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SUBMITTED ELECTRONICALLY VIA EDIS

Ms. Lisa Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, D.C. 20436

Re: Written Submission, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Investigation No. 332-596

Dear Secretary Barton,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we hereby submit our final written submission in *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, Investigation No. 332-596, per the Federal Register notice issued on February 6, 2023.¹ Further, as requested in that notice, a summary of PhRMA's position on this investigation is attached hereto as Appendix A for inclusion in the ITC's report.

As discussed during the lengthy two-day hearing held on March 29-30, the ultimate purpose of this investigation is to provide the fact base for the U.S. Trade Representative to determine whether to support the proposed extension of the TRIPS waiver for COVID-19 vaccines² to COVID-19 therapeutics and diagnostics. To answer this question, it is critical to identify the problem that we are trying to solve, to assess whether the proposed solution (i.e., extension of the TRIPS waiver) would help address that problem and, if so, consider whether the potential benefits of the solution outweigh the harms. As detailed in our Pre-hearing Brief and further below, the evidence – including the fact that the existing TRIPS waiver has not been utilized – simply does not support extending the waiver to therapeutics.

First, the evidence shows that governments around the world have access to affordable COVID-19 therapeutics. Supply significantly exceeds demand, even if we were to assume per capita consumption levels equivalent to those in the United States. PhRMA member companies have

¹ COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities; Notice of Investigation and Scheduling of a Public Hearing,” 88 Fed. Reg. 7757 (Feb. 6, 2023).

² WTO Ministerial Conference, *Ministerial Decision on the TRIPS Agreement Adopted 17 June 2022*, WTO Doc. WT/MIN(22)/30 (Jun. 22, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True> (hereinafter, “TRIPS waiver”).

successfully worked bilaterally with governments and generic manufacturers in developing countries, as well as with multilateral organizations and mechanisms such as COVAX, the Medicines Patent Pool (MPP), Global Fund and UNICEF, to provide access pathways for these innovations to all countries, including the least developed, and are fully committed to providing global access to COVID-19 vaccines and treatments.³

Second, to the extent that patients in some countries may not have the same level of access as here in the United States, this is not due to a lack of affordable doses, but rather to last-mile administration challenges and regulatory or systemic barriers in those markets. With worldwide demand for therapeutics waning and governments and the World Health Organization (WHO) declaring an end to the public health emergency,⁴ the evidence does not support the need to increase supply of COVID-19 therapeutics. In a purported effort to respond to COVID-19 more effectively, USTR is considering an extension of the waiver of IP commitments for medicines that have combatted COVID-19 so effectively that President Biden terminated the national emergency related to the pandemic.⁵ Given this reality, the Administration, rather than support a TRIPS waiver extension, should work collaboratively with other governments and industry to ensure that patients globally have access to the existing supply surplus.

Third, no evidence has been presented to demonstrate that waiving commitments to protect intellectual property (IP) will address the real barriers to accessing the existing supply of COVID-19 therapeutics. Calls to “suspend” IP protections disregard the fact that without credible and certain IP rights, companies would be unable to justify the significant investments needed to research and develop innovative medicines. Moreover, as demonstrated during the COVID-19 pandemic, IP has enabled R&D partnerships to swiftly develop COVID-19 solutions in record time and facilitated hundreds of partnerships globally to manufacture COVID-19 vaccines and treatments at scale.⁶ While TRIPS already anticipates the use of compulsory licensing, it does so as a limited exception to an innovator’s patent rights and seeks to make them a measure of last resort. In practice, compulsory licenses, as demonstrated during the COVID-19

³ For example, Pfizer is working through its initiative, Accord for a Healthier World, and with WHO, UNICEF, Global Fund and COVID GAP to improve access to PAXLOVID™ for vulnerable populations globally. See, e.g., Press Release, Pfizer, Pfizer to Supply Global Fund Up to 6 Million PAXLOVID™ Treatment Courses for Low- and-Middle-Income Countries (Sep. 22, 2022), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-treatment>. Merck & Co., Inc. (Merck), also signed an agreement 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 105 middle- and low-income countries. See Press Release, Merck, Merck and Ridgeback Announce Supply Agreement with UNICEF for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine (Jan. 18, 2022), <https://www.merck.com/news/merck-and-ridgeback-announce-supply-agreement-with-unicef-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine/>.

⁴ WHO, Statement on the Fifteenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic (May 5, 2023), [https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic).

⁵ The White House, Bill Signed: H.J.Res. 7 (Apr. 10, 2023), <https://www.whitehouse.gov/briefing-room/legislation/2023/04/10/bill-signed-h-j-res-7/>.

⁶ See Appendices 1 (COVID-19 Vaccines: Production and Uptake) and 2 (Expanding the TRIPS Waiver is Unnecessary and Harmful) to PhRMA’s Pre-hearing Brief.

pandemic, are rarely the best mechanism for meaningfully improving patient access, and certainly no evidence has been provided that greater flexibility is needed to grant compulsory licenses for COVID-19 therapeutics.

Finally, even if one were to erroneously assume that extension of the waiver to COVID-19 therapeutics would help address patient access concerns, any “benefit” would be significantly outweighed by the harm that an extension of the waiver would inflict on innovation (both for and beyond treating COVID-19), American workers and patients around the world. The existing waiver has significant legal and political ramifications and inappropriately signals that IP protections are a barrier that should be waived to address any global crisis. These implications exist even though no government has utilized the waiver on COVID-19 vaccines. Extending the waiver to therapeutics would exacerbate these harms without providing any tangible benefits in terms of patient access.

For these reasons, the innovative biopharmaceutical industry repeats its call for the Administration and all policymakers to reject any expansion of the TRIPS waiver and instead focus on solving evident challenges to distributing and administering the global surplus of COVID-19 vaccines and treatments. At a time when research and development have never been more important, our industry shares the goal to help ensure widespread availability of this surplus, a commitment to invest in research for unmet medical needs and hopes that all governments and stakeholders will refocus on these shared objectives.

I. Foreign Governments Have Access to Affordable COVID-19 Therapeutics

The innovative biopharmaceutical industry has worked around the clock to research, develop and deploy COVID-19 therapeutics for the world’s population. As discussed below, PhRMA member companies have pursued a variety of bilateral and multilateral mechanisms to prioritize global access to affordable COVID-19 therapeutics. 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. As a result, more than 130 countries – including all Global Fund-eligible low- and middle-income countries in all regions of the world – are eligible to receive COVID-19 therapeutics at either no cost or significantly reduced cost.⁷

In the first months of the pandemic,⁸ PhRMA member companies secured bilateral agreements to expand access to COVID-19 therapeutics, including for some of the world’s most vulnerable countries and populations. For example, in May 2020, just two weeks after the U.S. Food and Drug Administration granted emergency use authorization for remdesivir to treat COVID-19, Gilead signed royalty-free voluntary licensing agreements with nine generic companies in India, Pakistan and Egypt to manufacture and distribute remdesivir to 127 countries.⁹ The licenses cover all low- and lower-middle-income countries, as well as upper-middle-income countries

⁷ UNICEF COVID-19 Dashboard, <https://www.unicef.org/supply/covid-19-market-dashboard>.

⁸ WHO declared the novel coronavirus (COVID-19) outbreak a pandemic on March 11, 2020.

⁹ Reuters, Gilead Licenses Remdesivir Production to India and Pakistan (May 13, 2020), <https://asia.nikkei.com/Business/Pharmaceuticals/Gilead-licenses-remdesivir-production-to-India-and-Pakistan>.

with limited access to health care.¹⁰ Gilead and its licensees have been fulfilling real-time global demand since October 2020, making remdesivir available for over 13 million patients to date.¹¹ Gilead has also donated more than 2 million vials of remdesivir since the beginning of the pandemic to countries with significant needs, including Armenia, Georgia, India and Indonesia. Eli Lilly similarly made royalty-free voluntary licensing agreements with eight generic companies in India, in addition to donating an initial 400,000 doses of baricitinib to the Indian Government.¹²

Merck made royalty-free voluntary licensing agreements with five Indian generic manufacturers “at risk,” meaning prior to beginning Phase 3 clinical studies and more than six months before the first marketing authorization had been granted, to accelerate availability of molnupiravir to India and other middle-income countries.¹³ Merck provided these manufacturers with significant support to facilitate the development and marketing authorization of their products, for example by providing comprehensive technical packages describing the molecule and manufacturing process; sharing expertise related to clinical studies and the sourcing of active pharmaceutical ingredients; providing data from Merck’s clinical development program directly to regulators, such as the Drugs Controller General of India (DGCI), in support of their regulatory submissions; and making Merck’s product available for use in bioequivalence studies to support WHO prequalification applications. This close, labor-intensive collaboration between Merck and its licensees was critical, as molnupiravir was still in clinical development when the generic manufacturers began their work in parallel. In September 2022, the first generic WHO prequalification for a COVID-19 antiviral was granted to molnupiravir manufactured by one of Merck’s generic licensees.¹⁴ Merck additionally established local manufacturing and supply partnerships with companies in Brazil and China, as well as donated 100,000 courses of treatment to Direct Relief, a global humanitarian aid organization, for distribution to programs serving refugees in Ukraine, Egypt, Syria, Rwanda and Gaza.

Recognizing the far-reaching benefits of working with multilateral institutions, PhRMA member companies also partnered with the MPP, Global Fund, UNICEF and others to help expand access. For example, Merck signed an agreement with the MPP that further diversified the manufacturing base for quality-assured molnupiravir across Asia, Africa, Europe and North

¹⁰ Gilead Access Partnerships, <https://www.gilead.com/purpose/medication-access/global-access/access-partnerships>.

¹¹ Gilead, Gilead’s Path to Equitable Global COVID-19 Treatment Access (Oct. 4, 2022), <https://stories.gilead.com/articles/gilead-path-to-equitable-global-covid-19-treatment-access>.

¹² Press Release, Eli Lilly, Lilly Accelerating Baricitinib’s Availability in India Following Receipt of Permission for Restricted Emergency Use as a COVID-19 Therapy via Donations and Licensing Agreements (May 4, 2021), <https://investor.lilly.com/news-releases/news-release-details/lilly-accelerating-baricitinibs-availability-india-following#:~:text=Lilly%20is%20offering%20donations%20of,in%20India%20during%20the%20pandemic>.

¹³ Press Release, Merck, Amid Humanitarian Crisis in India, Merck Announces Voluntary Licensing Agreements with Five Indian Generics Manufacturers to Accelerate and Expand Global Access to Molnupiravir, an Investigational Oral Therapeutic for the Treatment of COVID-19 (April 27, 2021), <https://www.merck.com/news/amid-humanitarian-crisis-in-india-merck-announces-voluntary-licensing-agreements-with-five-indian-generics-manufacturers-to-accelerate-and-expand-global-access-to-molnupiravir-an-investigational-ora/>.

¹⁴ WHO, First Molnupiravir Generic Prequalified (Sept. 21, 2022), <https://extranet.who.int/pqweb/news/first-molnupiravir-generic-prequalified>.

America and helped create access pathways for generic molnupiravir in more than 100 low- and middle-income countries following appropriate regulatory approvals.¹⁵ 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.^{16,17} Both Merck and Pfizer additionally signed supply agreements with UNICEF (from which the Global Fund could procure) for their COVID-19 therapeutics, agreeing to make a combined total of over 13 million doses available for procurement and delivery.^{18,19,20} As a result of these efforts, a February 2023 report by the WHO and the Access to COVID-19 Tools Accelerator (ACT-A) – the multilateral mechanism launched in April 2020 responsible for the equitable distribution of COVID-19 vaccines, therapeutics and diagnostics – announced that enough antiviral treatments had been secured from the biopharmaceutical industry to address current demand.²¹

The biopharmaceutical industry has embraced its leadership role in responding to COVID-19 and continues to evolve manufacturing practices and partnerships to outpace global demand so that vaccines and treatments are accessible as quickly as possible. In addition to the 13 million courses made available to low and middle-income countries through the Global Fund and UNICEF, over 70 million courses of COVID-19 therapeutics were purchased by governments in 2022, an amount which far exceeded demand in 2022 (19 million courses) and has built up

¹⁵ 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), <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-countries/>.

¹⁶ 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), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing>.

¹⁷ Press Release, Medicines Patent Pool, 35 Generic Manufacturers Sign Agreements with MPP to Produce Low-cost, Generic Versions of Pfizer's Oral COVID-19 Treatment Nirmatrelvir in Combination with Ritonavir for Supply in 95 Low- and Middle-income Countries (Mar. 17, 2022), <https://medicinespatentpool.org/news-publications-post/35-generic-manufacturers-sign-agreements-with-mpp-to-produce-low-cost-generic-versions-of-pfizers-oral-covid-19-treatment-nirmatrelvir-in-combination-with-ritonavir-for-supply-in-95-low-and-middle-income-countries>.

¹⁸ 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), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-unicef-4-million-treatment-courses-novel>.

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

²⁰ Press Release, Pfizer, Pfizer to Supply Global Fund Up to 6 Million PAXLOVID™ Treatment Courses for Low- and Middle-Income Countries (Sep. 22, 2022), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-supply-global-fund-6-million-paxlovidtm-treatment>.

²¹ World Health Organization, Update on the Rollout of COVID-19 Tools: A Report from the ACT-A Tracking and Monitoring Task Force – 15 February 2023 (Mar. 2, 2023), <https://www.who.int/publications/m/item/update-on-the-rollout-of-covid-19-tools--a-report-from-the-act-a-tracking---monitoring-task-force---15-february-2023>.

stockpiles (more than 30 million courses) large enough to exceed anticipated total global demand in 2023.²² In fact, even if every country in the world were to increase its demand for COVID-19 treatments to the same level as the United States (for which uptake is significantly higher than other high-income countries), current production capacity would be more than sufficient to satisfy demand and there would still be a global surplus of COVID-19 treatments at the end of 2023.²³

Claims of shortages of COVID-19 therapeutics to justify the proposed extension of the TRIPS waiver rely on increasingly disparate estimates of a suppressed hypothetical global demand that is not supported by any evidence. Only a small number of low and middle-income countries are requesting COVID-19 therapeutics even when they are available at no cost. For example, as of May 1, 2023, UNICEF has only delivered 144,862 of the 7 million available doses of COVID-19 therapeutics to 14 countries and territories due to lack of requests.²⁴ COVID-19 therapeutics remain available for any country, particularly low- and middle-income countries, that request them. Similarly, countries that have purchased COVID-19 therapeutics now have larger stockpiles than they anticipated due to lower uptake than expected.²⁵ As discussed in the next section, policymakers should focus on the actual obstacles to ensuring access, including the many regulatory and administrative delays, last-mile challenges and continued hesitancy toward the use of COVID-19 vaccines and treatments, as well as multiple trade barriers. Abandoning the global IP system that enabled the rapid response to COVID-19 not only does nothing to improve access to existing COVID-19 therapeutics but risks the development of future treatments for new COVID-19 variants, long COVID-19 and other medical conditions.

Finally, through the MPP mechanism, royalty-free licensed generic manufacturers of COVID-19 therapeutics can produce doses at reduced costs and are individually responsible for determining the price of their product with purchasers. Despite the success of the MPP in expanding access to COVID-19 therapeutics in low- and middle-income countries, analyses were submitted to the ITC alleging that MPP-participating generic manufacturers are not providing COVID-19 treatments at competitive prices.²⁶ Unfortunately, the methodological approaches taken in these studies are poorly described and therefore not able to be replicated and fully evaluated. To the limited extent the methods are described, there are several shortcomings. First, the trade data used for API costs is not purpose-fit for this type of study as the data are often old and not granular nor descriptive enough to ensure accuracy. Second, the API data used in the analysis is limited to India, even though API is made in many other geographic locations. Third, the definition of production costs is too narrow. For example, product development and

²² Airfinity (science.airfinity.com). See Appendix 2 to PhRMA's Pre-hearing Brief: Expanding the TRIPS Waiver is Unnecessary and Harmful.

²³ Id.

²⁴ UNICEF COVID-19 Dashboard, <https://www.unicef.org/supply/covid-19-market-dashboard>. Accessed May 1, 2023.

²⁵ Airfinity (science.airfinity.com). See Appendix 2 to PhRMA's Pre-hearing Brief: Expanding the TRIPS Waiver is Unnecessary and Harmful.

²⁶ Barber MJ and Gotham D, Working Paper, Estimated Cost-based Generic Prices for Investigational COVID-19 Antivirals (April 12, 2023).

bioequivalence studies are not included in production costs even though generic manufacturers must perform these tasks to make their products available to patients.²⁷

II. Governments Should Focus on Addressing Regulatory, Last-Mile and Trade Barriers that Prevent Patient Access to COVID-19 Therapeutics

As noted during the hearing in response to questions from Commissioner Schmidlein concerning the real barriers to access, demand for COVID-19 therapeutics has been far less than expected due to regulatory and administrative delays and barriers, last-mile distribution and administration challenges, and multiple trade barriers that impede access. As a result (and discussed above in Section I), many low- and middle-income countries have not prioritized supply of COVID-19 treatments from NGOs, manufacturers and governments even when they are donated or offered at no cost or significantly reduced cost. Critically, none of these challenges will be addressed by extending the TRIPS waiver to COVID-19 therapeutics.

A. Regulatory and Administrative Delays and Barriers

The various global access pathways for COVID-19 therapeutics still require that the products have been authorized or approved in the countries where they are delivered. Unfortunately, few low- and middle-income countries, including only five countries in Africa, have authorized or approved novel COVID-19 therapeutics for use in their markets even though several therapeutics are pre-qualified by the WHO. Despite the abundant supply of two COVID-19 oral antiviral treatments, molnupiravir and PAXLOVID™, which are authorized by multiple Stringent Regulatory Authorities, the vast majority of low- and middle-income countries have not authorized their use. Of the 27 low-income countries (nine percent of the world's population), only Rwanda has authorized the use of PAXLOVID™, while none have authorized the use of molnupiravir. Further (and mindful of Chairman Johanson's questions concerning particular access challenges in middle-income countries), of the 109 middle income countries (71 percent of the world's population), only 16 and 10 countries have authorized the use of molnupiravir and PAXLOVID™, respectively.²⁸

Even in middle-income countries where COVID-19 therapeutics have been authorized or approved as safe and effective, administrative delays or negative decisions can prevent access. For example, the South African Health Products Regulatory Authority (SAHPRA) authorized a limited quantity of molnupiravir for "compassionate use" in February 2022, but the product remained limited to use in the private sector after the National Essential Medicines List Committee (NEMLC) rejected its use in the public sector.^{29,30} SAHPRA did not authorize use of PAXLOVID™ until January 2023, but the NEMLC previously rejected its use in the public

²⁷ Ion Economics, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities: Critique of Cost Buildup Analyses (May 4, 2023).

²⁸ Airfinity (<https://science.airfinity.com>).

²⁹ Press Release, SAHPRA, SAHPRA Has Authorised Access to Molnupiravir (Feb. 17, 2022), <https://www.sahpra.org.za/news-and-updates/sahpra-has-authorised-access-to-molnupiravir/>.

³⁰ Reuters, S. Africa Allows Use of Merck COVID Pill But Government Not Buying (Feb. 17, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/south-africas-health-regulator-approves-merck-covid-treatment-pill-2022-02-17/>.

sector, claiming that the product would not be feasible to administer in a timely manner after symptoms began because South Africa did not allow self-testing for COVID-19, and so patients must be tested at clinics, hospitals or private testing sites, delaying diagnosis.^{31,32} In India, the Indian Council of Medical Research (ICMR) rejected the inclusion of both molnupiravir and PAXLOVID™ in its national treatment guidelines for COVID-19.^{33,34} ICMR claimed that the products lacked clinical benefit and, in the case of molnupiravir, had “major safety concerns” despite prior authorization by the Central Drugs Standard Control Organisation. These decisions resulted in Indian manufacturers with voluntary licenses to produce molnupiravir taking write-off for unsold stock and expressing hesitancy over whether to seek authorization for generic versions of PAXLOVID™.³⁵ In Brazil, Merck entered into a voluntary partnership with the Oswaldo Cruz Foundation, also known as FIOCRUZ, the public sector research and development organization, for the local production, distribution and sale of molnupiravir in Brazil’s public health system, the *Sistema Único de Saúde* (SUS), as soon as emergency use authorization was granted.³⁶ Molnupiravir had previously been authorized by the Brazilian Health Regulatory Agency (ANVISA) as safe and effective. However, Brazil’s National Committee for Health Technology Incorporation (CONITEC), responsible for advising the Brazilian Ministry of Health on the incorporation of health technologies into the SUS system, subsequently rejected the inclusion of molnupiravir even though it was determined to be cost-effective.³⁷ As a result of this decision, molnupiravir is currently unable to be accessed through the public sector in Brazil.

B. Last-Mile Distribution and Administration Challenges

Even before the COVID-19 pandemic, public health experts highlighted in-country delivery and administration barriers as among the most important obstacles to accessing medicines in

³¹ Press Release, SAHPRA, SAHPRA Registers Paxlovid, An Anti-Viral Medicine For COVID-19 (Jan. 30, 2023), <https://www.sahpra.org.za/press-releases/sahpra-registers-paxlovid-an-anti-viral-medicine-for-covid-19/>.

³² Business Day, Government Advisers Say It Is Not Feasible for State To Use Pfizer’s COVID-19 Pill (Mar. 24, 2022), <https://www.businesslive.co.za/bd/national/health/2022-03-24-government-advisers-say-it-is-not-feasible-for-state-to-use-pfizers-covid-19-pill/>.

³³ Economic Times, Molnupiravir Not Included in COVID-19 Treatment Guidelines as Its Harms Outweigh Benefits: ICMR (Jan. 12, 2022), <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/molnupiravir-not-included-in-covid-19-treatment-guidelines-as-its-harms-outweigh-benefits-icmr/articleshow/88859184.cms>.

³⁴ Economic Times, No Merit Seen in Including Paxlovid in COVID Treatment: ICMR (May 7, 2022), <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/no-merit-seen-in-including-paxlovid-in-covid-treatment-icmr/articleshow/91384547.cms>.

³⁵ Economic Times, Drugmakers Seem To Be in No Hurry to Launch COVID Antiviral Pill Paxlovid (Jun. 14, 2022), <https://health.economictimes.indiatimes.com/news/pharma/drugmakers-seem-to-be-in-no-hurry-to-launch-covid-antiviral-pill-paxlovid/92190207>.

³⁶ FIOCRUZ, COVID-19: Fiocruz and MSD Sign an Agreement To Produce the First Oral Antiviral Drug in Brazil (May 9, 2022), <https://portal.fiocruz.br/en/news/covid-19-fiocruz-and-msd-sign-agreement-produce-first-oral-antiviral-drug-brazil>.

³⁷ CONITEC, Molnupiravir for Patients Infected with SARS-CoV-2: Non-hospitalized Patients at High Risk of Worsening Illness (Aug. 2022), https://www.gov.br/conitec/pt-br/midias/relatorios/2022/20220912_relatorio_763_molnupiravir_covid-19.pdf.

developing countries.³⁸ Longstanding obstacles to the efficient delivery of health products in developing countries include challenges in warehousing (e.g., lack of adequate storage facilities, security issues and limited use of technology); distribution (e.g., limited availability of transportation, infrequent distribution to rural areas, last-mile delivery failures due to geographic and transportation constraints and coordination problems), and inventory and supply management (e.g., lack of systematic data collection to inform forecasting and inadequate methods of inventory control).³⁹ Indeed, WTO members have cited a long list of much-needed, non-IP improvements to health care systems.⁴⁰ Experts have also noted the unique challenges arising from the public-sector distribution model employed by many developing countries, in which government entities carry out key supply chain functions such as storage and distribution of medicines, and these responsibilities often are fragmented across multiple agencies and levels of government.⁴¹

These and other longstanding barriers have impeded efficient delivery of COVID-19 medicines to populations in need, undermining the global response to the pandemic. Last-mile distribution and administration challenges have resulted in the destruction of unused COVID-19 vaccines and countries around the world turning away vaccine donations – an obstacle that even the Administration has acknowledged.⁴² Similar in-country delivery barriers have inhibited efforts to deploy rapidly COVID-19 therapeutics and diagnostics. As a result of these delivery bottlenecks, many populations face difficulty accessing COVID-19 vaccines and therapeutics despite ample

³⁸ Kraiselburd, Santiago and Yadav, Prashant. Supply Chains and Global Health: An Imperative for Bringing Operations Management Scholarship into Action, *Production and Operations Management* 22 (2), 377-381 (Feb. 2012), <https://asrames.org/wp-content/uploads/2012/04/Kraiselburd-and-Yadav-Supply-Chains-and-Global-Health.pdf>.

³⁹ Steele, Pamela, Subramanian, Lakshmy and Tolani, Foyeke. Interventions to Improve Access to Medicine in Developing Countries: Mapping WHO's Building Blocks and Supply Chain Functions, *ACTA Scientific Pharmaceutical Sciences*, Vol. 3 Issue 7 (July 2019), https://dspace.lib.cranfield.ac.uk/bitstream/handle/1826/15713/Access_to_medicine_in_developing_countries-2019.pdf. See also: Yadav, Prashant. Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform, *Health Systems & Reform*, Vol. 1 Issue 2 (Apr. 2015), <https://www.tandfonline.com/doi/full/10.4161/23288604.2014.968005>; Matowe, Lloyd. Improving Pharmaceutical Supply Chain Management Systems in Resource-Limited Countries: Time to Change Approaches to Capacity Building, *Journal of Pharmacy and Pharmaceutical Sciences*, Vol. 4 Issue 2 (Sep. 2015), <https://www.rroij.com/open-access/improving-pharmaceutical-supply-chain-management-systemsin-resourcelimited-countries-time-to-change-approaches-to-capacity-building.pdf>.

⁴⁰ See Council for Trade-Related Aspects of Intellectual Property Rights, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on The TRIPS Agreement and Public Health*, Appendix 1, ¶ 72, WTO Doc. IP/C/76 (Nov. 23, 2016) (offering remarks from the United States on the agreement among WTO Members at the Trilateral Public Health Workshop about the need for various improvements to healthcare systems); *id.* at ¶ 50 (highlighting procurement and tariffs); 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, 296-297 (2022) (citing additional comments from the European Union and the United States).

⁴¹ Yadav, Prashant. Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform, *Health Systems & Reform*, Vol. 1 Issue 2 (Apr. 2015), <https://www.tandfonline.com/doi/full/10.4161/23288604.2014.968005>.

⁴² Relman, Eliza, *Business Insider*, Jen Psaki Says South Africa Turned Down the US's Offer of Additional COVID-19 Vaccine Doses (Nov. 29, 2021), <https://www.businessinsider.com/jen-psaki-says-south-africa-turned-down-us-offer-of-more-vaccine-doses-2021-11>.

production and supply of these products. Efficient supply chains for the delivery of vaccines, therapeutics and other health products are a critical component of pandemic response and of effective health systems more broadly. Recognizing the scale of distribution and administration challenges in 2021, the G20 High Level Independent Panel on pandemic preparedness and response has recommended that “[m]assive effort has to go into developing in-country systems for agile, last-mile delivery of essential supplies,” including vaccines, therapeutics and other health supplies such as oxygen cylinders.⁴³

Health workforce challenges also remain major concerns. In fact, governments surveyed by the WHO have cited health workforce challenges as the most common obstacle to scaling up access to COVID-19 therapeutics and diagnostics.⁴⁴ Health workforce challenges were the most-cited bottleneck for therapeutics in 61 of 95 countries (64 percent) surveyed by the WHO, and for diagnostics and testing in 53 of 95 countries (56 percent). Both at the height of the COVID-19 pandemic and currently, many developing countries face severe shortages of health workers, greatly limiting their capacity to administer COVID-19 therapeutics and other essential medicines and health services. For example, countries in the WHO African Region have a ratio of 1.55 health workers per 1,000 people, well below the WHO threshold density of 4.45 health workers per 1,000 people needed to deliver essential health services and achieve universal health coverage.⁴⁵ The WHO has projected a shortfall of approximately 10 million health care workers worldwide by 2030, concentrated primarily in low- and middle-income countries.⁴⁶

Governments have acknowledged the urgent need to strengthen the health workforce in response to the COVID-19 pandemic. The 2021 “Rome Declaration” adopted by leaders of the G20 and other states recognized the need to “[i]nvest in the worldwide health and care workforce,”⁴⁷ and the 2021 “Declaration of G20 Health Ministers” called on member countries to “expand and transform the recruitment, development, education, training, distribution, retention and financing of the health and care workforce.”⁴⁸ At an October 2022 meeting, G20 Health Ministers expressly acknowledged “the importance of training the workforce” from low- and middle-income countries “to bridge the gap in accessing” vaccines, therapeutics, and diagnostics.⁴⁹

⁴³ Report of the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response (June 2021), <https://pandemic-financing.org/wp-content/uploads/2021/07/G20-HLIP-Report.pdf>.

⁴⁴ World Health Organization, Third Round of the Global Pulse Survey on Continuity of Essential Health Services During the COVID-19 Pandemic (Feb. 7, 2022), <https://www.who.int/news/item/07-02-2022-essential-health-services-face-continued-disruption-during-covid-19-pandemic>.

⁴⁵ World Health Organization, Chronic Staff Shortfalls Stifle Africa’s Health Systems: WHO Study (June 22, 2022), <https://www.afro.who.int/news/chronic-staff-shortfalls-stifle-africas-health-systems-who-study>.

⁴⁶ Rivlin, Adrienne and Lumley, Tara, Why is There a Global Medical Recruitment and Retention Crisis? World Economic Forum (Jan. 9, 2023), <https://www.weforum.org/agenda/2023/01/medical-recruitment-crisis-davos23/>.

⁴⁷ Global Health Summit: Rome Declaration (May 21, 2021), https://global-health-summit.europa.eu/rome-declaration_en.

⁴⁸ Declaration of the G20 Health Ministers. G20 Italia, Sep. 5-6, 2021, https://www.salute.gov.it/imgs/C_17_pagineAree_5459_8_file.pdf.

⁴⁹ Chair’s Summary: Health Ministers’ of the G20 (Oct. 28, 2022), <http://www.g20.utoronto.ca/2022/221028-health.html>.

C. Trade Barriers that Impede Access to Medicines

Throughout the COVID-19 pandemic, our industry encouraged the United States and other WTO members to formalize and pursue a robust trade and health agenda to address and resolve the multiple trade barriers that impeded, and continue to impede, access to COVID-19 medicines, including tariffs, export restrictions and customs barriers.⁵⁰ Multiple WTO members, including geographically diverse countries at various levels of economic development, advanced constructive proposals along these lines, including proposals to eliminate tariffs, discipline export restrictions, enhance regulatory cooperation, and improve trade facilitation measures.⁵¹ Additional support for such initiatives was voiced in other international fora – including the G7 and the G20 – well in advance of the WTO’s TRIPS waiver decision.⁵² And yet, the WTO’s Twelfth Ministerial Conference produced no concrete commitments to reduce or eliminate any of these trade barriers, while adopting the TRIPS vaccine waiver. For example, the most topical deliverable, the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, includes a variety of recognitions, recollections and reiterations but does not require any new meaningful actions or commitments by Member States.⁵³

Rather than seek to resolve these longstanding and serious trade barriers, the Administration aligned itself with foreign governments that purported to seek a TRIPS waiver based on concerns about access to medicines but that themselves are prolific users of trade restrictions that limit such access. For example, export restrictions imposed in India to ensure domestic supply of

⁵⁰ See, e.g., ABPI, EFPIA, IFPMA, PhRMA, WTO Twelfth Ministerial Conference: A Critical Opportunity to Strengthen the Global Trade and Health Agenda, <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/V-Z/WTO-Twelfth-Ministerial-Conference---A-Critical-Opportunity-to-Strengthen-the-Global-Trade-and-Health-Agenda.pdf>.

⁵¹ As detailed in PhRMA’s Pre-Hearing Brief at p. 37, this includes proposals from the European Union concerning trade facilitation, regulatory cooperation and disciplining export restrictions, and proposals from the “Ottawa Group” to limit export restrictions on medical goods, reduce tariffs, and improve trade facilitation, among other proposals. See General Council, *Urgent Trade Policy Responses to the COVID-19 Crisis, Communication from the European Union*, WT/GC/231 (Jun. 4, 2021) and General Council, *COVID-19 and Beyond: Trade and Health, Communication from Australia, Brazil, Canada, Chile, the European Union, Japan, Kenya, Republic of Korea, Mexico, New Zealand, Norway, Singapore, and Switzerland*, WT/GC/223 (Nov. 24, 2020).

⁵² As detailed in PhRMA’s Pre-Hearing Brief at p. 37, this includes the May 2021 G20 “Rome Declaration,” which acknowledged “the central role of the WTO, and the importance of open, resilient, diversified, secure, efficient and reliable global supply chains across the whole value chain related to health emergencies.” Similarly, the September 2021 “Declaration of the G20 Health Ministers” recognized the urgent need “to eliminate WTO-inconsistent barriers that jeopardize the effective operation of the supply chains for essential medical goods.” See Global Health Summit: The Rome Declaration (May 21, 2021), https://www.governo.it/sites/governo.it/files/documenti/documenti/Approfondimenti/GlobalHealthSummit/GlobalHealthSummit_RomeDeclaration.pdf; and Declaration of the G20 Health Ministers (5-6 Sep. 2021), [https://reliefweb.int/sites/reliefweb.int/files/resources/G20_Italia_2021_Health_Declaration_ f inal_05092021_OFFICIAL.pdf](https://reliefweb.int/sites/reliefweb.int/files/resources/G20_Italia_2021_Health_Declaration_f inal_05092021_OFFICIAL.pdf).

⁵³ 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), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True>.

COVID-19 vaccines significantly stifled vaccination efforts in Africa.⁵⁴ Eliminating trade barriers would have a direct, positive impact on access to COVID-19 tools in developing countries – unlike the June 2022 TRIPS waiver, which has not benefitted a single patient nearly one year after its adoption.

It is well-documented that trade barriers imposed before and during the pandemic have impeded access to medical goods, including COVID-19 vaccines and treatments. The World Bank and the WTO have jointly recognized that “[d]uring the first two years of the pandemic, suppliers stepped up global shipments of therapeutics, vaccines, diagnostic gear, and personal protective equipment. Barriers to the movement of goods, people, and technology, however, hampered that effort.”⁵⁵ The WTO has documented more than 60 types of “trade-related bottlenecks” affecting critical COVID-19 products, including high tariffs and taxes, export restrictions, burdensome and duplicative requirements related to inspections and release of goods, divergent regulatory requirements and lack of coordination among border agencies.⁵⁶ These trade-related impediments are particularly prevalent in low- and middle-income countries, placing additional but unnecessary strain on health systems that already experience other significant challenges.⁵⁷

Recent analyses demonstrate that trade barriers imposed during the pandemic added significantly to the cost of medical goods. The WTO and the World Bank have demonstrated that trade policy measures introduced during the pandemic increased the import costs of medical goods by more than 60 percent compared to pre-pandemic levels, even when the effects of trade-liberalizing measures taken during this period were considered.⁵⁸ This figure does not account for longstanding trade barriers, such as tariffs and customs obstacles, that predate the pandemic but nonetheless further impede access to COVID-19 medicines and other countermeasures.

Large developing countries impose some of the highest tariffs in the world on imported medicines, resulting in significantly higher costs for health systems and patients.⁵⁹ Even relatively low import tariffs have been found to significantly increase the final retail price of medicines in developing countries because of multiple percentage mark-ups that are added to the

⁵⁴ See, e.g., Nikkei Asia, *Africa’s vaccination push hampered by India export curbs* (Apr. 22, 2021), <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Africa-s-vaccination-push-hampered-by-India-export-curbs>.

⁵⁵ World Trade Organization and World Bank Group, *Trade Therapy: Deepening Cooperation to Strengthen Pandemic Defenses* (June 2022) at p. 9, https://www.wto.org/english/res_e/booksp_e/tradetherapy2022_e.pdf.

⁵⁶ World Trade Organization, *Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19* (October 2021), https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf.

⁵⁷ World Trade Organization and World Bank Group, *Trade Therapy: Deepening Cooperation to Strengthen Pandemic Defenses* (June 2022) at p.3, https://www.wto.org/english/res_e/booksp_e/tradetherapy2022_e.pdf.

⁵⁸ *Id.* at p. 85, Figure 2.10d.

⁵⁹ As detailed in PhRMA’s Pre-Hearing Brief at p. 39, the WTO reported in 2020 that Members’ average applied most-favored nation (MFN) tariff on medicines was 2.1 percent, but many Members maintained higher tariffs on medicines, including Argentina (7.7 percent); Brazil (7.8 percent), Colombia (5.7 percent), Congo (5.0 percent), India (10.0 percent), Indonesia (3.8 percent), Korea (6.9 percent) and Thailand (7.6 percent). See World Trade Organization Secretariat, *Trade in Medical Goods in the Context of Tackling COVID-19* (Apr. 2020), https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf.

base import price by distributors along the distribution chain.⁶⁰ In Brazil and India, for example, tariffs on medicines have been found to increase their final price by up to 80 percent of the original sales price ex-factory.⁶¹ One study estimated that the annual financial burden of tariffs and trade facilitation inefficiencies on imported pharmaceuticals is as high as \$6.2 billion in China, \$2.6 billion in Brazil, \$737 million in India, \$663 million in Mexico, \$290 million in Turkey, \$251 million in Indonesia and \$177 million in South Africa.⁶² The study found that the resulting financial burden on patients in these countries can constitute a substantial portion of annual out-of-pocket spending on medicines.⁶³ The same study concluded that, due to the compounding effect of import tariffs, the tariff-induced premiums on the price of pharmaceuticals paid for by the governments of Brazil, India, Indonesia and similarly situated countries exceed the tariff revenues initially collected by these governments' customs authorities – suggesting that industrial policy or some other objective, rather than government revenue, is the rationale for these tariffs.⁶⁴ It is notable that many of these governments advocated for a TRIPS waiver, and continue to advocate for a TRIPS waiver expansion, based on purported concerns about access to medicines while simultaneously maintaining trade policies that raise the cost of medicines for their citizens.

As the primary global institution responsible for promoting and ensuring open and rules-based international trade, the WTO, rather than waiving longstanding commitments to protect IP, should play a leading role in encouraging countries to eliminate trade barriers that impede the distribution of biopharmaceutical products, including COVID-19 vaccines and treatments, across borders.

III. Greater Flexibility to Issue Compulsory Licenses Will Undermine the IP Rights that Enabled the Unprecedented Response to COVID-19 and Not Increase Patient Access to COVID-19 Therapeutics

During the hearing, several of the Commissioners sought further information on the use of compulsory licensing, or the lack thereof, both during the COVID-19 pandemic and more broadly. As Commissioner Karpel astutely asked at the hearing, what “evidence do we have that more compulsory licenses or greater ability to successfully get a compulsory license will increase access to ... therapeutics?” The short answer is none.

⁶⁰ Bauer, Matthias, *Tariffs on Medicines: Estimating the Real Cost of Emerging Markets' Protectionism* (2017), European Centre for International Political Economy Policy Brief No. 03/2017, <https://euagenda.eu/upload/publications/untitled-103457-ea.pdf>.

⁶¹ *Id.* at p. 1.

⁶² *Id.*

⁶³ Specifically, “[w]hen measured in per cent of annual out of pocket spending on medicine, the financial burden ‘directly’ imposed on patients is highest in South Africa (36.2 per cent), Russia (24.0 per cent), Turkey (15.7 per cent), Brazil (13.5 per cent) and China (11.5 per cent), followed by Mexico (7.7 per cent), Indonesia (5.8 per cent), and India (4.5 per cent).” *Id.* at p. 19.

⁶⁴ Specifically, “[t]he financial burden of import tariffs and trade facilitation inefficiencies that can be attributed to government spending on medicines exceeds tariff revenues by 3.36bn USD in China, 1.97bn USD in Russia and 1.35bn USD in Brazil, followed by 360m USD in Mexico, 171m USD in India, and 15m USD in Indonesia. In other words, due to the compounding effect of import tariffs, governments alone tend to finally pay (or reimburse) between two and six times the amount they collect as tariff revenues at the border, while they would save that amount if trade would take place at zero tariffs.” *Id.* at pp. 19 and 21.

As detailed in our Pre-hearing Brief (Section II), the limited use of compulsory licensing is not surprising given the availability of significantly better alternatives for ensuring patient access, including voluntary licensing, and the chilling effect that they have on innovation.

The World Trade Organization (WTO) Agreement on Trade-Aspects of Intellectual Property Rights (TRIPS) is a comprehensive agreement signed by the vast majority of countries worldwide, establishing minimum intellectual property (IP) protections. TRIPS includes limited exceptions or mechanisms (which some refer to as “flexibilities”) through which WTO Members may allow third parties to undertake an otherwise IP-infringing act, subject to certain conditions.

With respect to patents, one of the limited exceptions and mechanisms include the use of a patent “without authorization of the patent holder,”⁶⁵ often referred to as “compulsory licensing.” That mechanism was negotiated and agreed by WTO Members as a measure of last resort. For example, TRIPS requires that compulsory licenses “may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms.”⁶⁶ That condition precedent “may be waived ... in the case of a national emergency or other circumstances of extreme urgency.”⁶⁷ In short, the TRIPS agreement was purposefully designed to encourage voluntary arrangements and enable the unauthorized use of patents only in exceptional circumstances.

TRIPS is also subject to transition periods for certain member states recognizing economic and administrative constraints. For example, since the adoption of TRIPS, least developed countries (LDCs) – including several of those calling for the waiver and its extension – are not required to implement the agreement subject to transition periods that have been renewed in 2005, 2013, and most recently in 2021.⁶⁸ LDCs are not required, under the current transition period, to implement TRIPS until July 1, 2034.⁶⁹ In addition, LDCs are not required to implement TRIPS provisions related to patents and undisclosed data on pharmaceutical products per the 2001 “Declaration on the TRIPS agreement and public health.”⁷⁰ This transition period has similarly been extended and is currently not scheduled to expire until January 2033.⁷¹

However, some WTO members use existing TRIPS “flexibilities” and actively promote expanding limited exceptions to inappropriately advance longstanding industrial policies. Indeed, the same members supporting the TRIPS waiver have advanced for decades similar proposals throughout multilateral organizations. As highlighted by various witnesses, some WTO members

⁶⁵ See TRIPS Agreement, Article 31.

⁶⁶ TRIPS Agreement, Article 31(b).

⁶⁷ Id.

⁶⁸ TRIPS Agreement, Article 66(1).

⁶⁹ Council for Trade-Related Aspects of Intellectual Property Rights, *Extension for the Transition Period Under Article 66.1 for Least Developed Country Members*, ¶ 1, WTO Doc. IP/C/88 (June 28, 2021).

⁷⁰ WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, ¶ 7, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001),

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (hereinafter, “Doha Declaration”).

⁷¹ Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations With Respect to Pharmaceutical Products*, WTO Doc. IC/P/73 (Nov. 6, 2015).

routinely threaten to use compulsory licensing provisions to achieve inappropriate leverage in pricing negotiations and to advance forced localization policies. U.S. Administrations have specifically called out such practices in engaging with their trade partners.⁷² The TRIPS waiver, including the 2022 decision on vaccines and the pending decision on whether to extend the waiver to therapeutics and diagnostics, has only further emboldened foreign competitors to advance these agendas (discussed further below in subsection C).

Proponents of extending the TRIPS waiver to therapeutics and diagnostics repeatedly, in their written comments and public hearing testimony, assert that compulsory licensing is necessary to reduce prices and facilitate access, and that compulsory licensing encourages innovation. Experience shows that compulsory licensing does not necessarily reduce medicine prices. In our Pre-hearing Brief, we highlight how antiretroviral medications produced locally under compulsory licenses cost 25 percent more than those obtained through international procurement mechanisms in nineteen out of thirty case studies.⁷³ In another example, a biopharmaceutical manufacturer produced an antiretroviral medication at a cost that was cheaper than the corresponding generic products.⁷⁴ As such, it cannot be assumed that any COVID-19 therapeutics produced under a compulsory license will be less costly or more accessible to patients than existing supplies (which as highlighted in Section I include products provided at no cost or a significantly reduced cost).

Evidence also shows that countries that have issued compulsory licenses have seen declining or stagnating imports of medicines from countries with significant innovative biopharmaceutical industries and experienced delays in the launch of new treatments.⁷⁵ Despite better alternatives, countries that choose to issue compulsory licenses send signals to biopharmaceutical innovators that their patents are not safe, dissuading them from investing in a country or entering into arrangements with local entities to introduce new innovative medicines in market.

Moreover, waiver proponents have presented no evidence to justify their assertion that compulsory licensing encourages biopharmaceutical innovation. Rather, proponents have relied

⁷² See, e.g., 2020 Special 301 Report, at p. 14 (Apr. 2020), https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (highlighting that “[t]o maintain the integrity and predictability of IP systems, governments should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions. Such licenses should not be used as a tool to implement industrial policy, including providing advantages to domestic companies, or as undue leverage in pricing negotiations between governments and right holders. It is also critical that foreign governments ensure transparency and due process in any actions related to compulsory licenses.”).

⁷³ Pre-hearing Brief at 25 (citing Reed F. Beall, Randall Kuhn & Amir Attaran, Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement, 34 Health Affairs 493, 493 (2015).

⁷⁴ MSF, *Untangling the Web of ARV Price Reductions*, 18th Edition (July 2016), https://msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/UTW_Drug_Profiles_LPV_r.pdf. In addition, the biopharmaceutical manufacturer utilized the MPP to allow generic manufacturers to produce and supply the therapeutic to 102 developing countries spanning the globe. *Id.*

⁷⁵ Borrell, J-R, Patents and the faster introduction of new drugs in developing countries, *Applied Economics Letters*, 12 (2), 379–382 (2005); Cockburn I, Lanjouw J & Schankerman M, Patents and the Global Diffusion of New Drugs, *American Economic Review*, 106(1), 136-64 (2016); Berndt E & Cockburn I, The hidden cost of low prices: limited access to new drugs in India, *Health Affairs*, 33(9):1567-75 (2014).

on outdated and irrelevant research to advance this unjustified claim. For example, one witness has asserted that “compulsory licensing can indeed encourage innovation,” based on a single working paper that examined how U.S. compulsory licensing of German-owned patents during World War I may have affected subsequent innovation in the chemical industry and on an “economy-wide” basis.⁷⁶ Another witness has made similar claims based on a 45-year-old analysis of the research and development expenditures of companies in a variety of industries during the year 1975.⁷⁷

It is inappropriate to draw conclusions about the effects of compulsory licensing on modern biopharmaceutical innovation based on these studies. It is widely recognized that the biopharmaceutical industry is exceptionally reliant on patent protection, owing to distinctive economic characteristics including “the costly, lengthy, and risky nature of innovative research and development (R&D) and the much lower investment required for generic drugs.”⁷⁸ Moreover, the importance of patent protection to biopharmaceutical innovation has only increased in recent decades due to scientific and technical advances that result in more complex clinical trials and increased R&D costs.⁷⁹ Analyses that predate these developments and involve other industries provide no insight into the harmful effects of compulsory licensing on modern biopharmaceutical innovation.

Furthermore, compulsory licensing does not necessarily promote local production of medicines or accelerate access. When Brazil issued a compulsory license for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch the generic version of the medication.⁸⁰ Finally, as highlighted in our Pre-hearing Brief, compulsory licensing does not address systemic barriers to access, and does not necessarily improve health outcomes for patients.

⁷⁶ Submission by Brook K. Baker on Behalf of Health Global Access Project, Inc. (Mar. 15, 2023), at p. 8 (citing to Moser, Petra. Patents and Innovation in Economic History, NBER Working Paper No. 21964, February 2016). Notably, while HGAP presents the paper’s findings as representing the views of the National Bureau of Economic Research, the paper expressly disclaims that it “has not been peer reviewed or been subject to the review by the NBER Board of Directors that accompanies official NBER publications,” and that it “do[es] not necessarily reflect the views of the National Bureau of Economic Research.”

⁷⁷ Prehearing Brief by Third World Network (Mar. 20, 2023), at p. 11 (citing to F.M. Scherer, The economic effects of compulsory patent licensing, Monograph Series of Finance and Economics, New York University, 1977, as summarized in FM Scherer, Comments in Robert Anderson and Nancy Gallini (Eds), competition policy and intellectual property rights in the knowledge-based economy, University of Calgary Press, Alberta 1998).

⁷⁸ Cockburn, Iain and Long, Genia, The Importance of Patents to Innovation: Updated Cross-industry Comparisons with Biopharmaceuticals, Expert Opinion on Therapeutic Patents Vol. 25, Issue 7 (Apr. 30, 2015).

⁷⁹ For example, clinical trials are generating three times the data collected ten years ago and trial protocols have become significantly more complex. See The Dynamic U.S. Research and Development Ecosystem, Pharmaceutical Research and Manufacturers of America, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Industry-Profile-2022/The-Dynamic-US-Research-and-Development-Ecosystem-3.pdf>.

⁸⁰ Bond, Eric and Saggi, Kamal, Compulsory Licensing, Price Controls, and Access to Patented Foreign Products (Apr. 2012), http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf.

IV. Extending the TRIPS Waiver to COVID-19 Therapeutics is Unnecessary, Counterproductive and Would Harm the Global IP System, Exacerbate a Bad Precedent and Undermine American Innovation and Leadership

As detailed in our Pre-hearing Brief, the Administration’s support for the TRIPS waiver was offered absent any meaningful consultation with industry experts or evidence that waiving international IP obligations would promote the development or manufacturing of additional COVID-19 vaccines. At the time of the waiver decision, more than 14 billion vaccine doses had been produced, with existing capacity to continue producing more than enough to vaccinate the world even in the event that new concerning variants were to emerge.⁸¹ Critically, almost a year after its introduction, there has been no demonstrable evidence that the waiver has meaningfully impacted patient access to COVID-19 vaccines.

Nor, as indicated above, has it been demonstrated that extending the waiver or granting any additional “flexibilities” to the TRIPS Agreement is necessary or would increase patient access to COVID-19 therapeutics. On the contrary, as the governments of Mexico and Switzerland noted in a communication to the TRIPS Council on November 1, 2022:

we do not face a situation where we have an IP-induced lack of access to or a lack of manufacturing capacity of COVID-19 therapeutics and diagnostics. As a consequence, no adjustments to the IP system seem to be required. If the decision were extended nonetheless, it would even have a detrimental effect and leave us ill-equipped to fight the COVID-19 pandemic and potential future pandemics effectively.⁸²

Indeed, the evidence shows that extending the waiver would undermine the incentives needed to promote new medicines to combat COVID-19 and other diseases, jeopardize patient safety and supply chains, increase the risk of counterfeits and weaken U.S. leadership in biomedical discovery, counter to the Administration’s stated objectives concerning the growth of American infrastructure, innovation and employment.⁸³ This question of harm was raised extensively by the Commissioners during the hearing and we agree with Commissioner Kearns that there are three thematic ways to assess the harm of extending the waiver: (1) the legal ramifications of the existing vaccines waiver; (2) the global political message that the waiver and its potential extension sends to the world regarding IP rights; and (3) the “slippery slope” concerns with extending the waiver.

⁸¹ Source: Airfinity (<https://science.airfinity.com>); see Appendix 1 to PhRMA’s Pre-hearing Brief: COVID-19 Vaccines: Production and Uptake.

⁸² Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from Mexico and Switzerland: TRIPS Council Discussion on COVID-19 Therapeutics and Diagnostics: Evidence and Questions on Intellectual Property Challenges Experienced by Members*, IP/C/W/693 (Nov. 1, 2023), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W693.pdf&Open=True>.

⁸³ See, e.g., Exec. Order No. 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* (Sep. 12, 2022), <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/>.

A. *The Legal Ramifications of the TRIPS Waiver for COVID-19 Vaccines*

As explained in our Pre-hearing Brief (Section II.D), and contrary to some group’s assertions, the TRIPS waiver disrupts the existing balance of the TRIPS Agreement, whereby “[t]he protection and enforcement of IP rights . . . contribute[s] to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”⁸⁴ Perversely, many of the proponents of extending the waiver assert that the waiver has little legal import, and yet continue to argue for its extension to therapeutics and diagnostics.

To recap, the 2022 TRIPS waiver decision applies to patents claiming inventions necessary for production and supply of COVID-19 vaccines, as well as the ingredients and processes necessary for the manufacture of those vaccines.⁸⁵ Substantively, the waiver appears to undermine a number of the existing requirements related to compulsory licensing and blithely asserts “that Article 39.3 of the Agreement [related to the provision of RDP] does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.”⁸⁶ The latter appears to disregard any regulatory data protection for that product, even though there is no such exception or mechanism in TRIPS (Article 31 applies solely to patents).

With regard to compulsory licensing, and with no explicit regard of the Article 31*bis* mechanism, the waiver appears to create yet another mechanism to allow for exceptions to the requirement in Article 31(f) that compulsory licenses be issued predominantly to supply the domestic market.⁸⁷ Article 31*bis* includes a number of anti-diversion requirements to ensure that the exported products actually reach eligible destinations and are not diverted to more lucrative markets. The waiver appears to significantly dilute these anti-diversion requirements. Eligible Members acting under the waiver are only required to take “all reasonable efforts to prevent [] re-exportation,” and all Members are required to “ensure the availability of effective legal means to prevent the importation into and sale in their territories of products manufactured” under the waiver that have been diverted to their markets.⁸⁸

In addition, the waiver appears to dilute the requirement in Article 31(h) that the issuance of a compulsory license be accompanied by the payment of adequate remuneration to the patent owner, by stipulating that Members “may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs.”⁸⁹ The waiver also creates a significant risk of inadequate remuneration by referencing and endorsing as “good practice” the tiered royalty

⁸⁴ TRIPS Agreement, Article 7.

⁸⁵ TRIPS waiver, ¶ 1 and footnote 2.

⁸⁶ TRIPS waiver, ¶ 5.

⁸⁷ TRIPS waiver, ¶ 3(b).

⁸⁸ TRIPS waiver, ¶ 3(c).

⁸⁹ TRIPS waiver, ¶ 3(d).

method advocated by the WHO and UNDP, which is inherently ill-suited for ensuring adequacy of remuneration.⁹⁰

The proposal is to extend the existing waiver, with all of its legal ramifications, *mutatis mutandis* to COVID-19 therapeutics and diagnostics.

B. The Waiver and Its Proposed Extension to Therapeutics and Diagnostics Inappropriately Assume that IP is a Barrier to Access and are Part of Broader Efforts to Undermine Effective Protection and Enforcement of IP Rights

Many of the governments and groups that initially pushed for the waiver are fundamentally opposed to IP protections, including the baseline protections required by the TRIPS Agreement. As such, they seek to extend the waiver not to promote patient access, but rather to establish further precedents for undermining IP protection and enforcement. Indeed, in an exercise of bootstrapping, proponents for the extension cite the original waiver decision as establishing “an important precedent . . . that intellectual property rules are a barrier to accessing medical tools.”⁹¹ Extending the waiver will simply serve to perpetuate this myth and undercut the ability of the U.S. and other like-minded governments to appropriately call out failures by other governments to protect American innovation (discussed further below in subsection C).⁹²

⁹⁰ See TRIPS waiver, footnote 4. For a critique of the tiered royalty method, see Eric M. Solovy, *The TRIPS Waiver for COVID-19 Vaccines, and Its Potential Expansion: Assessing the Impact on Global IP Protection and Public Health*, *Ctr. Intell. Prop. x Innovation Pol’y* (2022), <https://cip2.gmu.edu/wp-content/uploads/sites/31/2022/12/GMU-C-IP2-Solovy-PolicyBrief-TRIPS.pdf>; see also generally Eric M. Solovy & Deepak Raju, *The UNDP/WHO remuneration guidelines: a proposed formula for inadequate remuneration for compulsory licensing in violation of the TRIPS agreement*, 16 *J. IP Law & Practice* 1192-1202 (2021).

⁹¹ See, e.g., IP Watchdog, *With Decision Looming on Extension of TRIPS IP Waiver, House Dems Want More Info, Industry and Advocacy Groups Battle for Public Narrative* (Nov. 11, 2022), <https://ipwatchdog.com/2022/11/11/decision-looming-extension-trips-ip-waiver-house-dems-want-info-industry-advocacy-groups-battle-public-narrative/id=152916/>.

⁹² Other myths that have been repeated during this investigation that merit rebuttal include claims that the U.S. is a prolific user of compulsory licensing (it is not) or that companies engage in “evergreening” to extend their patent terms (which is legally impossible).

With regard to the first claim, it appears to rest on a fundamental lack of understanding of Federal Acquisition Regulation (FAR) clause — FAR 52.227-1, Authorization and Consent — that provides that the Government “authorizes and consents” to the use and manufacture of any invention covered by a U.S. patent in performing the contract, and the underlying statutory authority (28 U.S.C. §1498). Importantly, the Government includes FAR 52.227-1 in contracts because it is required boilerplate language, not because the Government anticipates that it will be invoked frequently. Nor does it indicate that the U.S. Government is granting a compulsory license each time that this language is included in a procurement contract. On the contrary, the purpose of the language is to ensure that performance of the contract for the U.S. Government cannot be halted by an injunction against the contractor in a patent suit. Rather, **in the event** that a patent is infringed, the patent holder’s sole relief is to seek monetary damages (“reasonable and entire compensation”) against the Government in the Court of Federal Claims. In turn, FAR 52.227-3 (on patent indemnity) requires the contractor to indemnify the Government for monetary damages levied against the Government as a result of the inclusion of FAR 52.227-1. As such, these FAR provisions do not reflect an intent to grant a compulsory license to the contractor, but rather to establish a mechanism for ensuring contract performance and remedying any patent infringement, with the cost of reasonable and entire compensation ultimately borne by the patent-infringing contractor.

Others have used the TRIPS waiver debate to opportunistically weaken global IP protection, including through the increased use of compulsory licensing in ways not contemplated under the TRIPS Agreement. After India and South Africa tabled the initial TRIPS waiver proposal in October of 2020, several countries considered or passed legislation expanding their compulsory licensing regimes beyond what is accepted under international norms. For example, Brazil considered mandating that right holders share necessary trade secrets, technical information and know-how as part of its compulsory licensing regime, a concept that the United States has opposed.⁹³ Malaysia, months after throwing its support behind the TRIPS waiver, announced that it would utilize the compulsory licensed hepatitis C treatment to boost medical tourism.⁹⁴ Indonesia even disregarded a voluntary licensing agreement already in place between the right holder and generic manufacturers to supply the Indonesian market with a COVID-19 therapeutic and issued a compulsory license for the same product.⁹⁵

The potential abuse by WTO Members of the compulsory licensing system suggests that expanding opportunities to utilize TRIPS flexibilities such as compulsory licenses could increasingly degrade incentives for investment in the development of new medicines in those countries (and beyond). This would greatly disrupt the balance between protection of IP rights and facilitation of technology transfer intended under the TRIPS Agreement.⁹⁶

Similarly, as part of the broader crusade against IP protections, some proponents have sought to undermine the provision of any IP protections for COVID-19 therapeutics asserting that biopharmaceutical companies have made only minor changes to existing products to extend the patent terms on the existing products (a practice described as “evergreening”). “Evergreening” is a pejorative term that is used to undermine legitimate innovation. Allegations of “evergreening” purposefully conflate principles of invention, patentability, patent term, and how inventions are ultimately commercialized. Patent policy, as underpinned by the TRIPS Agreement, is grounded in the concept that an invention is patentable when three criteria are met: novelty, non-obviousness and utility. So long as these criteria are met, an invention is patentable. Indeed, this is the standard for all inventions in any technological field – **whether it is a pioneering invention or an improvement on an existing invention**. The “evergreening” claim implies that periods of patent protection are improperly extended. The reality is that once a patent is granted, the owner receives a 20-year basic patent term from the date of application, and any new patent’s term does not extend the original 20-year term of any patent(s) covering the original invention. These false claims also ignore and discount the value of innovative changes to existing biopharmaceutical products.

These frontal assaults on IP protections reveal the true intent of the waiver extension proponents. Further, they underscore the need for the U.S. International Trade Commission to focus its report on the evidence that the U.S. Government should assess in determining whether it is necessary or appropriate to support an extension of the TRIPS waiver to therapeutics and diagnostics versus second-guessing the merits of global and domestic IP rules, an exercise better performed by other agencies and organizations.

⁹³ IAM, Brazil on the Cusp of Passing Landmark Compulsory Technology Transfer Law (Aug. 19, 2021), <https://www.iam-media.com/article/brazil-the-cusp-of-passing-landmark-compulsory-technology-transfer-law>.

⁹⁴ Code Blue, Malaysia To Offer Hepatitis C Drug To Medical Tourists (Nov. 16, 2021), <https://codeblue.galencentre.org/2021/11/16/malaysia-to-offer-hepatitis-c-drug-to-medical-tourists/>.

⁹⁵ Geneva Network, Why Patents Matter to Indonesia (Aug. 23, 2022), <https://geneva-network.com/research/why-patents-matter-to-indonesia/>.

⁹⁶ 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, 253, 286-287 (2022).

C. *The Proposed Extension of the Waiver Would be Difficult, If Not Impossible, to Confine to COVID-19*

As highlighted in our Pre-hearing Brief (Section III), extending the TRIPS waiver would negatively affect medical and technological innovation on multiple dimensions. IP protections drive investments in innovation, facilitate innovative partnerships and encourage continuous refinement of existing medicines and technologies. Weakening IP protections for new COVID-19 diagnostics and therapeutics would not only threaten innovation in COVID-19-related solutions, but also threaten innovation aimed at treating other diseases. Many COVID-19 therapeutics use ingredients and biotechnological methods with applications far beyond COVID-19. For example, certain COVID-19 therapeutics authorized for emergency use in the United States can be used to treat HIV, hepatitis C and rheumatoid arthritis. Moreover, 57 percent of treatments in the COVID-19 pipeline are also being developed for other conditions, including cancer, autoimmune disorders, central nervous system disorders, cardiovascular disease, endocrine disorders and other infectious diseases. Cancer, the second leading cause of death in the United States, accounts for 42 percent of the 370 clinical trials being conducted for other conditions.⁹⁷ Similarly, medicines currently being developed to exclusively treat COVID-19 are highly likely to have applications beyond COVID-19. Furthermore, not only do many COVID-19 antivirals and antibodies treat or potentially treat other indications, it is impossible to identify the many medicines being used to treat the broad range of symptoms suffered by patients with acute or long COVID-19.

This complexity confounds the understandable desire of the Commissioners to define the universe of “COVID-19 therapeutics” that would be swept under an extension of the TRIPS waiver.⁹⁸ On the contrary, extending the TRIPS waiver could lead to relaxed rules for compulsory licensing of patents on multipurpose medicines and pharmaceutical ingredients.⁹⁹ It would be difficult, if not impossible, to guarantee that multipurpose medicines produced under a compulsory license are used only for COVID-19 treatment.¹⁰⁰ Some of the waiver proponents sought to minimize this concern during the hearing by asserting that any compulsory licenses

⁹⁷ Airfinity (science.airfinity.com). See Appendix 2 to PhRMA’s Pre-hearing Brief: Expanding the TRIPS Waiver is Unnecessary and Harmful.

⁹⁸ Similarly, Commissioner Kearns asked for assistance in identifying the patent landscape of COVID-19 therapeutics. While this task suffers from the same problem that it is impossible to define the full universe of potential COVID-19 therapeutics, we would note that the World Intellectual Property Organization (WIPO) has just released an updated report on this topic. See WIPO (2023), COVID-19-related vaccines and therapeutics: Insights into related patenting activity throughout the pandemic, <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-23-en-covid-19-vaccines-and-therapeutics.pdf>.

⁹⁹ The original TRIPS waiver applies to “the subject matter of a patent required for the production and supply of COVID-19 vaccines,” which includes “ingredients and processes necessary for the manufacture of the COVID-19 vaccine.” See WTO Ministerial Conference, *Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022*, ¶ 1, n. 2, WTO Doc. WT/MIN(22)/30 (Jun. 22, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>; see also 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 4 (Dec. 2022), <https://cip2.gmu.edu/wp-content/uploads/sites/31/2022/12/GMU-C-IP2-Solovy-PolicyBrief-TRIPS.pdf>.

¹⁰⁰ 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 12 (Dec. 2022), <https://cip2.gmu.edu/wp-content/uploads/sites/31/2022/12/GMU-C-IP2-Solovy-PolicyBrief-TRIPS.pdf>.

granted under an extended waiver would be limited to use for treating COVID-19 and that innovative biopharmaceutical companies and their governments would be able to challenge any abuses of those compulsory licenses. And yet, many of the waiver extension proponents explicitly characterized previous attempts by governments and companies to counter such abuses and other failures to protect IP as “undue influence” and “bullying.” Politically and legally, it will not be feasible to police and remedy abuses of the waiver if extended to COVID-19 therapeutics.

Separate from the impossibility of ensuring that the waiver would be limited to the use of products for the treatment of COVID-19, the waiver would jeopardize the quality, safety and efficacy of the resulting COVID-19 therapeutics, increase pressure on supply chains and fuel opportunities for bad actors to supply adulterated, substandard or counterfeit versions of treatments. These concerns are not hypothetical. For example, the failure to implement TRIPS-level IP protections in some countries has been correlated with wide availability of counterfeit medicines,¹⁰¹ undermining efforts to improve access to medicine and threatening patients’ health and safety. By forfeiting additional American IP to countries and other entities, expansion of the TRIPS waiver would hurt patients in low- and middle-income countries the most since those patients would be most likely to be exposed to any adulterated, substandard or counterfeit versions of treatments.

In addition to these safety, quality and efficacy concerns, waiving commitments to protect U.S. innovation through an extended TRIPS waiver would allow and encourage global competitors of the United States to authorize domestic companies to produce the patented product for national industrial purposes. Now, more than ever, is not the time for the Administration to weaken American medical innovation and leadership, outsource American manufacturing jobs or jeopardize the United States’ ability to respond to future pandemics. These very real threats and the value of American innovation in the biopharmaceutical sector are detailed in Section III.B and IV of PhRMA’s Pre-hearing Brief. In addition, as requested by Commissioner Stayin during the hearing, attached as Appendix B to this submission is state-specific employment data showing the total number of jobs directly and indirectly supported by the development and manufacturing of COVID-19 therapeutics and vaccines in the United States.

Finally, consistent with the broader intent of the waiver proponents highlighted above in subsection B, the precedent of this waiver will not be limited to this pandemic. On the contrary, proposals have already been released to impose similar waivers in the event of future pandemics.¹⁰² Meanwhile, other IP opponents have their eyes set on other targets, including waiver of the TRIPS commitments for green technology to counter climate change.¹⁰³ These

¹⁰¹ Maria Nelson, Michelle Vizurraga & David Chang, Counterfeit Pharmaceuticals: A Worldwide Problem, 96 Trademark Rep. 1068 (2006), https://www.inta.org/wp-content/uploads/member-only/resources/the-trademark-reporter/vol96_no5_a6.pdf.

¹⁰² See, e.g., WHO, Zero Draft of the WHO CA+ for the Consideration of the Intergovernmental Negotiating Body at its Fourth Meeting - WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response (“WHO CA+”) (Feb. 1, 2023), https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf.

¹⁰³ See, e.g., Herbert Smith Freehills, UN Secretary-General Calls for Removal of Intellectual Property Constraints on Sharing of Renewable Energy Technology (June 1, 2022), <https://hsfnotes.com/ip/2022/06/01/un-secretary-general-calls-for-removal-of-intellectual-property-constraints-on-sharing-of-renewable-energy-technology/>.

broad attacks on IP rights fail to realize that without the baseline IP protections afforded by TRIPS, innovators will be woefully ill-equipped and not incentivized to develop the technological solutions that we will need to address these critical global challenges.

Conclusion

In short, the significant efforts of the U.S. innovative biopharmaceutical industry – underpinned by the global IP system – have resulted in a global surplus of COVID-19 vaccines and treatments. Challenges accessing those treatments, whether they be regulatory barriers or in-country distribution and administration obstacles, will not be addressed by extending the TRIPS waiver. On the contrary, extending the waiver will weaken American medical innovation and leadership, outsource American jobs and jeopardize the country’s ability to respond to future pandemics and health crises. As such, the evidence shows that the waiver should not be extended to COVID-19 therapeutics. Thank you again for the opportunity to provide input into this critical investigation.

Sincerely,

/s/ Kevin Haninger

Kevin Haninger
Vice President, International Policy

**Appendices to PhRMA's
Written Submission**

**COVID-19 Diagnostics and Therapeutics:
Supply, Demand, and TRIPS Agreement
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APPENDIX A

**Pharmaceutical Research and Manufacturers of America
U.S. International Trade Commission, Inv. No. 332-596
*COVID-19 Diagnostics and Therapeutics:
Supply, Demand, and TRIPS Agreement Flexibilities*
Summary of Position for Inclusion in the Report**

The evidence does not support extending the TRIPS waiver to COVID-19 therapeutics.

First, the evidence shows that governments around the world have access to affordable COVID-19 therapeutics. Supply significantly exceeds demand, even if we were to assume per capita consumption levels dramatically increased to become equivalent to those in the United States. PhRMA members have successfully worked with governments and generic manufacturers in developing countries, as well as with multilateral organizations and mechanisms such as COVAX, the Medicines Patent Pool, Global Fund and UNICEF, to provide access pathways for these innovations to all countries and are fully committed to providing global access to COVID-19 vaccines and therapeutics.

Second, to the extent that patients in some countries may not have the same level of access as here in the United States, this is not due to a lack of affordable doses, but rather to regulatory, last-mile administration and systemic barriers in those markets. With worldwide demand for COVID-19 therapeutics waning and governments and the WHO declaring an end to the public health emergency, the evidence does not support the need to increase supply of COVID-19 therapeutics.

Third, no evidence has been presented to demonstrate that waiving commitments to protect intellectual property (IP) will address the real barriers to accessing COVID-19 therapeutics. On the contrary, without credible and certain IP rights, companies would be unable to justify the significant investments needed to research and develop innovative medicines. Moreover, as demonstrated during the COVID-19 pandemic, IP protections have enabled foundational R&D and partnerships to develop COVID-19 solutions in record time and facilitated hundreds of collaborations globally to manufacture COVID-19 vaccines and therapeutics at scale. While TRIPS already anticipates the use of compulsory licensing, it does so as a limited exception to an innovator's patent rights and seeks to make them a measure of last resort. In practice, compulsory licenses, as demonstrated during the COVID-19 pandemic, are rarely the best mechanism for meaningfully improving patient access, and no evidence has been provided that greater flexibility is needed to grant compulsory licenses for COVID-19 therapeutics.

Finally, even if one were to erroneously assume that extension of the waiver to COVID-19 therapeutics would address patient access, any "benefit" would be significantly outweighed by the harm a waiver extension would inflict on innovation for treating COVID-19 and other medical conditions. U.S. workers supporting biopharmaceutical manufacturing and development would suffer as well. The existing waiver has significant legal and political ramifications and inappropriately signals that IP protections are a barrier that should be waived to address any global crisis. These implications exist even though no government has utilized the waiver on

COVID-19 vaccines. Extending the waiver to therapeutics would exacerbate these harms without providing any tangible benefits in terms of patient access.

For these reasons, the innovative biopharmaceutical industry repeats its call for the Administration and all policymakers to reject any expansion of the TRIPS waiver and instead focus on the shared objective of solving challenges to distributing and administering the global surplus of COVID-19 vaccines and therapeutics.

APPENDIX B

Total Number of Jobs Directly and Indirectly Supported by Development and Manufacturing of COVID-19 Treatments and Vaccines in the United States

State	Total: All Industries	Biopharmaceutical Manufacturing	Scientific Research	Other Services	Finance & Real Estate	Business Services	Distribution	Health Care and Education	Other Manufacturing
Total: United States	421,700	99,200	67,200	58,400	48,000	46,600	44,500	37,700	20,100
Alabama	2,630	470	650	370	270	290	260	250	80
Alaska	10	-	10	-	-	-	-	-	-
Arizona	5,630	1,080	1,460	750	640	610	500	460	130
Arkansas	1,060	170	390	130	50	100	90	90	40
California	55,880	13,030	8,190	8,110	6,080	6,770	5,930	5,000	2,770
Colorado	7,040	1,530	1,150	1,050	870	770	740	630	300
Connecticut	1,620	360	390	200	180	160	140	140	40
Delaware	120	30	20	20	10	20	10	10	10
District of Columbia	190	10	120	10	30	20	-	-	-
Florida	26,140	3,980	7,050	3,600	4,050	2,870	2,150	2,010	430
Georgia	6,520	680	1,840	950	1,000	790	590	510	150
Hawaii	260	10	120	40	20	30	20	20	-
Idaho	870	90	300	130	80	90	70	80	20
Illinois	21,180	4,180	2,590	3,040	2,520	2,680	2,480	1,980	1,710
Indiana	18,450	4,760	1,290	2,900	1,460	2,300	2,400	1,810	1,530
Iowa	6,560	2,540	520	740	580	470	830	560	320
Kansas	4,270	1,370	530	530	370	410	450	380	250
Kentucky	2,360	490	510	300	170	280	250	220	140
Louisiana	2,980	220	1,340	420	230	280	220	260	20
Maine	3,200	1,200	250	400	290	300	340	270	150
Maryland	9,190	2,360	1,460	1,270	960	950	1,040	870	280
Massachusetts	10,780	2,520	1,880	1,400	1,260	1,220	1,060	1,040	410
Michigan	12,580	3,400	1,740	1,700	1,070	1,460	1,300	1,210	700
Minnesota	7,170	1,800	1,060	1,000	780	710	760	690	370
Mississippi	1,450	370	370	180	100	140	120	130	40
Missouri	9,110	2,340	1,110	1,320	1,040	940	1,050	770	550
Montana	1,820	620	300	240	140	100	190	160	70
Nebraska	4,330	1,130	880	550	420	380	460	380	140
Nevada	1,670	330	430	230	200	170	150	120	30
New Hampshire	420	150	60	50	30	50	40	30	10
New Jersey	20,580	4,820	2,390	2,820	2,490	2,470	2,400	1,920	1,260
New Mexico	1,490	400	350	200	110	130	110	140	50
New York	27,640	8,730	3,750	3,030	4,340	2,550	2,230	2,220	790
North Carolina	35,710	9,500	3,710	5,120	3,690	4,130	4,220	3,300	2,050

