SPPI Southwest Public Policy Institute

May 5, 2023

Secretary Lisa R. Barton
United States International Trade Commission
500 E Street, SW
Washington, D.C., 20436

Written submission re: USITC Investigation No. 332-596

Dear Secretary Barton,

I am concerned about the U.S. Trade Representative's request for an investigation by the U.S. International Trade Commission to "inform consideration of whether to extend flexibilities under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to COVID-19 diagnostics and therapeutics." (USITC Investigation No. 332-596.)

As the President of the Southwest Public Policy Institute, a research institute dedicated to improving the quality of life in the American Southwest by formulating, promoting, and defending sound public policy solutions, I have been focused on implementing innovative policy reforms that increase freedom and decrease government abuses. We have produced research showing the challenges that entrepreneurs, researchers, and businesses engaged in cutting-edge research are increasingly facing. Unfortunately, the proposal to extend the IP waiver under the TRIPS Agreement would worsen the burden on innovators and have disastrous consequences for the American Southwest and the nation.

Intellectual property protections are critical to incentivize the research, development, and production of products and services. The importance of intellectual property protections are especially pronounced when it comes to the creation and commercialization of new and innovative products that require massive upfront investment. The pharmaceutical industry's development of new, life-saving drugs is one of the most resource-intensive processes, and it would be decimated by the loss of intellectual property protections.

It takes between 10 and 15 years of research and development for a new drug to be perfected, pass clinical trials, and be available in pharmacies for consumers to use and derive benefits from. It costs nearly $3 billion per drug, and only about 0.02% of drugs in development ever do get produced and approved for sale to the public.

Drug manufacturers must earn enough money on their successful drugs to pay for

the research and development not only of those drugs themselves but also the other drugs that ultimately did not make it to the market and drugs currently under development. If the companies cannot make a profit, they will cease to exist. They must pay for research facilities using state of the art technologies, highly-educated scientists, and multiple rounds of trials that go into the creation of every new drug.

The costs of producing drugs can be expensive, but the benefits we reap are profound. Covid-19 vaccines saved an estimated 3.2 million American lives over just two years. There has also been incredible innovation in therapeutics and pills that treated Covid-19 and saved lives.

Early on in the pandemic, life sciences companies in the United States and other countries with robust intellectual property protections rushed to the forefront of research, quickly investigating, discovering, and repurposing many drugs that reduced the time of hospitalization and decreased mortality rates.

These discoveries would not have been possible without the intellectual property protections. Patents, trade secrets, and other IP rights enable companies to earn a return from their discoveries and inventions. But this all depends on the rule of law, both here and abroad. That includes the WTO's TRIPS Agreement. To threaten TRIPS is to threaten life-saving innovation.

This wrong-headed proposal ignores basic economic truths about incentives and the laws of supply and demand. I am worried about the negative effects it could have both on people's health and on the economies of the Southwest and the nation. The life sciences industry is one of our fastest-growing industries in the Southwest.[1] Tens of thousands of jobs could be put at risk by a decision that would harm this vital job-creating industry.

Extending and expanding the IP waiver would have detrimental effects not only for access to drugs in the United States, but it would also stifle access to drugs in the world. It is no wonder that eight in 10 drugs in development worldwide are produced in the United States. This leadership is in no small part due to the fact that U.S. law provides some of the strongest intellectual property protections in the world, according to both the Property Rights Alliance's 2022 International Property Rights Index and the U.S. Chamber of Commerce's 2022 International IP Index. Globally, drug innovation is highly correlated with IP protection.

The benefits of the breakthrough drugs produced in the U.S. and other countries with cultures of innovation expound to the world. Through voluntary licensing agreements and other partnerships, 13.4 billion doses of Covid-19 vaccines have been administered worldwide, covering 70% of the world population.

1 https://gardner.utah.edu/wp-content/uploads/LifeSci-FS-Aug2021.pdf?x71849

The proposal to expand the TRIPS waiver is premised on the idea that it would expand access to various drugs and treatments in the developing world. But the effect would actually be the exact opposite. Drugmakers would be reluctant to invest more in research and development. The supply of new drugs would dry up. Life-science innovators would be wary about sharing their formulas with and processes with overseas manufacturing facilities through voluntary partnerships and licensing agreements. TRIPS, by applying standardized rules to all member nations, provides the assurances needed to allow for partnerships and large-scale global distribution.

Consequently, I urge the U.S. government to oppose the expansion of the TRIPS waiver. Proponents of the waiver understandably are troubled by inequalities in access to Covid-19 therapeutics, but expanding the waiver would only make the problem worse now and in the future. We need to be prepared for the next pandemic. Only by strengthening IP protections worldwide can we make sure that every country will have the resources and access to effective life-saving drugs to respond from day one.

Respectfully,

Patrick M. Brenner