

IP Frontiers: The TRIPS COVID-19 Waiver



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On May 5, the Biden administration signaled the United States' support for a proposed waiver of certain World Trade Organization (WTO) rules that require member countries to enforce intellectual property (IP) rights, particularly those related to confronting

the COVID-19 pandemic. This article sets out an explanation of the proposed waiver, arguments of its proponents and opponents, and where the debate is expected to proceed.

WTO, TRIPS, and the proposed waiver

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement by nations of WTO to provide laws and systems for protecting IP rights within their borders. WTO members are required by TRIPS to have laws and legal procedures by which owners of rights in various types of IP (including copyrights, trademarks, patents, designs, and trade secrets) can prevent unauthorized use and misappropriation of their rights by others. TRIPS was intended to foster trade between WTO members by increasing protection available to IP rights holders upon entering markets in different countries and a country that does not abide by TRIPS may face discipline under WTO rules.

WTO rules also allow for some flexibility, addressing concerns that TRIPS could unjustly deprive people in developing countries from beneficial innovations arising from developed nations, medicines in particular. For example, under certain circumstances a WTO country may allow a party to use IP in exchange for compensation to its owner but without requiring the owner's



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consent, referred to as compulsory licensing. And under "exceptional circumstances" WTO rules also allow for a temporary waiver from requirements of TRIPS. A waiver, if not agreed to by consensus within WTO, may be authorized by a 75% majority vote of its members.

Last October, in view of the exceptional circumstances presented by the COVID-19 pandemic and international disparities in availability of vaccines and treatments, India and South Africa jointly proposed a waiver from TRIPS requirements that WTO countries enforce copyright, industrial designs, patents, and trade secrets where such IP relates to "prevention, containment or treatment of COVID-19," for a limited though as yet undetermined time period. Such a waiver would permit a WTO nation to loosen or eliminate its current procedures by which IP owners may prevent the use or misappropriation by others of their COVID-related patented, trade secret, or other proprietary technologies.

Support for a waiver

Over 100 countries have signaled support for a TRIPS waiver. Non-governmental parties that support the waiver include health and health rights organizations such as Partners in Health, Doctors Without Borders, Human Rights Watch, and Oxfam International, among others.

Those supporting the waiver argue that IP rights are impeding timely access to preventive and life-saving measures and that humanitarian health concerns and the shared goal of stopping the pandemic should outweigh IP rights given the exigencies of COVID-19. For example, they assert that IP rights are slowing vaccina-

tion efforts by preventing more distributed, widespread vaccine production by those other than patent-holders or their licensing partners. The current global demand for COVID-19 vaccines still far outpaces supply and relative availability of vaccines between more and less developed countries has been characterized as grossly inequitable. Further, continued proliferation of the virus poses a universal threat that worse variants may emerge, to the detriment of people of all nations. Under the proposed TRIPS waiver, a country could, within its borders, prevent developers of COVID-19 vaccines, treatments, and related technologies from enforcing such IP against third parties, who would then be free to use such technology without incurring liability for infringement.

Support for the waiver also derives from the belief that companies' unwillingness to share their COVID-related innovations is driven by a fear of losing monetary benefits of owning such IP. Similarly, proponents argue that many technologies that would be subject to the waiver were government-funded via taxes while yielding billions of dollars of revenue for the IP-holders, who should therefore not continue to monopolize the technologies. Further, some proponents assert that the economic impact resulting from a stall in the global economy will only worsen as time passes if broader access to IP relating to COVID-19 is not permitted.

Opposition to a waiver

Opponents include industry and trade organizations such as the American Intellectual Property Law Association (AIPLA), Intellectual Property Owners Association (IPO), National Foreign Trade Council (NFTC), National LGBT Chamber of Commerce (NGLCC), Pharmaceutical Research and Manufacturers of America (PhRMA), Small Business & Entrepreneurship Coun-

cil (SBE), and U.S. Chamber of Commerce, among others.

They note a lack of evidence that IP rights are in fact creating barriers to access to COVID-19 related technologies and assert, by contrast, that the IP system is facilitating rather than hindering current global collaborative efforts to combat COVID-19. For example, decades of investment in research and development in the field of vaccines, incentivized at least in part by the promise of IP protection, paved the way for an unprecedented rapid response to multiple, highly effective COVID-19 vaccines. Pharmaceutical companies also point out that reports of billions in revenue do not take into account expenditures and ignore, for example, prior, long-term investment in research and development. Eliminating protection of rights in such IP now would arguably have a chilling effect on current investments in research and development necessary for developing further improvements in COVID prevention and treatment or responding to a future crisis such as another pandemic. Protection of IP rights, opponents argue, and a safe expectation of compensation for historical and current investments, permitted private agreements between companies and governments that fostered partnerships essential for the development and growing availability of current vaccines.

As a practical matter, commentators also note that, notwithstanding the favorable optics of permitting countries to suspend protections on IP such as patent rights, a waiver may be ineffective in accelerating the expansion of vaccine availability. Obtaining a patent entails publicly disclosing the technology to be protected by the patent. However, significant other expertise is often required to fully practice a patented technology. For COVID-19 vaccines, such

expertise may include non-public trade secret information known to a patent-holder and technical know-how developed over many years by its scientists and engineers, and using it requires specialized facilities not easily replicated by others. Without compelling companies to disclose their trade secret information (which may underlie more than COVID-19 vaccines and treatments and whose value depends on its confidentiality) and to divert time to train other companies how to replicate their technology, merely permitting parties to use technology described in patents covering COVID-19 vaccines may fail to expedite global vaccination initiatives.

Further, as mentioned above, WTO rules already provide for government-authorized use of proprietary technology without authorization from the IP owner, such as under a compulsory licensing regime. Moreover, opponents of a waiver point to collaborations already taking place and pledges by pharmaceutical companies as evidence that a TRIPS waiver is unnecessary. For example, there are collaborations between Eli Lilly and Company and Indian drug firms Sun Pharma, Cipla, and Lupin; between BioNTech and Fosun Pharma; between Moderna and Catalent Inc.; between Oxford-AstraZeneca and the Serum Institute of India; and between pharmaceutical companies and the WTO's COVAX facility for providing vaccines to developing countries. Further, Moderna pledged to not enforce its COVID vaccine patents during the pandemic and Oxford/AstraZeneca pledged to sell vaccines at cost.

Proponents of a waiver assert that such voluntary efforts are insufficient to meet the demands of the moment. The risk that countries may relax IP protection under a TRIPS waiver may motivate IP holders to further escalate such voluntary collabora-

tive efforts. But with collaborations and voluntary licenses already taking place, a TRIPS waiver may create confusion and counterproductively hinder the fight against COVID-19.

Future directions

A TRIPS waiver could be implemented by agreement of 123 of the WTO's 164 members. Support from the United States likely increased the chance of passage, though significant effort remains to craft the ultimate terms of a waiver before it is agreed to. For example, the Biden administration indicated support for a waiver targeted to patents on COVID-19 vaccines, whereas the broader waiver proposed by India and South Africa would extend to copyrights, industrial designs, patents, and trade secrets related to preventing, containing, and treating COVID-19. And a waiver's duration and method for determining when it would end have yet to be decided.

Over the coming months, parties on both sides of the debate will likely remain deeply involved in not only supporting or opposing WTO's adoption of a TRIPS waiver but also, perhaps just as importantly, crafting a waiver's specific terms and application. Through such efforts, the WTO will try to strike an appropriate and effective balance to encourage swift marshaling of all global efforts to end the pandemic without disrupting the incentives of IP protection regimes that help drive innovation, advancing the indisputably universal goal of ceasing the deaths and suffering COVID-19 continues to wreak worldwide.

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