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POST-HEARING COMMENTS OF STEPHEN EZELL

Before the

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

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The Information Technology and Innovation Foundation (ITIF) herewith submits follow-on input and information subsequent to topics and questions raised by International Trade Commission commissioners during hearings pertinent to Investigation No. 332-596, "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities."

ITIF contends that a World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property (TRIPS) intellectual property rights (IPR) waiver for COVID-19 diagnostics and therapeutics is unnecessary, unwarranted, and even counterproductive—just as it was for COVID-19 vaccines. While that's for many reasons, ITIF focuses here on three. 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 already exists today. Third, and most fundamentally, the reality that—far from being a barrier to access to COVID-19 vaccines, therapeutics, or diagnostics—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).

ADVOCATES FOR COVID-19 TRIPS IPR WAIVERS HAVE FAILED TO ESTABLISH THAT IP CONSTITIES A BARRIER TO ACCESS TO COVID-19 VACCINES, DIAGNOSTICS, OR THERAPEUTICS

From the very beginning, the case for the need for a waiver on IP rights related to COVID-19 vaccines, diagnostics, and therapeutics has been highly tendentious and speculative. India and South Africa submitted their petition to the TRIPS Council in October 2020. As the very petition itself acknowledged, "To date, there is no vaccine or medicine to effectively prevent or treat COVID-19."[1] Why then, was there any kind of need to waive IP rights for technologies and innovations that didn't even exist? It shows that intellectual property rights were and have never been a barrier to the world getting access to needed COVID-19 vaccines, therapeutics, and diagnostics.

Moreover, the waiver petition provided no credible evidence that IP constitutes a barrier to access. The waiver petition vaguely referenced "several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients."[2] The first of two cited instances pertained to Labrador Diagnostic LLC, a patent-licensing firm which—although it did file a suit against a French firm, bioMerieux SA, developing coronavirus tests, in order to ensure that its IP was not infringed—had actually committed to offering its patents royalty-free to any company developing coronavirus tests.[3] (So even the example they cited at the very outset unwittingly showed the power of responsible voluntary licensing, vitiating the need for a broad waiver for COIVD-related IP.) The second instance simply referenced Kentucky Governor Andy Beshear's call for 3M to release a patent on N95 respirators.[4] Although, of course, just like with COVID-19 vaccines or therapeutics, IP rights were never the issue with N-95 masks. As Kaitlin Wowak, a supply chain expert and assistant professor at the University of Notre Dame, noted, "how fast products like N95s [can be] made is determined by three primary factors: the complexity of the equipment used to make the product, the availability of raw materials, and the availability of trained workers."[5] Thus, from the very beginning, advocates for an IP waiver were making such a case in order to perpetuate their specious broader narrative that IP rights constitute a barrier to access to medicines.

But that was it; on those two incredibly thin reeds, with nary any serious evidence whatsoever that IP rights were inhibiting access to COVID-19 treatments—let alone the fact that no COVID-19 vaccines or

therapeutics even existed at the time—the petitioners took the radical step to call for a suspension of all IP rights pertinent to COVID-19 technologies throughout the duration of the pandemic. In short, as ITIF has noted, if intellectual property has ever constituted a real problem during the course of the COVID-19 pandemic, it was only that innovative life-sciences companies needed to create the IP—that is the technology, knowledge, and knowhow—required to invent safe, effective, and new-to-the-world COVID-19 vaccines, diagnostics, and therapeutics. Indeed, access to medicines fundamentally depends upon and presupposes the existence of medicines—and the reality is that IP rights are a fundamental enabler of such innovative medicines, not a barrier to their access.

Moreover, even after countries agreed to the COVID-19 IPR vaccines waiver, 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 all along in getting COVID-19 vaccines, diagnostics, and therapeutics to the global public (once they could be manufactured at scale) has been much more about logistics, distribution, and public healthcare infrastructure challenges, not IP.

Rapidly Inventing Breakthrough COVID-19 Vaccines, Therapeutics, and Diagnostics

The speed with which innovators were able to bring forth effective COVID-19 vaccines (and even therapeutics) was unparalleled in human history. For instance, in 2017, a GlaxoSmithKline representative noted that, "It can take up to $1 billion and 20-50 years to create and fully distribute a vaccine at scale."[6] Before the pandemic, it took an average of 10 years to develop a new-to-the-world vaccine.[7]

That the Pfizer-BioNTech COVID-19 vaccine arrived a mere 347 days after the virus was first detected is a testament to the tremendous bench strength of the life-sciences industry in countries such as the United States and Germany which recognize that robust IP rights are an essential enabler of life-sciences innovation.[8] But that was just the tip of the reponse. Today, 10 vaccines have been approved for emergency or full use by at least one stringent regulatory authority recognized by the World Health Organization (WHO): Pfizer–BioNTech, Oxford–AstraZeneca, Sinopharm BIBP, Moderna, Janssen, CoronaVac, Covaxin, Novavax, Convidecia, and Sanofi–GSK. Overall, by the end of 2022, more than 30 vaccines had been approved for general or emergency use by nations around the world.[9]

The pace of COVID-19 therapeutics development was likewise exceptional. Gilead Sciences' COVID-19 therapeutic, remdesivir, received U.S. Food and Drug Administration (FDA) Emergency Use Approval (EUA) a mere 123 days after the virus was first detected in a patient sample; Eli Lilly's antibody treatment, bamlanivimab, received its EUA within 315 days. By November 2022, 37 COVID-19 treatments were authorized for use somewhere in the world, with over 865 more candidates in clinical development, and at least another 830 in preclinical development.[10] Of those 37 authorized treatments: only remdesivir and baricitinib are fully approved (meaning, approved beyond an emergency use approval) in at least one jurisdiction; 16 are approved in the United States, United Kingdom, or European Union; 21 are approved only in countries other than the United States, United Kingdom, and European Union; and 7 are endorsed by the WHO. For those treatment candidates in clinical development, 415 are in late stage (phase three or later) testing.

Considering health care is not a one-size-fits-all proposition, these myriad innovations provide patients and healthcare providers with a variety of treatment options, including antiviral, monoclonal, or anti-

inflammatory treatments; oral, intramuscular injection, or intravenous-infusion delivery; and inpatient or outpatient settings. Furthermore, the therapeutic types include small molecules, antibodies, proteins, nucleic acid-based therapies, cell therapies, and traditional medicines. In other words, these treatments are not all the same. Nor are they simply modified copies of existing options. Just as the variety of COVID-19 vaccines (mRNA, protein subunit, viral vector, Whole-Virion Inactivated Vero Cell-derived platforms, etc.) provided the global population with a range of preventative options, the greater variety of treatments allows healthcare providers to tailor subsequent care to the needs of their patients.[11] This is vital for those with allergy concerns, adverse drug interactions, delivery method limitations, and other healthcare complications. A potential waiver of IP rights for innovative COVID-19 treatments would deter investment in the wide variety of patient-benefitting treatment approaches and risk diminishing the availability of innovative alternative treatment options should new strains of the coronavirus emerge.

A SUFFICIENT SUPPLY OF COVID-19 THERAPEUTICS AND DIAGNOSTICS EXISTS, OBVIATING ANY NEED FOR A WAIVER

Once innovative life-sciences companies had conquered the challenge of creating safe and efficacious vaccines and therapeutics, the challenge turned to manufacturing these at scale and distributing them to the global population. While this process took time to ramp up (albeit at a rapid pace), it has postioned the world with a sufficient supply of both vaccines and therapeutics today, with the experiencing showing that IP rights were an enabler, not an inhibitor, of the massive scaling up of production of COVID-19 vaccines and therapeutics.

For instance, when Serum Instute CEO Adar Poonawalla was asked if vaccine rollout was slowed because vaccine patentholders were licensing too few manufacturers to make them, he responded, "No. There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines."[12] Poonawalla actually cited the lack of global regulatory harmonization as a far greater cause of delays in the vaccine rollout.[13] And even Médecins Sans Frontières' Rose Scourze acknowledged (in a January 20, 2021 BBC interview) that suspending patent rights "wouldn't produce millions of more vaccines."

Today, over thirteen billion COVID-19 vaccine doses have been administered worldwide.[14] To be sure, distribution challenges in many developing countries slowed the initial rollout. For instance, in December 2020, developing countries turned away some 100 million COVID-19 vaccines because they were reaching their expiration date.[15] More recently, with 200 million unused doses, AstraZeneca's COVID-19 vaccine partner Serum Institute halted production in April 2022. As the Serum Institute's CEO Adar Poonawalla noted at the time, "I have even offered to give free donations to whoever wanted to take it."[16] Similarly, Aspen's South Africa COVID-19 vaccine plant has faced closure over a lack of sufficient orders for COVID-19 vaccines.[17] In fact, India and South Africa stopped producing vaccines months before the June 2022 vaccines waiver decision because there was already a surplus global vaccine supply. Indeed, one of the chief advocates for the vaccines waiver, Indian Minister of Commerce and Industry Shri Piyush Goyal, unwittingly admitted to the fundamental unnecessity of it in the first place, noting prior to the decision that "vaccines have already lost relevance."[18]

But just as life-sciences innovators were able to rapidly scale to meet global COVID-19 vaccine needs, likewise today an adequate supply of COVID-19 therapeutic treatments exists. For instance, November 2022

data from Airfinity indicates a contracted supply of 67.3 million therapeutic treatments, whereas the total production exceeded 81.9 million.[19] In fact, of the more than 35 million doses of COVID-19 treatments purchased by governments and non-governmental organizations (NGOs) for low- and middle-income countries, only 10 million were administered as of September 2022.[20] That more than 70 percent of the therapeutics already paid for by countries went unused suggests that neither their price nor their lack of availability has been a fundamental problem.

The experience of countries having to destroy vaccines unused shows how logistical and distributional issues have long been a much bigger challenge with getting medicines, whether on-patent or off, to those who need them in the developing world. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public sector facilities in developing countries only 40 percent of the time.[21] A 2019 study found that the mean availability of 12 priority essential medicines for women in sub-Saharan African ranged from 22 percent to 40 percent and for children ranged from 28 to 57 percent.[22] If medicines cannot reach remote areas, patients are less able to access them. A 2009 survey of 36 countries found that 15 common generic medicines listed on the WHO Essential Medicines list are frequently unavailable in either the public or private sectors, with regional availability ranging from 29 percent in Africa to 54 percent in the Americas.[23] Indeed, the vast majority of drugs—at least 95 percent—on the WHO's Essential Medicines list are off-patent, and thus potentially available in generic versions. Whether it comes to essential medicines or COVID-19 vaccines or therapeutics, a far greater challenge than IP rights has been nations' underdeveloped public health infrastructure and the fact that many people live in rural areas, far from care.

IP RIGHTS ENABLE VOLUNTARY LICENSING THAT HAS DRAMATICALLY SCALED PRODUCTION OF COVID-19 VACCINES AND THERAPEUTICS

The legal certainty that IP rights confer has proven crucial in facilitating the dissemination of the know-how and technology that partners need to manufacture complex COVID-19 vaccines and therapeutics at the production standards required to do so safely and reliably. Indeed, nearly 300 vaccines partnerships and collaborations have been established among manufacturers worldwide, 229 of which have involved tech transfer and know-how sharing. Likewise, today, over 140 collaborations for the production and distribution of COVID therapeutics are in place, over 92 percent of which entail some form of technology transfer.[24] Gilead alone has signed nine VLAs with generic manufacturers for remdesivir, covering 127 countries. Likewise, Pfizer's 38 VLAs cover 95 countries, and Merck's 31 VLAs cover 105 countries.

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 (MPP). According to the organization's website, the MPP facilitates development and increases access to life-saving medicines by partnering "with civil society, governments, international organisations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations."[25]

Courtesy of these VLAs, there are now more than 200 production sites for COVID-19 treatments spread across more than 30 countries, including Bangladesh, Brazil, Egypt, India, Indonesia, Kenya, Pakistan,

Paraguay, Singapore, and South Africa. (Note: Bangladesh, Egypt, India, Indonesia, Pakistan, and South Africa all voiced support for the extended waiver.) India alone maintains at least 70 of these sites.

Thus, not only is an expanded TRIPS waiver for COVID-19 therapeutics and diagnostics wholly unnecessary given the range of treatment options, but it is also redundant given the overwhelming efforts at global collaboration through voluntary licensing agreements.

Instead of simply being forced to divulge their IP or see it be compulsorily licensed to other manufacturers, in light of the extreme complexity of manufacturing COVID-19 vaccines and therapeutics, companies should have the right to evaluate potential license partners and ensure that they can meet the production standards required to safely and reliably produce COVID-19 vaccines or treatments before entering into license arrangements with them. Indeed, this is critical for it would be disastrous if defective vaccines or therapeutics were produced at facilities not properly equipped to produce such complex treatments. As Phil Stevens and Mark Schultz have convincingly written, there's simply no evidence that invalidating IP rights would achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries such as Brazil and India.[26]

Not only have life-sciences innovators extensively voluntarily licensed IPRs to produce COVID-19 vaccines and therapeutics, they've made extensive donations of vaccines and therapeutics. For instance, by October 2021, Gilead donated over 450,000 vials to India, 10,000 vials to Georgia, 3,000 vials to Armenia, and 100,000 vials to Indonesia, complementing local generic supplies of remdesivir provided through VLAs.[27] In May 2021, Lilly committed donations of baricitinib, bamlanivimab, and etesevimab to Direct Relief.[28] In January 2023, Direct Relief donated enough therapies to treat more than 350,000 patients with mild to moderate COVID infections and over 80,000 for severe infections.[29]

It's also important to make the point that, far from inhibiting access to medicines, robust intellectual property rights actually encourage their diffusion. For instance, in their report, "Patents and The Global Diffusion of New Drugs," Cockburn, Lanjouw, and Schankerman studied 642 new drug launches in 76 countries from 1983 to 2002. They found that the speed/extent of diffusion strongly associated with countries' patent and price regulation systems. Moreover, they found that moving from a regime of no product patents to long product-patent terms reduces drug launch lags by 55 percent.[30]

Nor are compulsory licenses for innovative medicines the answer. In their report "Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement," Beall, Kuhn, and Attaran analyzed 30 compulsory licenses of HIV/AIDS retroviral drugs against 673 comparable procurements. They found that "Compulsory licensing often delivered suboptimal value compared to intl. procurement alternatives" and that the prices countries ultimately paid were higher in two-thirds of cases, with a price premium of 25 percent.[31]

Permitting countries to waive IPRs could undermine these 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 in 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.

CONCLUSION

In conclusion, waiving IP sets a terrible precedent, disrupts and disincentivizes innovation ecosystems, is a barrier to start-ups and SMEs generating capital, reduces R&D, results in fewer new uses and products, and negatively impacts employment both within the pharmaceutical industry and the broader economy, all while doing nothing to solve the real problems surrounding access to healthcare innovation in developing countries. Waiving IPRs would not increase the number of COVID-19 therapeutics or the global supply thereof. ITIF encourages global policymaker to turn their attention to more-significant challenges as we try to turn the page on this terrible pandemic.

Thank you for your consideration.

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NOTES

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