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## An Unnecessary Proposal

### A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines

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In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health.

Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two-decades-old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North-South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19.

#### BACKGROUND

In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules

for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 . . . until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”<sup>1</sup> India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic.

In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”<sup>2</sup>

Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.<sup>3</sup> One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”<sup>4</sup> A spokesperson for the

European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID-19-related medicines and technologies.”<sup>5</sup> In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021.

## **BALANCING IP RIGHTS AND ACCESS TO MEDICINES NOT NEW TO WTO**

This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub-Saharan Africa, could not afford the high-priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.

Article 8 of the WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health . . . provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”<sup>6</sup> It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions.

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”<sup>7</sup> But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make

patented products or use patented processes even though they do not have the permission of the patent holders.<sup>8</sup>

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>9</sup> In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.<sup>10</sup> In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.<sup>11</sup>

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market-based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

## **DOES A NOVEL VIRUS PRESENT NOVEL ISSUES?**

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”<sup>12</sup>

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business-as-usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”<sup>13</sup>

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least-developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”<sup>14</sup>

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case-by-case and product-by-product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”<sup>15</sup> But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for . . . profitability in decision-making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”<sup>16</sup>

This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration

of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.<sup>17</sup> To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long-standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long-term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”<sup>18</sup> The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know-how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas-based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in

the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.<sup>19</sup>

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”<sup>20</sup> This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights.”<sup>21</sup> Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

## CONCLUSION

The solution is not another impassioned and prolonged multilateral impasse inside the WTO. The solution is

multilateral action in international institutions and international endeavors outside the WTO. It is the slow pace and the uncertain success in those other global arenas that have led developing countries to seek a waiver from the WTO. Rather than continuing to press for an unnecessary WTO waiver, they should redouble their combined efforts to reach solutions in those other arenas. And the United States, the European Union, the United Kingdom, and other developed countries should do more to work with them toward that end.

In no event should IP rights become legal obstacles to ensuring early access to affordable medicines for everyone in the world during a pandemic that has already killed more than a million people worldwide and threatens to kill millions more. But also, in no event should WTO members act in ways that would eliminate the incentives that are essential to inspire the innovations that make new medicines possible.

The right balance in the WTO trade rules on IP is a balance that provides all countries with sufficient flexibility to protect IP rights while also promoting access to life-saving medicines.<sup>22</sup> For COVID-19 medicines, there is no proof at this time that this balance does not exist. Maintaining this balance must remain the aim of the WTO, and it must be the aim of every endeavor of multilateral cooperation in the fight to end this pandemic.

## NOTES

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