

March 22, 2023

Inv. No. 332-596
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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: Submission of Oral Hearing Statement, Investigation No. 332-596

Dear Secretary Barton,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I hereby submit my oral hearing statement for the public hearing in *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, Investigation No. 332-596, scheduled to commence at 9:30 a.m. on Wednesday, March 29, 2023.

Sincerely,

/s/ Kevin Haninger

Kevin Haninger
Vice President, International Policy

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
Public Hearing Oral Statement: March 29-30, 2023

My name is Kevin Haninger, Vice President of International Policy at the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the innovative U.S. biopharmaceutical industry. PhRMA member companies and the more than 900,000 women and men that they directly employ across the United States are devoted to inventing, manufacturing and distributing medicines that enable people to live longer, healthier and more productive lives.

PhRMA appreciates the opportunity to testify in this important investigation that not only will shape how the U.S. Government assesses ideological calls to extend the TRIPS waiver to COVID-19 diagnostics and therapeutics, but also will underscore the essential role of intellectual property (IP) protections in driving U.S. innovation – particularly in the biopharmaceutical sector – and the significant contributions that our sector makes to the U.S. economy, jobs and patients around the world.

Consistent with our pre-hearing brief, I would like to focus on five points during my testimony.

First, the biopharmaceutical industry innovated and produced safe and effective vaccines and treatments to combat COVID-19 in record time. Within just one year of the World Health Organization (WHO) declaring a public health emergency, innovative biopharmaceutical companies from around the world developed, manufactured and deployed multiple COVID-19 vaccines, including vaccines that use innovative mRNA and viral vector-based technologies.

By the start of 2022, 20 companies were manufacturing enough doses to supply COVID-19 vaccines to the entire global population by the end of the year. Today, thanks to more than 15.5 billion COVID-19 vaccine doses produced and delivered around the world, more than 70 percent of the global population (5.6 billion people) have received at least one dose of a COVID-19 vaccine and more than 2.3 billion people also have received at least one booster. Existing COVID-19 vaccine production capacity is more than sufficient to meet the demand of any person that wants a vaccine.

These unprecedented achievements – fueled by decades of investment and hundreds of global partnerships founded on IP protections – are estimated to have saved as many as 20 million lives and averted over 80 million hospitalizations.

The development of safe and effective COVID-19 treatments has been equally successful. Several medicines, including antivirals and antibodies, have been approved or authorized by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency for the treatment of COVID-19, and yet these treatments reflect just three percent of the pipeline of potential COVID-19 treatments.

Over 70 million courses of COVID-19 antivirals were produced by the end of 2022, an amount which far exceeded demand in 2022 (19 million), and existing stockpiles (more than 30 million) are large enough to exceed anticipated total global demand in 2023.

Critically, even if every country in the world were to increase its per capita demand for COVID-19 treatments to the same level as the United States – for which uptake is significantly higher than not only low- and middle- but even other high-income countries – then current production would be more than sufficient to satisfy demand, and a global surplus of COVID-19 treatments would continue to exist at the end of 2023.

Second, industry’s success in combatting COVID-19 was founded on intellectual property protections, including the baseline protections provided by the TRIPS Agreement. IP plays a critical role at each stage of the innovation and development process, from providing the certainty and predictability needed to secure critical investments to enabling R&D partnerships to develop and create the background technology and know-how used in several of the COVID-19 vaccines and treatments.

IP protections ensured by the TRIPS Agreement also have facilitated hundreds of partnerships globally to manufacture COVID-19 vaccines and treatments at scale.

Concerning COVID-19 treatments alone, IP has enabled more than 140 manufacturing partnerships spanning more than 30 countries, including such economically and geographically diverse countries as Brazil, India, Indonesia, Kenya, Singapore and South Africa.

PhRMA members are fully committed to providing global access to COVID-19 vaccines and treatments and have worked closely and successfully with organizations such as COVAX, UNICEF, the Global Fund and the Medicines Patent Pool, to provide access pathways for these innovations to all countries. 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 treatments at no cost.

Unfortunately, few countries have placed orders for these products through these programs. Further, few low- and middle-income countries – including only five countries in Africa – have approved or authorized existing new COVID-19 treatments for their own markets, even though several therapeutics are pre-qualified by the WHO. As a result, many low- and middle-income countries have refused donations of existing COVID-19 treatments from NGOs, manufacturers and governments despite those treatments being offered at no cost.

In short, neither supply nor cost nor IP is inhibiting patient access to COVID-19 vaccines and treatments.

Nonetheless, certain governments and entities continue to seek an extension of the TRIPS waiver to diagnostics and therapeutics – even as the existing waiver has proven unnecessary and has not been utilized.

As even USTR has noted, many proponents of expanding the TRIPS waiver are longstanding critics of the TRIPS Agreement for whom furthering TRIPS Agreement flexibilities is “a matter of principle.” It is critical that proponents of the waiver not be permitted to leverage this pandemic opportunistically to achieve their longstanding objective to weaken global IP rights.

As Switzerland and Mexico noted to the World Trade Organization (WTO) last November, “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.”

Underscoring these legitimate concerns is the fact – and my **third** point – that **extending the waiver would jeopardize the innovation underway to develop new COVID-19 treatments** to address new variants and the implications of long-COVID. As noted above, existing COVID-19 treatments represent just three percent of the potential pipeline. A TRIPS waiver expansion would jeopardize the entire pipeline – both the three percent already available to patients and the 97 percent still under development.

Even worse, these impacts would not be limited to just COVID-19 therapeutics. Nearly 60 percent of medicines being developed to treat COVID-19 either currently treat or are being developed to treat other conditions, such as cancers and auto-immune diseases. Similarly, medicines currently being developed primarily to treat COVID-19 are highly likely to have applications beyond COVID-19. An expanded TRIPS waiver could capture – and therefore jeopardize – each of these broad application markets.

Fourth, extending the waiver to COVID-19 therapeutics and diagnostics also would weaken American medical innovation and leadership, outsource American jobs and diminish our country’s ability to respond to future pandemics and health crises, all counter to the Administration’s stated objectives.

The innovative biopharmaceutical sector generates high-quality American jobs, powers economic output and exports for the U.S. economy, and is the foundation of one of the nation’s most dynamic innovation ecosystems. U.S.-headquartered multinational biopharmaceutical companies locate 90 percent of their R&D expenditures in the United States.

Our industry is among the top five employers of U.S. manufacturing jobs, with more Americans directly employed in biopharmaceutical manufacturing than in manufacturing in several other industries, including iron and steel, aerospace, petroleum and coal, and electric equipment and appliances.

America’s workers have been instrumental to the biopharmaceutical industry’s response to the COVID-19 pandemic. A surge in COVID-19 related research in the United States, plus record high U.S. exports of biopharmaceutical products, has generated over 400,000 U.S. jobs that directly and indirectly support the development and manufacturing of COVID-19 vaccines and treatments.

By jeopardizing these jobs and reducing America's global leadership in biopharmaceutical innovation and production, expansion of the TRIPS waiver would reduce our country's ability to respond to future pandemics.

Further, any expansion of the TRIPS waiver poses significant threats to patient safety and supply chains and increases the risk of counterfeits. Stringent regulatory authorities, like the FDA, and innovators working in cooperation with partners under voluntary licensing agreements, have ensured the quality, safety and efficacy of COVID-19 vaccines and therapeutics.

Finally, rather than expending finite resources on considering yet another misguided IP waiver, **policymakers should focus on the evident issues impacting distribution and administration of COVID-19 vaccines and therapeutics**, including weak health systems, inadequate infrastructure and last-mile distribution and administration challenges, such as cold storage, transportation and health workforce barriers.

Tragically, these challenges have been exacerbated by regulatory delays, export restrictions and other trade-related barriers. At a time when research and development have never been more important, our industry shares the goal of widespread availability of the existing vaccine and therapeutic surplus. Our companies encourage all governments and stakeholders to focus on the real challenges to achieve these shared objectives.

PhRMA greatly appreciates this opportunity to participate in today's hearing and stands ready to address any questions that the Commission may have.