



Frank Cullen, Executive Director
Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member

Inv. No. 332-596

Written Submission

Council for Innovation Promotion (C4IP)

Contains no CBI

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Frank Cullen

Executive Director

Council for Innovation Promotion (C4IP)



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April 26, 2023

Via Electronic Submission

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

Re: Investigation No. 332-596

The Council for Innovation Promotion appreciates the opportunity to submit written comments in connection with Investigation No. 332-596.

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. Founded and chaired by former directors of the U.S. Patent and Trademark Office, our coalition has distinguished itself as a valued partner to those considering policies impacting America's IP system.

Since its founding a few months ago, C4IP has sought to facilitate informed and balanced conversations on the proposed TRIPS waiver expansion, including a [discussion](#) with former U.S. Secretary of Commerce Gary Locke.

It is with that same intent that we submit comments to the Commission regarding waived obligations under the World Trade Organization TRIPS Agreement.

C4IP wholly supports the ITC as a forum for fact-finding and for recommendations to the U.S. Trade Representative in matters pertaining to tariffs, trade, and competitiveness.

And, on the TRIPS Agreement, the facts are clear. Extensive consultations with relevant experts — and a wealth of [data](#) on market dynamics — reveal that [extending](#) the [current intellectual property waiver](#) on Covid-19 vaccines to diagnostics and therapeutics would prove enormously counterproductive.

Stripping developers of the internationally recognized IP protections underpinning their products and processes will not lower barriers to access. However, it will create new ones in the form of stifled investment, innovation, and U.S. competitiveness.

Endorsing the proposed waiver expansion could threaten America's status as the world's leading developer of cutting-edge treatments and technologies.

Market Dynamics for Covid-19 Diagnostics and Therapeutics

The USITC has been [tasked](#) with investigating "the universe of existing COVID-19 diagnostics and therapeutics" and providing an overview of global market dynamics.

That investigation will surely reveal the truth that logistical, regulatory, and infrastructure [challenges](#) — not intellectual property protections — were responsible for the delays and inequalities in the deployment of these products. Many developing countries are struggling with last-mile logistics, including providing adequate transportation and storage for treatments. Others lack the necessary medical infrastructure and healthcare workforce.

[No IP-induced shortages](#) exist for Covid-19 diagnostics or therapeutics. In fact, quite the opposite is true. Strong IP has enabled an unprecedented pace of research, development, and production to safely occur at qualified facilities around the world.

When companies know their discoveries are protected, they are ready and willing to share their technological know-how with other entities to save lives. Indeed, Covid-19 therapeutic manufacturers have signed [over 400](#) voluntary licensing and manufacturing agreements, entered into partnerships with multilateral organizations, and approved tiered pricing policies to bolster global accessibility of the treatments.

[Pfizer](#) and [Merck](#), for instance, have willingly licensed their patents to the United Nations-backed [Medicines Patent Pool](#) — enabling generic producers worldwide to manufacture their respective antivirals, Paxlovid and Molnupiravir.

As C4IP recently [underscored](#), governments and NGOs have "large stockpiles of treatments going unused" as a result. Meanwhile, diagnostics manufacturers have reported "large surpluses of tests available for order."

Indeed, in September 2022, low- and middle-income countries had only disbursed [10 million](#) of the more than 35 million treatments donated by governments and NGOs. Overall, manufacturers have produced more than 70 million courses of Covid-19 antivirals and built stockpiles of more than 30 million, which are predicted to surpass total global demand in 2023. Meanwhile, demand for diagnostic products has also not exceeded the supply.

Put plainly: Extending the TRIPS waiver — and suspending IP protections for Covid-19 diagnostics and therapeutics — will not add more of either product to the global arsenal. Indeed, extending the waiver will jeopardize the number of current — and future — diagnostics and therapeutics in the global market.

Impact of Weakening IP: Stifled Innovation

An expanded waiver would strike a severe blow to innovation by calling support for fundamental IP rights into question. Even over the course of this investigation, a host of patents will remain in jeopardy — crippling the IP-intensive industries that [make decisions to invest](#) and innovate based on those protections.

Innovators must be able to obtain meaningfully enforceable patents to attract investments into cutting-edge research and development, commercialize their products, and recoup outlays. This is particularly true within sectors, like life sciences, where innovations demand steep initial investments — to the tune of [\\$2 billion](#) — and can take a [decade or more](#) to reach the market.

Intellectual property is the source of continued breakthroughs in modern medicine. And right now, many people here and around the world continue to be [infected](#) by the coronavirus with severe health consequences — even death. New and sustained investments in additional Covid-19 therapies are needed to address the ongoing impacts of this pandemic.

Unfortunately, expanding the TRIPS waiver to include Covid-19 therapeutics and diagnostics will stunt these life-saving investments. In the absence of IP protections, it would become far harder for innovative companies to earn returns that are [commensurate](#) with their investments. No reasonable CEO would spend \$2 billion developing a Covid-19 therapy under these conditions.

Worse still, while diagnostics, therapeutics, and vaccines manufactured for Covid-19 may be the first products impacted by the global weakening of IP protections, they will not be the last. Indeed, when the original TRIPS waiver was debated in May 2022, [UN Secretary-General António Guterres](#) hinted that renewable energy technology "must be treated as essential and freely-available global public goods." He added that "removing obstacles to knowledge sharing

and technological transfer — including intellectual property constraints — is crucial for a rapid and fair renewable energy transition."

Further extending the TRIPS waiver's scope would continue us down a perilous path — one on which the investment incentives required to pursue innovative inquiries are squandered, and other countries can insist on a "right" to a vast range of U.S. patented technologies. Plus, it will cause harm to the public, who will be deprived of urgently needed medical solutions.

Impact of Weakening IP: Hampered U.S. Economic Competitiveness

Of equal concern, by allowing companies in other countries to appropriate U.S.-developed technologies, the TRIPS waiver expansion would hamper the United States' global economic competitiveness. There would be significant consequences for U.S. businesses in sectors ranging from clean energy to software to high-tech manufacturing.

Strong IP protection is the backbone of America's innovation ecosystem, supporting the alignment of U.S. economic interests with global public health. Today, [IP-intensive U.S. research industries](#) create millions of jobs, improve billions of lives, and generate trillions of dollars in economic activity.

And the U.S.-led breakthroughs in combating Covid-19 merely scratch the surface of our potential. American scientists are hard at work, pursuing innovative solutions that are fit to tackle the world's most pressing problems. The [revolutionary mRNA technology](#) underlying many Covid-19 products, for instance, can transform the entire healthcare landscape and yield cures to previously fatal diseases.

Forcing American innovators to give up technology like this to other countries, especially those considered adversaries, remains to be unwise from both an [economic and strategic standpoint](#).



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Any one of them could exploit the technology to further their objectives — potentially with nefarious intent and at the United States' expense.

And this decision to sacrifice America's IP and competitive edge would be needlessly made, as it would not boost the global supply of Covid-19 diagnostics and therapeutics.

Closing Remarks

Global public health is best served by encouraging innovative investments that lead to breakthroughs in quality of life and stimulate economic development. Strong patent protection has long allowed the United States to advance this aim to the betterment of billions of lives.

The United States imprudently backed the original TRIPS waiver for Covid-19 vaccines, even though [no IP-induced shortages](#) existed then either. Let us not make the same mistake twice.

Thank you again for the opportunity to comment, and we invite you to consider us a resource as you continue to investigate this critical issue in the weeks ahead.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen', with a long horizontal flourish extending to the right.

Frank Cullen

Executive Director

Council for Innovation Promotion (C4IP)

Appendix

500-word summary for inclusion in ITC's final report:

The Council for Innovation Promotion is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

C4IP wholly supports the ITC as a forum for fact-finding. And, on the TRIPS Agreement, the facts are clear. Extensive consultations with relevant experts — and a wealth of data on market dynamics — reveal that extending the current intellectual property waiver on Covid-19 vaccines to diagnostics and therapeutics would prove enormously counterproductive.

More rapid and equitable deployment of COVID-19 products has only ever been limited by logistical, regulatory, and infrastructure challenges. No IP-induced shortages exist.

In fact, strong IP has enabled an unprecedented pace of research, development, and production to safely occur at qualified facilities around the world. When companies know their discoveries are protected, they are prepared to share their technological know-how with other entities to save lives.

Indeed, Covid-19 therapeutic manufacturers have signed over 400 voluntary licensing and manufacturing agreements to bolster global accessibility of the treatments. Governments and NGOs have "large stockpiles of treatments going unused" as a result. Meanwhile, diagnostics manufacturers have reported "large surpluses of tests available for order."

Extending the TRIPS waiver will not add more of either product to the global arsenal. An expanded waiver would, however, strike a severe blow to innovation by calling support for fundamental IP rights into question.

Innovators must be able to obtain meaningfully enforceable patents to attract investments into cutting-edge research and development, commercialize their products, and recoup outlays. This is particularly true within sectors, like life sciences, where innovations demand steep initial investments — to the tune of \$2 billion — and can take a decade to reach the market.

Unfortunately, expanding the TRIPS waiver will stunt these life-saving investments. In the absence of IP protections, it would become far harder for innovative companies to earn commensurate returns.

And while diagnostics, therapeutics, and vaccines manufactured for Covid-19 may be the first

products impacted by the global weakening of IP protections, they will not be the last. Further extending the TRIPS waiver's scope would continue us down a perilous path — one on which the investment incentives required to pursue innovative inquiries are squandered, and other countries can insist on a "right" to a vast range of U.S. patented technologies.

Of equal concern, by allowing other countries to appropriate U.S.-developed technologies, the TRIPS waiver expansion would hamper U.S. global economic competitiveness. Strong IP protection is the backbone of America's innovation ecosystem. Today, IP-intensive U.S. research industries create millions of jobs, improve billions of lives, and generate trillions of dollars in economic activity.

Forcing American innovators to give up valuable technology to other countries, especially those considered adversaries, remains unwise. Any one of them could exploit the technology to further their own objectives at the United States' expense.

The United States imprudently backed the original TRIPS waiver for Covid-19 vaccines, even though no IP-induced shortages existed then either. Let us not make the same mistake twice.