May 4, 2023

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

RE: USITC Investigation No. 332-596, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities

Dear Secretary Barton:

The Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American healthcare. It is an inclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable, high-quality care accessible to all Americans. Among the council's top priorities are improving healthcare access for people without health insurance, accelerating the growth of health information technology, reforming healthcare payment systems to incentivize quality and positive patient outcomes, improving patient safety, and addressing the healthcare workforce shortage.

HLC writes today to express concerns over proposals to limit intellectual property protections for COVID-19 diagnostic tools and therapeutics under the World Trade Organization's TRIPS agreement. We believe that doing so could have devastating implications for the future of biopharmaceutical research and development and for our economy more broadly. At the same time, the evidence indicates that such a TRIPS waiver would not meaningfully expand access to COVID-19 diagnostics and therapeutics for patients. We can look to the effect of the TRIPS waiver for COVID-19 vaccines as evidence of this fact.

While we applaud the Biden administration's work to scale up vaccine and therapeutic production and distribution, it is a mistake to use the pandemic as a means of undercutting intellectual property protections.

The WTO TRIPS vaccine waiver rested on arguments that patent protections hinder vaccine production in developing nations. The evidence, however, simply fails to support such speculative claims. By the time the TRIPS waiver came into force in June 2022, total global supply of vaccines -- that is, vaccine produced and delivered to its destination for administration -- stood at more than 15 billion doses.[1] The world's largest COVID vaccine manufacturer, the Serum Institute of India, amassed a surplus of vaccine doses so large -- at one point surpassing 200 million -- that it halted production entirely at the end of 2021.[2]

[1] https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm
[2] https://www.fiercepharma.com/pharma/200m-unused-doses-astrazenecas-covid-vaccine-partner-serum-institute-halts-production

On the other hand, intellectual property protection, including the TRIPS agreement, provided the underlying infrastructure biopharmaceutical companies needed to bring COVID-19 vaccines to market in record time. Absent our strong global IP regime -- which started when the TRIPS agreement came into force in the mid-1990s -- researchers would have had less incentive to pursue the kind of risky and uncertain research projects that put us within striking distance of mRNA vaccines before COVID-19 even arrived.[3] For decades prior to the pandemic's onset, scientists did research into mRNA vaccines without successfully launching a single product. But the knowledge they gained in doing so prepared the way for an effective response when the crisis hit.[4] Now, they are working to harness the same technology to address a host of other serious ailments such as HIV, hepatitis C, malaria, and cancer.[5]

If the WTO moves forward with the proposal to expand the COVID-19 vaccine waiver to encompass diagnostics and therapeutics, as well, the decision will threaten the very foundation of this system of innovation in the U.S. life sciences sector. Meanwhile, competitors and adversaries will pounce on the opportunity to seize and exploit American-discovered medical breakthroughs for themselves. The result would effectively require U.S. biotech firms to create and subsidize their own competitors. Such an outcome would provide China a decided advantage in global innovative competitiveness while weakening U.S. competitiveness and global leadership in a leading area of innovation.

Handing over the hard-earned intellectual property underlying American-discovered COVID-19 treatments would harm our economy and the hundreds of thousands of workers in jobs supported by the research and manufacturing of these products. The production of COVID-19 vaccines and therapeutics here in the United States supports nearly half a million jobs in research, manufacturing, and sectors outside of the biopharmaceutical space.[6] If other countries start their own production efforts, it is likely that many of these jobs will disappear. Just consider how global IP theft -- even under the strong enforcement regime made possible by the TRIPS agreement -- already hurts our economy. According to recent estimates, the annual economic cost of IP theft is as great as $600 billion.[7] Any weakening of IP protection would exacerbate this problem by effectively legalizing it.

The most direct and immediate damage from a TRIPS waiver extension will occur in our life sciences sector, as investors lose confidence in the security of the intellectual property at its heart. Today, the U.S. biopharmaceutical industry supports over 4.4 million jobs and spends more on R&D than any other industry.[8,9] It contributed $2.9 trillion to the U.S. economy in 2021.[10] Writ large, our innovation economy encompasses 45 million jobs in IP-intensive industries.[11] A broad loss of investor confidence in the security of IP protection could have disastrous consequences.

Indeed, it may already be doing so. "Dry powder" at private equity firms globally reached a record $3.2 trillion in 2022,[12] and stood at just under $300 billion in the United States.[13] These are funds readily available for venture investment as managers calculate opportunity. The security of IP protection is always top of mind in such calculations. Investors are carefully watching U.S. decisions at the WTO.

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[3] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#:~:text=Patents%20Back%20to%20top,novelty%2C%20inventiveness%20and%20industrial%20applicability.
[4] https://www.nature.com/articles/d41586-021-02483-w
[5] https://www.nature.com/articles/s41591-021-01393-8
[6] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/2022-09-30-PhRMA-TRIPS-Waiver-Expansion-FINAL_November-2022.pdf p. 8 (MATH: 99 + 67 + 58 + 48 + 47 + 44 +38 + 20 = 421 (in thousands))
[7] https://www.nbr.org/wp-content/uploads/pdfs/publications/IP_Commission_Report_Update.pdf p. 1
[8] https://qa-phrma.mrmdigital.com/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf p. 1
[9] https://www.trade.gov/selectusa-biopharmaceuticals-industry
[10] https://go.bio.org/rs/490-EHZ-999/images/TEConomy_BIO_2022_Report.pdf?_ga=2.133761480.778822959.1680226073-1974032405.1680226073 p. 3
[11] https://www.nbr.org/wp-content/uploads/pdfs/publications/ip_commission_2021_recommendations_mar2021.pdf p. 1
[12] https://www.statista.com/statistics/513838/value-of-private-equity-dry-powder/
[13] https://www.axios.com/2023/01/14/venture-capital-dry-powder-2023

Uncertainty over the future of IP may be introducing an additional element of caution into investment decisions right now.
And while the worst of the pandemic is behind us, American drug researchers are not done working to improve treatment options against the virus. Rather, they are hard at work running hundreds of additional clinical trials involving other COVID-19 treatments in the development pipeline.[14] Such research could yield treatments for illnesses well beyond COVID-19 -- yet if the treatments were developed in relation to the pandemic, an extension of TRIPS flexibilities would destroy the IP protection in these additional applications as well.

The future of these research projects depends on our continued support for strong intellectual property protections that reward scientists, entrepreneurs, and investors for taking on massively risky and expensive tasks. Consider that according to recent research, the cost of developing a single vaccine against epidemic infectious disease can exceed $1 billion, including the cost of the inevitable failed candidates in the drug development process.[15] Successful candidates can take over a decade to reach patients.[16] The failure rate for this research area stands at 94 percent.[17] Thus, the ability to retain a period of temporary exclusivity through IP protections is not a trivial factor in the process. Rather, it is the singular enabler for undertaking risky projects in the first place.

Moreover, there is little credible evidence that intellectual property has prevented access to COVID-19 vaccines and therapeutics. To the contrary, the IP system helped foster additional collaboration across organizations to expand treatment access. Many of these arrangements took place through the United Nations' Medicines Patent Pool (MPP), which facilitates partnerships between governments and biopharmaceutical companies to ensure that low- and middle-income countries have access to the vaccines and treatments they need.[18] For example, in November 2021 Pfizer and MPP signed a voluntary license agreement to supply generic versions of PAXLOVID to 95 low-and middle-income countries -- accounting for over half of the global population.[19] In January 2022, Merck signed a similar agreement with MPP to make low-cost versions of its antiviral, molnupiravir, available in 105 such countries.[20]

Policies that weaken intellectual property protection on the false premise that it prevents equitable access to COVID-19 vaccines and treatments may already be leading to a crisis in innovation. Without strong and predictable IP protections, the incentive to invest in future research and development is much diminished. For the sake of the millions of people in jobs supported by America's biopharmaceutical industry, the economic benefit it brings to our nation, and our ability to respond to future public health threats, the U.S. government should oppose expanding the TRIPS flexibilities.

Sincerely,

Mary R. Grealy
President

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[14] https://www.nature.com/articles/d41586-022-00562-0
[15] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext
[16] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext
[17] https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30346-2/fulltext
[18] https://medicinespatentpool.org/who-we-are/about-us
[19] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing
[20] https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir