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Judge Kathleen O'Malley (Ret.), Board Member

March 29, 2023

**RE: U.S. International Trade Commission Investigation No. 332-596: COVID-19
Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities**

**Oral Testimony of Frank Cullen
Council for Innovation Promotion (C4IP)**

Good afternoon. I appreciate the opportunity to speak to you today regarding waived obligations under the World Trade Organization TRIPS Agreement.

My name is Frank Cullen, and I am the Executive Director of the Council for Innovation Promotion — also known as C4IP. 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 USPTO directors, our coalition has distinguished itself as a valued partner to those considering policies impacting America's IP system. C4IP has sought to facilitate informed and balanced conversations on the proposed TRIPS waiver expansion.

And it is with that same intent that I stand before you today.

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 — have yielded no grounds for [extending](#) the [current IP waiver](#) on Covid-19 vaccines to diagnostics and therapeutics.

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.

Market Dynamics for Covid-19 Diagnostics and Therapeutics

The truth is, more rapid and equitable deployment of COVID-19 diagnostics and therapeutics 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 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.

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."

Put plainly: Extending the TRIPS waiver will not add more of either product to the global arsenal.

Impact of Weakening IP: Stifled Innovation

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 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 impossible 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.

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. 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 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, 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 scratch the surface of our potential. The [revolutionary mRNA technology](#) underlying many Covid-19 products, for instance, can transform the entire healthcare landscape.

Forcing American innovators to give up technology like this 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.

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.

We invite you to consider us a resource as you investigate this issue in the weeks ahead.

Thank you.