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TESTIMONY OF STEPHEN EZELL

Before the

U.S. International Trade Commission

Washington, D.C.

In the Matter of:	)	
	)	FR Doc. 2023-02466
"COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities"	)	Investigation No. 332-596

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TESTIMONY AS PREPARED FOR DELIVERY

Good day, Commissioners. Thank you for the opportunity to testify today, and also for your conducting a thorough investigation of this extremely important issue.

ITIF contends that a TRIPS IPR waiver for COVID-19 diagnostics and therapeutics is unnecessary, unwarranted, and even counterproductive—just as it was for COVID-19 vaccines.

While ITIF believes that's for myriad reasons, I'd like to focus on three today: First, the lack of a compelling rationale for COVID-19 IPR waivers in the first instance. Second, the reality that a sufficient supply of COVID-19 therapeutics exists. And third and most fundamentally, the reality that—far from being a barrier to access to COVID-19 vaccines or therapeutics—intellectual property rights have been instrumental in both their creation and the ability to manufacture them at scale globally through the responsible use of voluntary licensing agreements (VLAs).

First, the reality is that IP is not now—nor has it ever been—the central challenge in enabling global society to address the pandemic. In fact, the original COVID-19 TRIPS waiver petition actually acknowledges this, admitting that, "To date, there is no vaccine or medicine to effectively prevent or treat COVID-19." Yet despite the fact that no vaccines or therapeutics even existed to combat the virus, IP was already somehow a problem. Indeed, if IP were ever a problem in this pandemic, it was only that society had yet to invent the knowledge, technology, and know-how—that is, the IP—to confront this malady. Moreover, even after the vaccines waiver was agreed to, not a single country, company, or entity has notified the WTO of any intent to avail itself of the vaccine waiver's provisions, reiterating the futility of the initial agreement. This shows that the real challenge in getting COVID-19 vaccines and therapies to the global public all along has been more about logistics, distribution, and weak public healthcare infrastructure challenges, not IP.

Second, an adequate supply of COVID-19 treatments exists, as November 2022 data indicated a contracted supply of 67.3 million, while total production exceeded 81.9 million doses. In fact, of the more than 35 million doses of COVID-19 treatments purchased by governments and NGOs for low- and middle-income countries, only 10 million were administered as of September 2022. That more than 70 percent of the therapeutics already paid for went unused suggests that their price wasn't the fundamental problem. Moreover, according to Transparency Market Research, the $30.7 billion market for COVID-19 therapeutics in 2022 is projected to contract at a CAGR of -8.3% through 2031. The anticipated shrinking demand for COVID-19 therapeutics vitiates the contention that an IPR waiver is needed to further bolster their production.

Lastly, IP has proven a critical enabler of the massive global effort to create innovative COVID-19 vaccines, therapeutics, and diagnostics—and manufacture them at scale. As of November 2022, 37 treatments were authorized for use, with over 865 therapeutic candidates in clinical development, and another 830 in preclinical development.

The legal certainty that IP rights confer has proven crucial in facilitating the dissemination of the know-how and technology partners need to manufacture complex COVID-19 vaccines and therapeutics safely and reliably.

Indeed, nearly 400 vaccines partnerships and collaborations have been established among manufacturers worldwide, 88 percent of which entail tech transfer and know-how sharing. Likewise, today over 140 collaborations for production and distribution of COVID therapeutics exist, with at least 92 percent involving some form of technology transfer.

And many of these agreements are royalty-free, as more than 60 generic manufacturers utilize VLAs for COVID-19 therapeutics through bilateral agreements and non-profit organizations such as the United Nations-backed Medicines Patent Pool. Thanks to VLAs, over 200 production sites for COVID-19 treatments exist, spread across more than 30 countries, including at least 70 in India alone.

Certainly, there are other reasons to oppose the waiver: Permitting countries to waive IPRs could undermine productive voluntary licensing relationships, not to mention jeopardize the COVID therapeutics pipeline by creating disincentives to invest in the further R&D needed to develop clinical trial candidates. Compelling the divulsion of innovative techniques and platform technologies used to produce vaccines and therapeutics could compromise innovators' efforts to use these tools in developing treatments for other diseases. And a waiver risks putting U.S.-developed biomedical technologies directly into the hands of foreign adversaries—not to mention handing anti-IP advocates a cudgel to brandish as they seek to denigrate IP rights for other forms of technology of global import, from clean technologies to ICTs.

In conclusion, waiving IPRs would not increase the number of COVID-19 therapeutics or the global supply thereof, and ITIF therefore encourages the U.S. government to not endorse an expansion of the waiver to diagnostics and therapeutics and implores global policymakers to turn their attention to the far more real and significant challenges as we try to turn the page on this terrible pandemic.