINESS%20WIRE,COVID%2D19%20antiviral%20medicine%20for.

[38] Press Release, MPP, Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries (Nov. 16, 2021), *available at* https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries.

[39] Press Release, Pfizer, Pfizer to Supply UNICEF up to 4 Million Treatment Courses of Novel COVID-19 Oral Treatment for Low- and Middle-Income Countries (Mar. 22, 2022), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-unicef-4-million-treatment-courses-novel.

[40] Press Release, Pfizer, Pfizer to Supply Global Fund Up to 6 Million PAXLOVID™ Treatment Courses for Low-and-Middle-Income Countries (Sept. 22, 2022), *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-

with UNICEF to allocate up to 30 percent (three million courses) of its anti-viral supply to low and middle-income countries through the first half of 2022. These arrangements accelerated and diversified the production of molnupiravir and made it more accessible in more than 100 low- and middle-income countries.[41]

- **How can we work to promote a globally sustainable medical countermeasures (MCM) manufacturing system, including leveraging regional approaches to production and maintaining readiness of facilities between pandemic emergencies?**

PhRMA comment: PhRMA members are devoted to inventing, manufacturing and distributing medicines that enable people to live longer, healthier and more productive lives. Under the existing system, the U.S. biopharmaceutical industry is the world leader in new medicine research and innovation – producing more than half the world's new medicines in the last decade.

For the reasons already noted above in response to the first question under Article 10, it is unrealistic that, in addition to the existing system, biopharmaceutical companies around the world will be able to support a new MCM manufacturing system between pandemics. Instead, it is important to ensure that the existing innovation ecosystem is allowed to operate without restrictions and that barriers to equitable access are addressed in the appropriate fora. For example, proposed commitments that address topics with trade-related elements should be addressed in the WTO. PhRMA supports ongoing work in the WTO to promote open supply chains; address trade restrictions and unnecessary interference with international traffic and trade; and promote the voluntary transfer of technology and know-how into developed and diversified manufacturing capacity. Each of these topics, among others, were the subject of the WTO's response to the COVID-19 pandemic, adopted at the 12th Ministerial Conference in June 2022 and continue to be actively considered in multiple WTO bodies.[42]

For purposes of the Pandemic Agreement, to ensure "globally sustainable" manufacturing, more emphasis should be placed on ensuring that there is adequate government funding in place to support MCM procurement, strengthening health systems, reviewing the WHO's prequalification program to verify that it is fit for purpose and appropriately resourced, and bolstering national regulatory approval systems. A recent conference organized by the African Union Development Agency-NEPAD, WHO and the African Medicines Regulatory Harmonization program found that some "70 % of countries globally have weak national medicines regulatory systems" and that "stronger regulatory systems can increase equitable access to life-saving medicines".[43] In addition, during pandemics, high-income countries, in partnership with manufacturers, should ensure that

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treatment#:~:text=NEW%20YORK%2D%2D(BUSINESS%20WIRE,19%20Response%20Mechanism%20(C19RM).

[41] Press Release, Merck, Merck and Ridgeback Announce Supply Agreement with UNICEF for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine (Jan. 18, 2022), *available at* https://www.merck.com/news/merck-and-ridgeback-announce-supply-agreement-with-unicef-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine/.

[42] *See* WTO Ministerial Conference, *Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics*, WTO Doc. WT/MIN(22)/31 (Jun. 22, 2022), *available at* https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True.

[43] *Supra* n. 2.

a portion of real-time production of pandemic countermeasures is distributed to priority populations in low- and lower-middle-income countries.

With respect to "maintaining readiness of facilities between pandemic emergencies," to ensure their durability and sustainability, care should be taken that any new manufacturers (particularly in low- and lower-middle income countries) have a robust business plan and long-term financing in place, with projections for what they will produce and sell during non-pandemic times. This was one of the lessons learned from 2006-2019, when the U.S. government funded some middle income countries to establish local seasonal influenza vaccine manufacturers. Only one country's program, out of the initial 19 countries that were identified, succeeded and continues to have an active licensed vaccine manufacturer.[44]

Article 11, Transfer of Technology and Know-How

- **What measures could be taken, or incentives provided, to "strengthen existing, and develop innovative, multilateral mechanisms [under WHO], including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries"?**

PhRMA comment: Voluntary industry partnerships – such as VLs and contract manufacturing arrangements – are the best vehicles to promote the sharing of technology for biopharmaceutical products. The World Intellectual Property Organization (WIPO) has taken a leading role in developing such mechanisms and is the appropriate multilateral organization for this work, which is not within the expertise of the WHO. In its recent report on the market for COVID-19 diagnostics and therapeutics, the U.S. International Trade Commission (ITC) recognized that many VLs on COVID-19-related patents offer licensees access to the licensor's technology (including technical know-how) to produce generic versions of the patented product and highlighted this feature as a key advantage of VLs.[45] In contract manufacturing arrangements, contract manufacturers often receive technology and know-how from the inventor in order to produce the inventor's product.[46]

Importantly, contract manufacturing and VL arrangements that support robust technology transfer would not be possible absent strong protections for IP rights. IP protections facilitate these agreements by reassuring rights holders that they can share their product designs, manufacturing technologies and know-how with others – including potential competitors –

[44] PATH, *Vietnam-produced seasonal influenza vaccine licensed for production and use*, (Jan. 15, 2019), *available at* https://www.path.org/our-impact/media-center/vietnam-produced-seasonal-influenza-vaccine-licensed-production-and-use/#:~:text=Rick%20Bright%2C%20BARDA%20Director%20and,Influenza%20Vaccine%20Capacity%20Building%20project.

[45] *See* International Trade Commission, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, USITC Pub. No. 5469 (Oct. 2023) (link), at 174-175, 177, 182 (hereinafter, "ITC Report").

[46] *See* WIPO, INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER FOR COVID-19 VACCINES ASSESSMENT OF THE RECORD 18, 56 (2023), *available at* https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf.

subject to enforceable rights in the event that those parties misappropriate the innovator's IP.[47] Without these safeguards, IP rights holders would not be willing to partner with other manufacturers or share their proprietary knowledge with them.

To the extent multilateral mechanisms are used to facilitate technology transfer, such sharing must be entirely voluntary under those systems. PhRMA and its members are also wary of the proliferation of new multilateral mechanisms with conflicting objectives. Certain longstanding mechanisms, such as the MPP, have proven more effective and protective of IP rights than newer mechanisms created in the specific context of the COVID-19 pandemic.[48] The MPP also has years of experience vetting and monitoring IP licensees to ensure they are equipped to produce safe and high-quality medicines.[49] The Administration should focus on strengthening existing mechanisms, like the MPP, that have a proven track record of protecting IP rights and promoting high-quality manufacturing.

- **What measures could be taken, or incentives provided, to "make available non-exclusive licensing of government-owned technologies, on mutually agreed terms as appropriate, for the development and manufacturing of pandemic-related products, and publish the terms of these licenses"?**

PhRMA comment: To the extent the WHO Pandemic Agreement commits the Parties to facilitate licensing of government-owned technologies, only *wholly* government-owned technologies should be subject to such commitments. Coverage of technologies with partial private ownership raises constitutional concerns (specifically, concerns related to the expropriation of private property without just compensation) and, for the reasons already noted above, could disincentivize manufacturers of pandemic-related products from accepting government funding and inhibit public private partnerships. Further, Parties must only commit to publish the terms of these technology licenses to the extent publication comports with national laws protecting and regulating disclosure of confidential commercial information.

- **In your view, is there a lack of transparency concerning information regarding pandemic-related products, their technological specifications, and manufacturing details? If so, could the establishment of a new mechanism at the WHO effectively address this lack of transparency?**

PhRMA comment: Extensive information about pandemic-related products is available in the public domain. Governments, private healthcare providers and manufacturers across the globe publish descriptions of the ingredients in and uses of COVID-19 products, including vaccines, therapeutics, diagnostics and personal protective equipment. In addition, as noted above, inventors of COVID-19 products often share technical product information, including

[47] *See generally*, Brant & Schultz.

[48] *See* Pharmaceutical Research and Manufacturers of America (PhRMA), Pre-hearing brief to the U.S. International Trade Commission in connection with Inv. No. 332-596, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, March 17, 2023 (hereinafter, "PhRMA ITC Prehearing Brief"), *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Policy-Papers/PhRMAs-Prehearing-Brief.pdf , at 16 and ITC Report, at 178-183 for descriptions of successful IP licensing agreements facilitated by the MPP during the COVID-19 pandemic.

[49] *See* ITC Report, at 182.

manufacturing details, with other manufacturers through VLs and contract manufacturing arrangements. Moreover, the ITC, WIPO, WTO and private organizations and authors have published comprehensive reports on the commercial, economic and legal conditions shaping markets for COVID-19 products.[50]

In any event, transparency initiatives focused on the dissemination of technological specifications and manufacturing process details for pandemic-related products fall outside of the WHO's mandate and expertise. Such initiatives may also jeopardize the confidential business information of key innovators in the medical sector (and may violate national laws that prohibit or regulate the disclosure of such information). This, in turn, would threaten the viability of future commercial partnerships and reduce the value of R&D investments aimed at developing new, innovative pandemic-related products.

- **What net impacts, positive or negative, would you envision arising from commitments presently outlined in Article 11.3, including:**
    - **"(a) commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;**

PhRMA comment: PhRMA opposes any provisions that would encourage or commit the parties to permanently or temporarily weaken international commitments to protect IP, including any waivers of protections guaranteed by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). Such waivers not only are demonstrably unnecessary to expand manufacturing of and access to pandemic-related products, but also threaten future medical innovation (and therefore, future pandemic preparedness).

Unfortunately, at its 12th Ministerial Conference, the WTO issued a Decision that waived certain IP rights related to patents "required for the production and supply of COVID-19 vaccines" and their necessary ingredients and manufacturing processes ("TRIPS waiver").[51] In so doing, this TRIPS waiver suspended several longstanding requirements for governments to protect patents and other IP for COVID-19 vaccine technologies, including those developed and produced in the United States. Experience with this TRIPS waiver has demonstrated that waiving commitments to protect IP disincentivizes innovation and does not increase access to medicines. While this TRIPS waiver has been in effect for a year and a half, to date no WTO Member has issued a CL under this TRIPS waiver or even notified the TRIPS Council of any measure taken to implement this TRIPS waiver. In other words, this TRIPS waiver has had no positive impact on the capacity

[50] *See, e.g.,* WIPO, INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER FOR COVID-19 VACCINES ASSESSMENT OF THE RECORD 18, 56 (2023), *available at* https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf; *see also* Brant & Schultz; ITC Report; WTO, COVID-19 AND WORLD TRADE, *available at* https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.

[51] *See* WTO Ministerial Conference, *Ministerial Decision on the TRIPS Agreement: Adopted June 17, 2022*, ¶ 1 and fn. 2, WTO Doc. WT/MIN(22)/30 (Jun. 22, 2022), *available at* https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True.

or distribution of COVID-19 vaccine manufacturing, or on patient access to COVID-19 vaccines. Further, there is no evidence that expansion of this TRIPS waiver to cover COVID-19 diagnostics and therapeutics would increase patient access to those products.

The TRIPS waiver serves as a recent example demonstrating that there is no reason to believe that waivers of IP rights positively impact the production and availability of pandemic-related products. However, such waivers *do* negatively impact medical innovation and divert government resources away from addressing actual barriers to pandemic preparedness. For example, governments unfortunately have devoted significant diplomatic and bureaucratic resources to the TRIPS waiver negotiations (and to consideration of its proposed expansion to cover diagnostics and therapeutics). These extensive resources would be far better spent tackling well-documented global trade and customs barriers, regulatory product approval challenges, consumer skepticism and last-mile delivery obstacles that actually harm global availability of critical medical products.[52] However, the WTO's 12th Ministerial Conference resulted in the adoption of the TRIPS waiver but produced no concrete commitments to reduce or eliminate any of these trade, customs or regulatory barriers. For example, the WTO's most topical deliverable, the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, included a variety of recognitions, recollections and reiterations but did not require any new meaningful actions or commitments by WTO Member States.

Waivers of IP rights also create uncertainty in the value of IP rights by creating risks that those rights "may be taken away abruptly by an unpredictable government decision lacking any procedural safeguards."[53] This uncertainty damages the investment returns that IP owners can receive for their rights, dissuades IP rights holders from bringing their products to new markets and reduces the ability of inventors to grant beneficial VLs.[54] Indeed, according to the Chief Executive Officer of a small biopharmaceutical company doing critical research in the COVID-19 space, "uncertainty around the ability to control and enforce our IP rights globally discourages investment ... especially from pre-revenue early-stage biopharmaceutical companies whose most important assets are their intellectual property."[55]

Further, strong and predictable IP rights reassure innovators that they can share (i.e., voluntarily license) their product designs, manufacturing technologies and know-how with others – including potential competitors – subject to enforceable rights in the event that those parties misappropriate the innovator's IP.[56] In this sense, IP rights engender trust among market participants and create opportunities for innovative partnerships. If IP protections are weakened, rights holders will be dissuaded from investing in further innovation, reaching new markets and engaging in innovative manufacturing partnerships. In sum, waivers of IP rights risk destabilizing the IP-based incentive systems that fuel medical innovation and manufacturing. In doing so, waivers of IP rights work *against*, not for, future pandemic preparedness.

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[52] *See* PhRMA ITC Prehearing Brief, at 35-41 (discussing these barriers to COVID-19 product access).

[53] Solovy TRIPS Waiver Article, at 7.

[54] *See* Solovy TRIPS Waiver Article, at 7.

[55] *See* Marc Busch, *The Market's Response to the TRIPs Waiver*, WILSON CENTER (July 14, 2023), *available at* https://www.wilsoncenter.org/article/markets-response-trips-waiver.

[56] *See generally*, Brant & Schultz.

- **(b) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and**

PhRMA comment: Please see our response above related to waivers or management of royalty provisions in Article 10. In addition, there is nothing in the TRIPS Agreement that would permit violations of patent rights or other IP rights when the research or development were funded, in whole or in part, by the government.

- **(c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, with qualified third-party manufacturers when the withholding of such information prevents or hinders urgent manufacture by qualified third parties of a pharmaceutical product that is necessary to respond to the pandemic"?**

PhRMA comment: In PhRMA's view, this language is unnecessary as many manufacturers of pandemic-related products already share trade secrets with qualified partners under VLs and contract manufacturing arrangements. The global response to COVID-19 involved many examples of this, including: (1) Gilead's and Merck's bilateral VLs for their COVID-19 therapeutics patents;[57] (2) each of the voluntary MPP licenses covering COVID-19 therapeutics patents;[58] (3) Lilly's voluntary licenses with eight Indian manufacturers to expand manufacturing capacity for baricitinib;[59] (4) AstraZeneca's partnerships with vaccine manufacturers across the globe; (5) Pfizer's manufacturing partnership with Biovac in South Africa; (6) Moderna's vaccine manufacturing agreement with Lonza; (7) Baylor College of Medicine's agreements with vaccine manufacturers in India and Indonesia; and (8) Novavax's vaccine supply agreement with the Serum Institute of India, among many others.[60]

[57] *See* ITC Report, at 175.

[58] *Id.*, at 182.

[59] *Id*. at 180.

[60] *See generally* Elize Massard da Fonseca et al., *Vaccine technology transfer in a global health crisis: Actors, capabilities, and institutions*, 52 RES. POLICY 1 (2023), *available at* https://www.sciencedirect.com/science/article/pii/S0048733323000239; *see also* WIPO, INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER FOR COVID-19 VACCINES ASSESSMENT OF THE RECORD 35, 37, 62-63, 71-72, 85, 95 (2023), *available at* https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-39-en-intellectual-property-and-technology-transfer-for-covid-19-vaccines-assessment-of-the-record.pdf; Apornrath Phoonphongphiphat, *Siam Bioscience to produce Oxford COVID-19 vaccine for ASEAN*, NIKKEI ASIA (Oct. 14, 2020), *available at* https://asia.nikkei.com/Spotlight/Coronavirus/Siam-Bioscience-to-produce-Oxford-COVID-19-vaccine-for-ASEAN.

Article 12, Access and Benefit Sharing

- **A key negotiating objective of the United States has been to ensure that all countries share pathogen samples and associated data, including genetic sequence data, from emerging outbreaks quickly and transparently to facilitate response efforts, including the rapid creation of safe and effective vaccines, diagnostic tests, and treatments.**
    - **What sample and data access impediments have you encountered in the past or what impediments would you envision based on the proposed Pathogen Access and Benefit Sharing (PABS) System in the Negotiating Text that might thwart or delay research efforts?**
- **Does implementation of Nagoya Protocol requirements impede the rapid development or deployment of vaccines, diagnostic test, and treatments? Explain.**
    - **How important is a commitment by negotiating parties to provide parties with the access to pathogen samples and data that are needed to contribute to rapid creation of safe and effective vaccines, diagnostic tests, and treatments?**

PhRMA comment: PhRMA supports prompt, unrestricted access to pathogen samples and genetic sequence data (GSD) to facilitate the rapid development of safe and effective pandemic-related products. To that end, PhRMA strongly opposes any language in the WHO Pandemic Agreement that would link access to pathogens and related GSD to the sharing of "benefits" obtained through utilization of those resources, thus creating unnecessary bureaucratic hurdles that would compromise the flexibility and cooperation needed in a pandemic response. Rather, the WHO Pandemic Agreement should address pathogen sample and GSD access as a standalone subject, and should not make it contingent on separate commitments to promote equitable access.

A framework that links pathogen access to benefit-sharing is inappropriate and counterproductive. (To the extent that such provisions seek to impose mandates on manufacturers, they would also raise constitutional concerns under the Takings Clause.) The core instrument adopting such a framework is the CBD's Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization ("The Nagoya Protocol").

The Nagoya Protocol encourages Parties to require that users of genetic resources (GR) obtain the prior informed consent (PIC) of countries with sovereign rights to those resources.[61] It further urges Parties to require that GR users share the benefits of their use, on mutually agreed terms (MAT), with relevant Indigenous communities and mandates, to the extent required by national law, that benefits of GR use be shared according to MAT with the providing country or

[61] *See* Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, arts. 6-7, Oct. 29, 2010, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (hereinafter "Nagoya Protocol").

country of origin.[62] In short, the Nagoya Protocol encourages Parties to adopt a package of enforceable ABS rules governing the acquisition and utilization of biodiversity resources.

Applying an ABS framework modeled on the Nagoya Protocol to pathogens of pandemic potential or to their GSD has proven to be perverse and create serious bottlenecks.[63] ABS systems exist to protect valuable, exhaustible biodiversity resources from over-exploitation and to allow the original stewards of those resources (i.e., countries of origin and Indigenous communities) to share in the development that does occur. The design of ABS systems encourages countries with sovereignty over biodiversity resources to withhold consent for others' access unless those users provide monetary payments or non-monetary compensation in return. Conversely, pathogens, by their very nature, have no inherent value worthy of protection and as such are not a resource for which any WHO member should be seeking compensation.

If applied to pathogens with pandemic potential and associated GSD, this model poses serious dangers to the rapid development of effective vaccines, diagnostics and treatments. Conditioning access to pathogen samples and GSD on benefit-sharing will delay or even thwart biopharmaceutical innovators' access to critical samples and data.[64] This will, in turn, impede development and deployment of lifesaving medical solutions. In some cases, innovators may even be forced to rely on the international spread of the virus in order to obtain samples. In other words, conditioning access to pathogens of pandemic potential and associated GSD on benefit-sharing will negatively impact pandemic preparedness and threaten lives on multiple dimensions.

- **Are alternative strategies for "access" to samples and data available and how do they compare in terms of effectiveness and efficiency?**

- **How might such commitments impact researchers and institutions?**

PhRMA comment: The U.S. National Institute of Allergy and Infectious Diseases' (***NIAID***) Biodefense and Emerging Infections Research Resources Repository (***BEI Resources***) is an example of a successful "access" mechanism for pathogen sample and data sharing between researchers and innovators.[65] BEI Resources has been working for decades to promote rapid, free, safe and secure sample and data sharing between qualified institutions. The BEI Resources

[62] *See* Nagoya Protocol, art. 5.

[63] A 2023 Report outlines how applying the Nagoya Protocol ABS model to disease outbreaks has blocked or delayed access to pathogen samples in several instances, namely Seasonal influenza, SARS-CoV-2, Zika, Monkeypox, Japanese Encephalitis, Foot and Mouth Disease, Ebola and African Swine Fever. The Report shows that delays or refusals for pathogen-sharing have led to: (i) sub-optimal seasonal influenza vaccine composition, including lack of regional representativeness; (ii) diagnostics that were not tailored or tested against original or new variants of pathogens; and (iii) skewed and non-representative epidemiology in genomic surveillance. Covington Report on the Impact of the Nagoya Protocol on R&D in Infectious Diseases (Jan. 17, 2023), *available at* https://www.cov.com/en/news-and-insights/news/2023/01/new-report-shows-that-politicization-of-sharing-pathogens-undermines-global-health-security.

[64] Abbie-Rose Hampton et al., *Equity in the Pandemic Treaty: Access and Benefit-Sharing as a Policy Device or a Rhetorical Device?* 51 J. L., MED. & ETHICS 217, 217-220 (2023) ("Additionally, the application of ABS rules in the global health policy arena has already led to fundamentally anti-scientific outcomes where, for example, vaccines have been developed using suboptimal pathogen strains due to researchers being unable to negotiate access to the most appropriate samples.").

[65] *See* https://www.beiresources.org/.

system has demonstrated its success in advancing infectious disease research, while also demonstrating its commitment to strong IP protections for sample depositors.[66] Outside the U.S., a similar mechanism exists called the European Virus Archive Global (EVA-G).[67] PhRMA supports efforts to establish mechanisms modelled off of BEI Resources in other jurisdictions. While BEI facilitates the safe and secure access to physical pathogens, numerous public databases facilitate the access to genetic sequence data (GSD) and associated digital sequence information, such as GenBank, GISAID and the European Nucleotide Archive (ENA).

For years, these data sharing systems have helped the scientific community exchange information about emerging infectious diseases and have fostered the rapid development of life saving vaccines and treatments for a range of pathogens. Biopharmaceutical companies leverage GSD databases to help identify new biological targets and the most relevant pathogen strains to support R&D for new medicines and vaccines. The primary advantage to using GSD is the speed at which it can be shared, accessed and compared – much more rapidly than physical pathogen samples. Ensuring the unrestricted global flow of genetic sequence data is increasingly important as the world faces an increasing likelihood of pandemics.

- **The Article 12 negotiating text proposes that sanctioned use of the WHO PABS System would be recognized as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol; such recognition would provide for the exemption of the pathogens covered under the PABS System from additional access and benefit sharing requirements.**
    - **How valuable would such an "exemption" be to U.S. stakeholders? What pathogens would benefit from exemption status?**

PhRMA comment: The U.S. is home to the world's most innovative biopharmaceutical sector. COVID-19 has demonstrated the role of American companies in developing life-saving vaccines, therapeutics and diagnostics. Although the U.S. is not a party to the Nagoya Protocol, American companies are directly affected by having to comply with the 100+ national ABS laws implementing it. Since October 2014, these companies are increasingly facing the delays and difficulties in accessing pathogens and GSD for their research and development. As a result, U.S. innovative pharmaceutical industry, and by extension, U.S. citizens' health security, is directly impacted by the application of the Nagoya Protocol to pathogens.

Therefore, PhRMA and its members oppose any system that links access to pathogens of pandemic potential or their GSD with so-called "benefit-sharing" commitments. Further, PhRMA takes the position that *all* pathogens and their GSD should be exempted from the CBD, Nagoya Protocol and national ABS instruments. When applied to critical pathogen samples and GSD, these ABS systems result in anti-public health outcomes by hindering researchers' and biopharmaceutical innovators' ability to develop lifesaving medicines. Instead, pathogens and

[66] *Id*.; *see also* NIAID, BEI RESOURCES REPOSITORY, *available at* https://www.niaid.nih.gov/research/bei-resources-repository.

[67] *See* https://www.european-virus-archive.com/.

GSD should be subject to specialized access instruments that are *not* linked to benefit-sharing and that promote rapid, free, safe and unencumbered dissemination of these critical resources.

To this end, the WHO Pandemic Agreement should address rapid pathogen sample and GSD access as a standalone subject, and should *not* make it contingent on separate commitments to promote equitable access. Further, prior to concluding the WHO Pandemic Agreement, the Parties to the CBD and Nagoya Protocol should explicitly confirm that those instruments do not apply to pathogens and GSD covered by the WHO Pandemic Agreement, in accordance with Article 4, Paragraph 4 of the Nagoya Protocol.

- **The Article 12 negotiating text envisions parties agreeing to set aside certain percentages of pandemic-related products (proposed in the current negotiating text as a minimum of 20%) and facilitating their exportability.**
    - **What, from your perspective, are the pros and cons of such a requirement?**
    - **Would such a requirement advance or hinder rapid research and development efforts?**

PhRMA comment: Consistent with the Berlin Declaration,[68] the U.S. innovative biopharmaceutical industry is willing to work with governments to design and fulfill an equitable access commitment in the WHO Pandemic Agreement which allows for more flexibility, to reflect the nature and epidemiology of the pandemic as well as the capabilities of the innovative company. In addition, in designing such a commitment it is critical to provide appropriate guardrails for repurposed products to safeguard patient supply to those medicines for the original indications. In PhRMA's view, such a commitment would be a positive development, as it would advance equitable access to pandemic-related products in low- and lower-middle-income countries, while drawing upon the various and variable strengths of innovators.

To secure such a commitment, Parties to the WHO Pandemic Agreement must reaffirm that: (1) this supply commitment will not have any implications for or linkages to pathogen-sharing or technology transfer (which should remain entirely voluntary); (2) they will not fulfill this supply commitment in any manner that prejudices IP rights associated with pandemic-related products; and (3) they will maintain free and open trade of pandemic-related products and their inputs.

- **The Article 12 negotiating text further envisions required monetary contributions from recipients of shared samples or data, including researchers and manufacturers, for privileges of access. What in your view is the monetary value of access that would be provided in terms of an annual or percentage-based contribution from your organization? How would requiring monetary contributions from academic, government, or other nonprofit research institutions impact, positive or negative, research?**

[68] *See* https://www.ifpma.org/news/berlin-declaration-biopharmaceutical-industry-vision-for-equitable-access-in-pandemics/.

PhRMA comment: As demonstrated by BEI Resources and other similar platforms, pathogen and GSD-sharing mechanisms are most successful when they facilitate rapid, secure and *open* access to these critical resources. At most, they require a small fee to cover the logistics cost of preserving and shipping samples. They do not require "benefit-sharing" on products or processes developed from these samples as that would disincentivize use of those samples and data. Replacing this open access, networked system with a WHO-controlled PABS will likely force many researchers and innovators to seek suboptimal samples from alternative sources,[69] or pressed to wait for the geographic spread of a pathogen to obtain a pathogen sample or sequence. In cases where entities must access pathogens or data from WHO subject to the negotiation of "mutually agreed terms", entities may be forced to curtail R&D expenditures on other projects in order to free up funds for pathogen and GSD access negotiations and payments. In turn, funding available for R&D aimed at future pandemic preparedness could be severely impacted. Finally, imposing upfront monetary contribution requirements would raise constitutional concerns under the Takings Clause and would be particularly punitive for small start-up biotechs.

- **The Article 12 negotiating text specifies other benefits that should be considered for provision to developing countries, including "(i) encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries . . . to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products; (ii) tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products . . .; and (iii) encouraging of laboratories . . . to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials."**

    - **How helpful would these additional measures be in advancing the rapid creation and/or production scaleup of safe and effective vaccines, diagnostic tests, and treatments? What are the risks or potential negative impacts could come from including such provisions?**

    - **What incentives might be provided to stakeholders to encourage/assure participation in such voluntary measures?**

PhRMA comment: As stated above, PhRMA opposes the linkage of such commitments to pathogen- or GSD-access. Further, PhRMA does not believe that this language is necessary in the WHO Pandemic Agreement, as biopharmaceutical innovators regularly engage in these activities on a voluntary basis and collaboration should not be forced.

As described above, during the COVID-19 pandemic, biopharmaceutical innovators engaged in extensive technology transfer and promoted global manufacturing of medical countermeasures through VLs and contract manufacturing arrangements. Many of these arrangements involved

[69] *See supra* n. 63 and Abbie-Rose Hampton et al., *Equity in the Pandemic Treaty: Access and Benefit-Sharing as a Policy Device or a Rhetorical Device?* 51 J. L., MED. & ETHICS 217, 217-220 (2023) ("Additionally, the application of ABS rules in the global health policy arena has already led to fundamentally anti-scientific outcomes where, for example, vaccines have been developed using suboptimal pathogen strains due to researchers being unable to negotiate access to the most appropriate samples.").

royalty-free or otherwise preferential IP licensing terms to developing country manufacturers. Biopharmaceutical manufacturers also offered donations of their products.[70] Others offered tiered pricing for purchase of their COVID-19 products (including not-for-profit prices in certain low-income countries).[71] The U.S. innovative biopharmaceutical industry is committed to engaging in a range of approaches to equitable access including voluntary technology transfer, manufacturing capacity-building and accessible pricing initiatives in future pandemics, as well.[64]

Critically, the success of such initiatives depends on the long-term ability of national governments – particularly those in low- and lower-middle-income countries – to build the necessary readiness in their healthcare systems; this includes maintaining effective medical product approval regimes (including where appropriate reliance on approvals or authorizations by stringent regulatory authorities), product storage and delivery infrastructures, and favorable trade and customs policies governing pandemic-related products. The strength of these initiatives also depends on countries' clinical trials infrastructure, pool of trained medical researchers and robust regulatory authorities. PhRMA urges the Administration to prioritize these factors in the WHO Pandemic Agreement negotiations.

Article 13, Global Supply Chain and Logistics (SCL) Network

- **The WHO SCL Network proposed in Article 13 envisions performing a range of functions ordinarily left to individual governments, institutions, or organizations.**
    - **What functions of Access to COVID–19 Tools-Accelerator (ACT–A) should or should not be institutionalized?**

PhRMA comment: As a general matter, it should be noted that manufacturers of brand medicines have robust systems in place to avoid major disruptions in their supply chains. These systems include inventory management systems that track, assess and estimate supply and demand and allow manufacturers to continuously monitor their supply and distribution lines to ensure sufficient supply, anticipate risk and avert significant disruptions. Companies also as standard practice put in place risk management plans that may include alternate manufacturing sites, inventory reserves and/or a range of global external suppliers and logistics planning to ensure continuity in shipping of supplies. Manufacturers are best positioned to manage and track their supply chains.

The proposed SCL Network goes beyond WHO's core mandate and expertise. Instead, topics with trade-related elements, such as the SCL Network, should be addressed by the WTO. Topics such as open supply chains and limitations on trade restrictions were discussed by the WTO as

[70] *See*, *e.g.*, Eli Lilly, Lilly plans donation of COVID-19 therapies to Direct Relief for use in low- and lower-middle-income countries (May 4, 2021), *available at* https://investor.lilly.com/news-releases/news-release-details/lilly-plans-donation-covid-19-therapies-direct-relief-use-low.

[71] *See* ITC Report, at 29, 239-241; *see also, e.g.*, Bhanvi Satija, *Pfizer to sell all its drugs in low-income countries at non-profit price*, REUTERS (Jan. 17, 2023), *available at* https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-sell-all-its-drugs-low-income-countries-non-profit-price-2023-01-17/; *Oxford AstraZeneca vaccine to be sold to developing countries at cost price*, THE GUARDIAN (Nov. 23, 2020), *available at* https://www.theguardian.com/global-development/2020/nov/23/oxford-astrazeneca-results-covid-vaccine-developing-countries.

part of its pandemic response, including at the WTO's 12th Ministerial Conference in June 2022, and continue to be considered in multiple WTO bodies.[72]

The question of whether to institutionalize the entities and functions conducted under the ACT-A umbrella requires considerable evaluation. While several reviews of the performance and impact of the various pillars of ACT-A have been conducted and some recommendations offered, a more thorough and fully independent, academic examination of the successes and failures of ACT-A needs to be conducted. The review should include all stakeholders involved in ACT-A comprehensively, which the current reviews did not do. Considerations of institutionalizing the core elements of ACT-A will also depend on critical non-WHO entities (Gavi, UNICEF, Global Fund, UNITAID, Path, Wellcome Trust, etc.) whose governing boards would decide whether their activities in such an ongoing endeavor would meet their core mission. All previous ACT-A pillars involved the equities of the biomanufacturing industry, yet the governance and daily decision making poorly integrated any of the major manufacturers. Institutionalizing ACT-A at WHO will hinder the inclusion of the developers and manufacturers of the pandemic vaccines, therapeutics and diagnostics due to the barriers imposed by WHO's interpretation of the Framework of Engagement with Non-State Actors (FENSA).

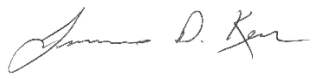
Whatever model is chosen, PhRMA would like to highlight the importance of including the private sector, and specifically manufacturers of pandemic products, so that the expertise and equities of the product developers can be integrated.

- **Should the U.S. consider incentives to encourage U.S. stakeholders' participation in such an effort and what would compelling incentives be?**

PhRMA comment: If the United States were to fund any such new activity, it should continue to advocate for the inclusion of all relevant stakeholders, i.e. in governance structures with decision making authorities (not only information sharing groups) including the biopharmaceutical industry conducting the R&D and manufacturing of pandemic-related products.

* * *

Thank you for your continued leadership and for the opportunity to provide comments. The U.S. Government has a significant role to play, and PhRMA stands ready to provide additional comments on future iterations of the Negotiating Text and all related matters.
Sincerely,



Larry Kerr
Deputy Vice President, International

[72] *See* WTO Ministerial Conference, *Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics*, WTO Doc. WT/MIN(22)/31 (Jun. 22, 2022), *available at* https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True.