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Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
Room 112A
500 E Street SW
Washington, DC 20436

Written comments regarding Investigation No. 332-596. These comments do not contain Confidential Business Information (CBI).

Merrill Matthews, PhD
Resident Scholar
Institute for Policy Innovation
1320 Greenway Drive, Ste. 820
Irving, TX 75038 USA

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RE: Investigation No. 332-596

Commissioners Johanson, Schmidtlein, Kearns, Stayin, and Karpel:

I and my colleagues at the Institute for Policy Innovation (IPI) would like to thank the U.S. International Trade Commission for the opportunity to comment on a proposed extension of the TRIPS intellectual property waiver for Covid-19 diagnostics and therapeutics.

The Institute for Policy Innovation is a non-profit, non-partisan public policy "think tank" based in Irving, Texas, and founded in 1987 to research, develop and promote innovative and non-partisan solutions to today's public policy problems. IPI is supported wholly by contributions from individuals, businesses and non-profit foundations.

By way of background, I am a resident scholar with IPI. I am also a past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists. And I currently serve as Chair of the Texas Advisory Committee to the U.S. Commission on Civil Rights.

I am writing to express strong opposition to any extension of the misguided waiver of commitments to protect intellectual property for Covid-19 diagnostics and therapeutics.

Doubling down on a fundamentally misguided IP waiver would represent a profound failure to learn the policy lessons of the pandemic—and undermine the U.S. response to future pandemics. In addition, it would signal to our most innovative firms that their intellectual property—and consequently, their substantial R&D investments—are no longer valued in America.

While the Covid-19 pandemic offered plenty of opportunities for policy missteps, one of the most egregious blunders was the June 2022 TRIPS waiver. After more than two

years of furious negotiation, the World Trade Organization followed the pleas of India, South Africa, and dozens of other low-income nations to waive commitments to protect IP for Covid-19 vaccines on the mistaken belief that this would speed global access.

Unfortunately, this was a solution in search of a problem. The TRIPS waiver did nothing to speed global vaccine access. Waiving IP commitments for Covid-19 vaccines, especially the highly effective Pfizer and Moderna vaccines developed here in the United States, failed to incentivize R&D or distribution, and indeed ignored the true cause of access delays: manufacturing and distribution challenges. Export controls proved a significant bottleneck for ramping up vaccine production. A shortage of cold storage, limited shipping capacity, and crumbling medical infrastructure impeded access around the globe. These are challenges that cannot be fixed by IP waivers. Even when tireless medical professionals were able to bring lifesaving shots to patients, they encountered severe vaccine hesitancy.

These were difficult challenges, but American manufacturers, policymakers, and medical professionals surmounted them with great effort. Globally, the United States assisted in the administration of more than 12.7 billion Covid-19 shots—and more than 72 percent of the world's population was inoculated against the virus.

As a result, it is clear that intellectual property did not limit the global vaccine rollout. On the contrary, IP fueled the years of research and development that created America's effective Covid-19 vaccines.

Moderna and Pfizer, working with BioNTech, developed the first trials of their mRNA vaccine candidates just two days after Chinese researchers and whistleblowers revealed Covid-19's genetic sequence. Indeed, by April 2021 vaccines were broadly available to the general population.

This rapid rollout was the result of more than a decade of research into the promising new field of mRNA research. Thanks to the confidence provided by America's iron-clad commitment to both global and domestic IP protections, firms were able to identify viable vaccine candidates underpinned by this revolutionary mRNA tech in just days, and run accelerated trials to ensure shots got in arms as quickly as possible. The speed with which these companies were able to develop, test, manufacture and deliver these vaccines was a modern-day miracle. And the companies did it mostly with their own capital, based on the assurance of strong U.S. IP protections.

Some advocates push for the expanding the TRIPS waiver to diagnostics and therapeutics based on the mistaken theory that handing developing countries valuable American IP will jump-start their nascent biopharmaceutical and diagnostic industries. But developing and manufacturing vaccines is a complex process that requires significant investment, infrastructure and expertise.

Even if IP commitments were waived with the stroke of a pen, developing countries would be hard-pressed to have the capacity or the funds to manufacture their own vaccines. The cost of setting up a dedicated mRNA facility can run north of $200 million—and that's before manufacturers try to address the severe staffing shortage of skilled life science labor.

Even with extant manufacturing capacity, timing vaccine demand proved challenging.

Consider India's Serum Institute (SI). After concerted advocacy, SI succeeded in inking technology transfer agreements to manufacture AstraZeneca's vaccine. But by December 2022, the Institute was forced to halt production after stockpiling 200 million

doses that ultimately went to waste. As the pandemic wound down, the real reason for the TRIPS waiver became clear—developing economies with generic manufacturers want to keep the idea of accessing U.S. technology through "compulsory licensing" alive and well. What advocates for an IP waiver miss is that undermining U.S. intellectual property for short-term gains reduces the incentives for world-leading American firms to invest in critical R&D.

Take drug development. New drugs require billions of dollars and years of research, development and clinical trials with no guarantee of success—indeed, failures far outnumber successes.

Innovators and investors take these enormous risks because they know that if successful, strong and predictable IP rights will protect their ability to recoup their massive investment in a new drug (as well as the cost of their many failures). Voiding IP rights on the global stage introduces enormous uncertainty for these firms—and the consequences of reduced R&D spending and risk-taking will be felt most acutely by patients seeking new treatments.

In addition, undermining IP cuts our future pandemic preparedness efforts off at the knee. It not an exaggeration to assert that without those IP protections, development and production of the mRNA vaccines would have taken much longer, if at all. And hundreds of thousands, if not millions, more people would have died of Covid-19 as a result.

The U.S. life science industry nimbly rose to the challenge posed by Covid-19 precisely because drug companies were able to rely on the rule of law, knowing that their investments, research, and expertise would be backstopped by strong IP protections. This expectation also fueled more than 370 separate voluntary manufacturing and licensing

deals. Policymakers should carefully consider the industry's strong track record of voluntary partnership, rather than rushing to the failed precedent of the original TRIPS waiver.

With the original TRIPS waiver, policymakers wrought far too much damage to our innovation ecosystem. Extending this IP waiver to Covid-19 diagnostics and therapeutics, while a win for developing countries looking for a free lunch of American know-how and geopolitical rivals hoping to weaken America's innovation capacity, would be a catastrophic blow to U.S. leadership on the world stage and the rule of law.

I and my colleagues at IPI respectfully urge the U.S. International Trade Commission to stand up for American innovators, investors, and risk-takers—and recommend no further extension of an IP waiver to Covid-19 diagnostics and therapeutics. Thank you for the opportunity to comment on this matter of crucial importance for American innovation.

Respectfully,

Merrill Matthews, PhD
Resident Scholar
Institute for Policy Innovation