



Regulatory Transparency Project

Unlocking Innovation & Opportunity

COVID Vaccine IP Waiver: A Pathway to Fewer, Not More, Vaccines

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Introduction

On May 5, 2021, United States Trade Representative Ambassador Katherine Tai issued a statement announcing the Biden administration’s support for waiving intellectual property protections internationally for COVID-19 vaccines. After decades of supporting strong intellectual property protections worldwide, the United States’ backing of a waiver proposal is a complete reversal of policy. Tai’s statement claims that “The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines.” Ostensibly, the purpose of the waiver, as Tai notes, is to “get as many safe and effective vaccines to as many people, as fast as possible.” Unfortunately, rather than generating more vaccines in the short term, a waiver of this sort is more likely to have longstanding consequences leading to less innovation.

There are multiple problems with waiving intellectual property rights in this situation – from the simple fact that the waiver is unnecessary to ensure broad access to COVID vaccines to the legitimate danger this action will pose for innovation. This paper briefly discusses the waiver and then explains the problems with the waiver in detail. Finally, the paper concludes with suggestions that could more effectively achieve the administration’s aim of “shots in arms” without eviscerating America’s best-in-the-world intellectual property system.

I. The Waiver and Next Steps

The proposed intellectual property (IP) waiver would create a broad-based exemption from an international treaty known as TRIPS (Trade-Related aspects of Intellectual Property Rights). TRIPS requires countries that are members of the World Trade Organization (WTO) to adhere to a set of standardized, minimum rules for IP protections under the laws of those member states. For example, a member state of the WTO must provide certain minimum protections for patented inventions under its laws such that innovators there or elsewhere will have the fruits of their inventive labors secured to them in that country. If a member state does not do this, then other member states can start a process at the WTO to impose trade sanctions on that country.

In October 2020, India and South Africa formally filed a request at the WTO for the IP waiver. The IP waiver would exempt countries from the requirements of TRIPS for patents, trade secrets, and other IP rights in technologies, drugs, or vaccines used to respond to the COVID-19 pandemic.¹ If the WTO adopts the IP waiver, countries could refuse to issue IP rights in—or refuse to protect existing IP rights in—technologies used to treat or respond to COVID-19. For example, it could

¹ The originally proposed IP waiver submitted by India and South Africa provided that the requirements and enforcement of TRIPS “shall be waived in relation to prevention, containment or treatment of COVID-19” for all relevant patents, copyrights, design protections, and trade secrets. See *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19* (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>. In late May 2021, India and South Africa submitted revised language (with the support of many other developing countries) calling for the waiver of the requirements and enforcement of TRIPS for all “diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.” The IP waiver would be in effect for at least three years. See *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text* (May 25, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.

mean that companies in those countries, such as generic drug companies, could ignore patents on vaccines for COVID-19.

The IP waiver applies more broadly than just patents, although many commentators have mistakenly assumed it is solely about waiving patent protections. With a few exemptions for things like copyrights in movies, the IP waiver covers patents, copyrights in works relevant to responding to COVID-19, industrial designs, and, perhaps most importantly, trade secrets. The valuable information in manufacturing and distributing COVID-19 vaccines is not disclosed in the molecules comprising the vaccines, and this valuable technical know-how is secured by trade secrets law. This is one reason why there has been a push for the IP waiver, as opposed to going through the existing provisions in TRIPS providing for compulsory licensing of patents. First, the compulsory licensing provisions are limited to only patents and thus do not apply to any other IP rights. Second, compulsory licensing is clearly an option of last resort in TRIPS, requiring exhaustion of reasonable efforts to obtain licenses and it requires a significant process for approving the compulsory licenses and the “adequate remuneration” that must be paid to the patent owner. Under the IP waiver, member states would gain access to all IP rights and would not have to pay anything.

While the IP waiver has been backed by numerous developing countries and organizations including the World Health Organization, a number of developed nations with strong innovation sectors initially declined to support the proposal. As time has passed, however, more countries have signaled their support, with Australia announcing its support in early September. The European Union, the United Kingdom, and Japan have notably opposed the IP waiver proposal. For the IP waiver to be enacted, there needs to be consensus among the 164 member countries of the WTO. Despite the significant resistance, the decision of the U.S. to support the IP waiver request may be sufficient to sway the remaining countries that oppose it.

An IP waiver would be devastating to innovation in a sector where it is critically needed, but a number of hurdles exist before it could be put into force. Even if universal support for the IP waiver can be rallied at the WTO, the next step would be negotiating the actual terms of the waiver. These negotiations began last June and they continue to this date; it is likely to still take much longer to reach agreement on the language.

On top of this, most countries have enacted domestic laws that, within each respective country, implement the requirements imposed by TRIPS. Once the IP waiver is approved and negotiated, countries will need to amend their domestic laws to accommodate the IP waiver. For example, the patent laws of the U.S. permit enforcement of any validly issued patent against any party who uses, without permission, the technology covered by that patent. If the goals of the IP waiver were implemented in the U.S., this would require that Congress change these longstanding provisions of U.S. intellectual property law. Similar changes would have to be made to various federal and state laws securing trade secrets under the U.S. law. Even though the waiver is ostensibly to improve the pandemic situation amongst developing nations, to have an effect the waiver will require major changes to the domestic intellectual property laws of the most innovative countries, like the U.S.

Finally, and most importantly, the waiver itself does not generate vaccine doses. Even if the IP waiver is agreed to and the terms are negotiated to everyone’s satisfaction and countries like the U.S. amend their domestic laws to implement the waiver, there must be manufacturing facilities in these countries that are fitted to produce the vaccines, sufficient input materials to use in these facilities, and distribution channels from these facilities to a country’s population before there are “shots in arms.” This last step will also take many months, if not years, to achieve.

II. What's Wrong with the Waiver?

The IP waiver has many problems, ranging from benign to potentially devastating. As noted above, even if the IP waiver is ratified and countries deny enforcement of intellectual property covering COVID-19 vaccines, that is only a small part of getting vaccines to people; while an IP waiver may seem to make it possible, it would not produce additional vaccines in the short term. More problematic, the IP waiver is likely to have long-term unintended consequences that could both hinder our response to future pandemics and impede innovation more generally.

A. Lack of Necessity

On the more benign side of the spectrum, the waiver is unnecessary as a matter of law or as a matter of fact. There is zero evidence that patents have blockaded the research, development, or distribution of any drugs or vaccines for the treatment of COVID-19. In fact, the evidence all supports the opposite proposition: effective and reliable patent rights have made it possible for companies like Moderna and BioNTech to obtain the billions of dollars in venture capital financing required to develop the radical mRNA technology platform. Moreover, IP rights have been the basis of innumerable licensing and other commercial arrangements between many companies, such as BioNTech licensing with Pfizer to manufacture and distribute its vaccine, AstraZeneca licensing the Serum Institute of India to make the vaccine, and Novartis and Sanofi producing Pfizer-BioNTech inoculations. Moderna also announced in October 2020 that it would license its intellectual property on request after the pandemic ends. Estimates are that there will be about 12 billion doses of vaccines produced by the end of 2021—almost double the world population.² This renders the IP waiver superfluous, at best.

As a matter of fact, more and more COVID-19 vaccines are being tested and approved worldwide. While there are three vaccines currently approved in the U.S. (Pfizer-BioNTech, Moderna, and Johnson & Johnson), there are over twenty vaccines that have been approved in at least one country. As of the end of September 2021, there are 231 total vaccines in development, with 30 in various stages of approvals or clinical trials.³ As more and more vaccines are approved by additional countries, this will boost vaccine availability. Specifically, both Moderna and Pfizer announced plans to increase vaccine production to satisfy worldwide need without needing to coerce disclosure of their trade secrets. By the time negotiations are completed at the WTO, let alone by the time any country is able to take advantage of the IP waiver, there will be many varieties (and surplus supply) of vaccines available throughout the world.

B. Short-Term Negative Impacts

One distinction between the proposed IP waiver and the existing compulsory licensing provisions in TRIPS is that the waiver would also allow for companies to be compelled to transfer their trade secrets and know-how information, along with allowing use of their patented technology. Proponents of the waiver assert that this tech know-how transfer would permit third parties to more easily jump into manufacturing of vaccines. This, then, should allow for more shots in arms, more quickly.

² See Duke Global Health Innovation Center, *Launch & Scale Speedometer: Vaccine Manufacturing*, <https://launchandscalefaster.org/covid-19/vaccinemanufacturing> (“Our analysis of 2021 projections from Covid-19 vaccine makers indicates that more than 12 billion doses could be produced this year.”).

³ See BIO COVID-19 Therapeutic Development Tracker (last visited Oct. 11, 2021), <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>.

While this may seem to be a short-term benefit, the forced transfer of trade secrets and know-how information creates an immediate negative impact for the companies who invested greatly in researching and developing these vaccines. It is possible for a patent to be used, such as via compulsory license, for a set period of time, after which the patent owner would again be able to enforce its patent against parties who thereafter continue to use the technology. Compulsory licensing for the period “during the pandemic” creates a meaningful limit on the rights given over a patent owner’s objections. The patent rights will still exist after the emergency is over until the natural expiration of the patent.

Trade secrets and know-how information, however, are only valuable so long as they are not generally known. By forcing companies to disclose their trade secrets and know-how “during a pandemic,” the information becomes public and thus any intellectual property rights the company had in that knowledge are immediately and forever extinguished. Further, once the trade secret is breached, it can fall into the hands of nations that are economic and strategic competitors of the U.S., such as China and Russia. To put it more quaintly, you can’t put the genie back in the bottle or the toothpaste back in the tube. If the proposed IP waiver is ratified, innovative companies who brought us the vaccines that will get us out of the current pandemic will be instantly divested of hard-earned property rights in their trade secrets and know-how. That is a significant hit for these companies to take.

C. Long-Term Negative Impacts

The most concerning aspect of the IP waiver is that it is the tip of a very dangerous iceberg. Despite Ambassador Tai’s statement that the Biden administration believes in intellectual property, its reversal of longstanding U.S. policy is a harbinger of what is likely to be a bigger, broader attack on intellectual property.

Thanks in part to existing intellectual property and its global protection through TRIPS, more than 280 partnerships and collaborations were formed to address the COVID-19 pandemic.⁴ Vaccines were developed and tested in record time and the production capacity for these vaccines was scaled up in mere months. Intellectual property makes it possible for companies to work together. It makes it feasible for companies to invest significant time and financial resources into uncertain projects. Intellectual property allows for the background research that occurred for decades that gave rise to today’s innovative mRNA vaccine technology. It allows companies to share, transfer, and license technology on terms that work for all involved through efficient transactions, which are also made possible by domestic laws and international treaties that have standardized commercial contracts. It is not an exaggeration to say that intellectual property is a key part of the pathway out of this pandemic.

The problem is, if intellectual property protections are weakened, companies will be highly unlikely to collaborate, uninterested in investing in research and development – both background research and product development – and unable to share, transfer, and license any technology that happens to be developed.

The IP waiver is part of a continuing effort to weaken intellectual property more generally. India and South Africa, which both have large generic drug industries in their countries, have previously supported efforts at the WTO to impose compulsory licenses or create other exemptions from

⁴ See John Zarocostas, *What next for a COVID-19 intellectual property waiver?* (May 21, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8137306/>.

TRIPS. Their efforts in pushing for the IP waiver during the COVID-19 were no surprise to anyone who knows about these longstanding debates and the international wrangling over IP protections. In fact, they proposed the IP waiver before any vaccines were approved for use in any countries, just as the Biden administration announced its support for the IP waiver in the early months of the initial distribution of the vaccines approved for emergency use.

Even at face value, the IP waiver will make companies leery of investing in products that might someday be taken by the government in an emergency. Healthcare innovators invest billions of dollars over decades to create and distribute life-saving and life-enhancing drugs that make manageable many diseases that were death sentences just two decades ago. Given the dramatic successes of patent and trade secret-protected innovation in developing in record time the vaccines and treatments to respond to this novel coronavirus, the last thing we should be doing is putting the protections given to healthcare innovation in peril. Ultimately, if the U.S. does not recognize the value of its innovative companies, they will cease to exist and we will miss out on not just the next vaccine, but the new generation of telecommunications, the latest electric vehicles, the safest water treatment, the most nutritious new foods, and more. To keep American innovation at its best, intellectual property – including patents, trade secrets, and know-how information – should be protected and protectable in the U.S.

III. Solutions to Fix the Real Problem

The solution to the current pandemic is not to waive intellectual property rights. Not only is the IP waiver unnecessary, but it is likely to have short- and long-term consequences that will be devastating—during the next pandemic and beyond. Moreover, the real bottlenecks to “shots in arms” are not intellectual property, but manufacturing capacity and capabilities, distribution channels, and manufacturing inputs. One vaccine producer has stated that its vaccine production requires 280 separate inputs provided through global supply chains.⁵ The waiver does nothing to address these issues – and, even if these issues could be addressed separately, once the IP waiver is approved by the WTO, it would still mean months or even years before any developing countries are able to take advantage of it.

A legitimate, effective, and less problematic solution would be to remove any regulatory blockades that are preventing the international trade and distribution of existing vaccine doses. Currently, the Biden administration is using the Defense Production Act (DPA) to put the U.S. government first in line to purchase American-manufactured vaccines. But as the number of vaccinated Americans continues to rise and anecdotes of surplus vaccines grow, the better option would be to allow these vaccines to be exported from the U.S. to countries that do not have vaccine manufacturing capabilities themselves. The Biden administration has already removed DPA restrictions on vaccine manufacturers that do not have Food & Drug Administration approval for their vaccines, including AstraZeneca, Sanofi/GlaxoSmithKline, and Novavax, allowing the release for export of tens of millions of stockpiled doses of vaccines that have been approved for use in other countries. It is time now to remove the DPA restrictions on Pfizer, Moderna, and Johnson & Johnson vaccines as well. To the extent there are any surplus vaccine doses, the U.S. should release those extra doses to be

⁵ See Charles Clift, *Scaling up covid-19 vaccine production: What are the problems and implications?*, *thebmjopinion* (March 17, 2021), <https://blogs.bmj.com/bmj/2021/03/17/scaling-up-covid-19-vaccine-production-what-are-the-problems-and-implications/>.

exported to all foreign countries that permit those vaccines to be used. This would get “shots in arms” without harming Americans or the U.S. intellectual property system.

Another policy the U.S. could enact that would have a positive effect in distributing vaccines globally is to assist in the development and maintenance of infrastructure and vaccine distribution capacities in developing countries. For example, it is not a lack of existing vaccine doses that prevents vaccines that must be kept at sub-zero temperatures from being effectively distributed to small communities in developing countries in tropical climates. If the “Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible,” as Ambassador Tai stated on May 5 in announcing support for the IP waiver, then the Biden administration should support efforts to create critical infrastructure and distribution capacities that are the real bottlenecks preventing this from happening in the developing world.

Lastly, another option would be for the U.S. to actively consider incentivizing developing countries to adopt cutting-edge technologies, like the mRNA platform. Encouraging countries to build development and manufacturing facilities for these technologies would help the countries to support their own citizens’ needs going forward, and potentially make it possible for these countries to participate in the race to develop vaccines in the next pandemic. As we have learned during COVID-19, the rapid invention, testing, and manufacturing necessary to bring vaccines to market in an emergency is a multinational effort, and adding more countries to such efforts the next time they are necessary would only be beneficial.

The time to solve the current pandemic is now – and the proposed IP waiver is not a policy that will make that happen. Getting existing doses to countries in need right now requires other policies, such as releasing for export stockpiled doses of vaccines. But now is also the time to get ready for the next pandemic, and continuing to offer effective and reliable intellectual property protection to innovative companies – and assisting developing countries in setting up facilities to develop and manufacture the platforms of tomorrow’s vaccines – will ensure that there will be rapid solutions for whatever comes next.