

The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security

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KEY TAKEAWAYS

The IP waiver for COVID-19 medical treatments will result in transfer of valuable patents and trade secrets to global competitors like China and Russia.

The IP waiver in the World Trade Organization will obliterate IP rights while not addressing the real problems preventing global distribution of vaccines.

If the Administration won't end its support, Congress should not enact any legislation seeking to implement the goals of the IP waiver in U.S. law.

The COVID-19 pandemic, as well as growing economic and strategic competition from China and other traditional competitors such as Russia, have made innovation, economic growth, and national security top policy concerns. All three are threatened by the Biden Administration's support for the proposed intellectual property (IP) waiver at the World Trade Organization (WTO). The Biden Administration should retract its support for the continuing negotiations of the IP waiver, and, if it fails to do so, then Congress should refuse to enact any implementing legislation of this waiver of the international commitment to honor the protection of IP rights.

Commentary about the proposed IP waiver at the WTO originally focused on its theft of patents for vaccines and other medical treatments for the COVID-19 virus.¹ As Heritage Foundation Research

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Fellow James Roberts explained recently, the IP waiver would facilitate the global theft of the patents that made possible the private investments necessary in creating new technologies like the mRNA vaccines that were invented and mass produced in unprecedented time.² The IP waiver would obliterate international protection for patent rights while leaving unaddressed the real problems that are impeding global distribution of vaccines to those who still need these vital medicines—problems such as eliminating the trade restrictions prohibiting international distribution of vaccines and creating distribution and transportation infrastructures in the developing world necessary to distribute the vaccines in those countries.³

If the U.S. continues to support and ultimately implement domestically the IP waiver, this would threaten far more destructive consequences than just its impact on patents and the innovation spurred by this key legal tool in the U.S. innovation economy. The IP waiver threatens *many* forms of IP rights, such as justifying the coerced disclosure of the trade secrets in the vital technical know-how used in creating the cutting-edge mRNA vaccines. This not only destroys the economic value and competitive advantage represented by these trade secrets—and the billions in investments that made them possible—but once this information is disclosed, it is impossible to recover it as a valuable trade secret.

The IP waiver raises broad concerns about innovation policy, economic policy, and even national security. The U.S. should oppose the IP waiver. Failing this change in foreign policy by the Biden Administration, Congress should refuse to implement the IP waiver domestically if the Biden Administration continues to pursue another disastrous foreign policy initiative on the heels of the debacle of the Afghanistan withdrawal.

What the IP Waiver Is and Is Not

There is much confusion about what the IP waiver would entail, both substantively and institutionally. This section describes what the WTO is, the international treaty from which IP protections would be waived, and the scope of the IP waiver. Last, this section will describe the effect of the IP waiver on U.S. innovators if the Biden Administration or Congress further pursues its goals under U.S. law.

The WTO and TRIPS. After the Biden Administration's May 5 announcement of its support for the IP waiver, negotiations about the specific text and requirements of the IP waiver are proceeding at the WTO.⁴ The WTO is the intergovernmental organization that facilitates international trade between countries, including administering the international

treaty known as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.⁵

TRIPS is an international treaty entered into in 1994 that requires countries that are members of the WTO to adopt and maintain a minimum level of intellectual property protections because laws regarding patents, copyrights, trade secrets, and trademarks are domestic laws in each country and enforceable only within that country's jurisdiction. TRIPS also harmonized these intellectual property protections between countries by ensuring a baseline of protections for all IP rights. If a member state of the WTO fails to implement in its domestic laws the legal requirements set forth in TRIPS for the protection of intellectual property rights, other member states can initiate proceedings at the WTO for violating TRIPS and seek authorization to impose trade-based sanctions against that member state.

TRIPS is the international treaty that the IP waiver would affect, releasing countries from their obligations to protect IP rights relating to any technologies necessary to respond to the COVID-19 pandemic without the threat of WTO-authorized sanctions. In addition to requiring countries to enact laws that protect new innovations in medical treatments and high-tech devices, TRIPS has a mechanism and process in Article 31 for a country to impose compulsory licensing on patented products or services,⁶ which, under Article 8, a country may adopt if it faces a "public health" emergency.⁷

"Compulsory licensing" occurs when a government authorizes someone to produce, sell, or use a patent *without permission from the patent owner*—imposing on the patent owner what would have been a "license" if the parties had negotiated an agreement in the free market. If a country imposes compulsory licenses on patent owners, TRIPS requires that the patent owner be paid "adequate remuneration,"⁸ or what is commonly referred to in the U.S. as "reasonable compensation." The substantive conditions and processes for a member state enacting compulsory licensing under Article 31 are generally known as "TRIPS flexibilities."

TRIPS Flexibilities. To understand the currently proposed IP waiver that is being negotiated at the WTO with the support of the United States, it is important to recognize three key facts about TRIPS flexibilities.

1. Article 31 in TRIPS is limited to only patents—and thus its authorization for compulsory licensing does not cover other intellectual property rights, such as the technical know-how that many companies protect as trade secrets.

2. Article 31 imposes a number of conditions and limitations on a member state's use of compulsory licensing, reflecting that this is an exception to the TRIPS rule regarding respect for and enforcement of patent rights, and that, therefore, compulsory licensing represents an option of last resort to achieving some overriding public interest objective.
3. Following logically from the prior point, the requirements mandated by Article 31 can be as lengthy and costly as any lawsuit filed in the U.S., such as requiring, before a compulsory license is imposed, that a commercial licensee or the government have "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."⁹

This substantive limitation of compulsory licensing to only patents and the procedural requirements set forth in Article 31 explain why the proposed IP waiver at the WTO is *not* a request by member states to authorize compulsory licensing of patented drugs and vaccines under Article 31. Rather, the IP waiver is a formal request to set aside *all* international protections under TRIPS for vaccines, drugs, or any other technologies necessary for the treatment of COVID-19 during the pandemic.¹⁰

This is unprecedented. The WTO has never before approved a wholesale waiver of TRIPS. The WTO has never even initiated formal negotiations of such a proposal, which is identified as "text-based negotiations" at the WTO. After the Biden Administration's announcement of U.S. support for the IP waiver, the WTO began text-based negotiations for the IP waiver in early June.

The IP Waiver Includes All IP for COVID-19 Treatments, Including Trade Secrets. The IP waiver was first submitted to the WTO by India and South Africa in early October 2020. Their original IP waiver declared 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.¹¹ After the U.S. announced its support for the IP waiver, India and South Africa (now joined by other member states) resubmitted a revised version in late May 2021, 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."¹² The IP waiver would be in effect for at least three years from the date the WTO adopts it.¹³

Such proposals for waivers from TRIPS have been made before—or have been threatened—but none has made it past the proposal stage, as key member states in the WTO (such as the U.S., Germany, Switzerland, and the United Kingdom) have opposed such measures. As a result, member states instead negotiated compulsory licensing processes, as permitted under Article 31 of TRIPS for patented drugs. For example, this is what happened approximately two decades ago for patented drugs used for the AIDS virus (HIV), although this agreement is confusingly referred to by the WTO as a “waiver,” given that it provided a blanket approval for compulsory licenses under Article 31 and provided several exemptions from some requirements under Article 31 if a country imposed a compulsory license.¹⁴

India and South Africa have been active in the past in seeking to implement—and even to expansively construe—TRIPS flexibilities. Both have large generic drug industries that benefit from loosened international protections of patented drugs created by the innovators that invest tens of billions of dollars and tens of thousands of labor hours to create modern medical miracles, such as treatments for hepatitis and cancer. India and South Africa likely thought the past would repeat itself with this new proposal for an IP waiver for the COVID-19 pandemic: It would serve as a negotiating anchor, similar to an opening offer in a contract negotiation between companies, by setting forth what they would ideally prefer to receive.

The original debate about the IP waiver focused on patents.¹⁵ This was likely a result of two accidental features of the recent policy debates over health care. The first was the past negotiations at the WTO resulting in compulsory licensing of patents under Article 31 for the AIDS pandemic.¹⁶ The second was the prominence of patents in domestic policy debates over drug prices and access.¹⁷

The IP waiver goes far beyond the waiver of patent rights. The IP waiver currently under consideration by the WTO would waive *all* relevant IP protections required by TRIPS for anything required for the treatment of the COVID-19 virus. It would waive protections of anything deemed necessary for an effective medical response to the COVID-19 virus, including design protections, copyrights, and—most important—*trade secrets*.

Tech Transfer. The waiver of IP protections for technical know-how and other confidential information is not an example of accidental overreach by the IP waiver advocates. This is essential to its function as a waiver of TRIPS for countries seeking to produce, sell, and use all vaccines, drugs, or other technologies, such as computer-based technologies, for responding to the COVID-19 virus.

The reason is that the key to producing vaccines based on the mRNA platform is not found solely in the patented products and methods that comprise this new technology. As with all radical, cutting-edge technologies that push the boundaries of human knowledge and skills, there is extensive *technical know-how* in manufacturing mRNA vaccines.

It is not enough to know what the mRNA platform is and how it functions biologically—a company or government agency must know how to mass produce billions of doses of safe and effective vaccines. Thus, a necessary function of the IP waiver is *tech transfer*—the transfer of technical know-how to foreign governments and companies so that they can effectively make, use, and sell the vaccines and other drugs to the populations in their own countries.

The goal of the IP waiver was never limited to *only* the elimination of the enforcement mechanisms at the WTO for countries like India or South Africa in refusing to enforce patents in their countries. The goal of the IP waiver is the *coerced transfer of technical know-how from the U.S. and European companies* that invested billions in creating the mRNA platform to foreign governments and companies.

This raises serious policy concerns for innovation, economic competitiveness, and national security, as will be addressed in the next part.

The Threat to U.S. Innovation, Economic Competitiveness, and National Security

Commentators have long recognized in the context of patents that failing to protect innovation properly destroys the promise of IP rights.¹⁸ People will not invest the billions required to create a new drug or vaccine—and to create the follow-on technologies and the commercial production and distribution chains necessary to distribute this drug in the health care market to patients—if the fruits of their productive labors are not secured to them. People easily recognize this moral principle in the context of a farmer investing a year of valuable labor to plant, grow, harvest, and then distribute a crop—and it applies equally to the modern biotech or pharmaceutical company that creates, develops, produces, and distributes a new drug.

Disclosure of Trade Secrets. The threat to innovation is magnified exponentially in the context of forced disclosures of trade secrets that protect valuable technical know-how—the inventions and commercial information created through the productive labors of scientists and businesspersons. In contrast to a trade secret, a patent is a public document that fully discloses all relevant information about the invention so that

someone skilled in the technical field can make and use the invention protected by the patent. Judges and scholars have long identified this as the *quid pro quo* of the patent system: The inventor receives a time-limited property right in a new and useful invention, and in exchange for this property right, society receives public disclosure of the invention.¹⁹ (Today, the U.S. patent term is 20 years from date of filing of the patent application, a global standard in patent term achieved through the harmonization brought about by TRIPS.²⁰)

A trade secret is an entirely different matter altogether. Valuable technical or commercial information that is actively kept secret is protected under trade secrets law.²¹ Reverse engineering or independent discovery are permissible for commercially valuable information protected under trade secrets law.²² The law prohibits only *piracy* of the trade secret—the wrongful acquisition of the information through theft or other improper means.²³

The law strongly protects trade secrets because once they are publicly disclosed, the proverbial cat is out of the bag. There is no way to take back the knowledge; as the popular Internet meme puts it, “there’s no way to unsee” what one has seen. Following disclosure, the trade secret is lost as a commercial asset that gave its owner a competitive advantage in the marketplace. Thus, the law strongly protects trade secrets.

For example, the federal government recently enacted the Defense of Trade Secrets Act of 2016 to make it easier for trade secret owners to seek legal relief in federal court.²⁴ This law was enacted partly in response to the growing threat posed by industrial espionage from foreign actors, such as China. Recent bipartisan legislation has been proposed to protect even more IP rights—including trade secrets—from theft by Chinese companies and government officials.²⁵

The original policy debate about the IP waiver focused on the removal of the international enforcement mechanisms for patent protections. This is one reason why the CEO of Moderna, one of the creators of one of two mRNA vaccines for COVID-19, said that he “didn’t lose sleep” after the announcement by the Biden Administration that it would support the IP waiver proposal by India and South Africa at the WTO.²⁶ He told reporters, “There is no idle mRNA manufacturing capacity in the world. You cannot go hire people who know how to make mRNA—those people don’t exist.... When we hire people that come from traditional pharma, *we have to train them in the art of mRNA.*”²⁷ He knows the real value in the mRNA vaccines—the value in the mRNA platform itself—is in the *technical know-how* that has evolved over the two decades that it has taken for mRNA technology to be researched and developed.

But his dismissive reaction was premature because the advocates for the IP waiver understood from the get-go that this was not about weakening or eliminating patent protections for vaccines, drugs, or other medical treatments for COVID-19. Of course, the evisceration of international respect for patent rights is one aspect of the IP waiver; there are certainly some patents on some drugs that foreign companies or governments would benefit from appropriating, such as the patent on Remdesivir, the first drug approved by the FDA to treat severe respiratory symptoms caused by COVID-19.²⁸

However, if this effort was only about patent rights, then India and South Africa would have sought only an automatic mandate under Article 31 of TRIPS for immediate compulsory licensing for all patents covering COVID-19 medical treatments (what was achieved almost two decades ago for the AIDS pandemic).²⁹ That is not the true goal of the IP waiver, nor is it what it states in its text.

The Real Reason. The IP waiver is a *complete* waiver from international protections provided by the TRIPS agreement for a period of *at least* three years for any “health products and technologies including 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.” This covers the technical know-how and other trade secrets that have been created by the scientists at Moderna, BioNTech, Pfizer, and all other companies licensed to make and sell mRNA vaccines.

In sum, the IP waiver would eliminate international commitments to and enforcement mechanisms for IP rights, including trade secrets. The IP waiver would not be automatically implemented in the U.S., but the Biden Administration, after supporting the IP waiver at the WTO, would very likely push for domestic implementation of its goals, such as the disclosure of trade secrets. Over 100 Congressional Democrats lobbied the Biden Administration to support the IP waiver before the Administration announced its support on May 5, 2021, and they will also push aggressively for domestic legislation to implement in the U.S. the goals of the IP waiver.³⁰ In her statement after the Biden Administration’s announcement of its support for the IP waiver, Speaker Nancy Pelosi (D-CA) declared it a “moral imperative” that the U.S. do everything possible to “defeat [COVID-19] everywhere.”³¹

Some people have suggested that the Biden Administration is merely engaging in political showmanship in the international arena with no real hope of implementation of any actual laws or policies in the U.S.,³² but that is highly unlikely to be the case. It would be anomalous for the Biden

Administration to support the adoption of the IP waiver at the WTO and then refuse to undertake the domestic actions required to implement that IP waiver for U.S. owners of IP who are covered by the waiver—especially given that many U.S. companies are owners of the valuable trade secrets in technical know-how concerning how to make and distribute the mRNA vaccines.

The charges of hypocrisy from the large contingency of developing countries at the WTO that the Biden Administration has courted favor with by supporting the IP waiver, as well as the resulting perception of another humiliating debacle in U.S. international policy, strongly suggest the Biden Administration, the Democratic leadership in Congress, and the numerous Democrats already supporting the IP waiver would push for implementing legislation in the U.S., and that this is not just political theater on the international stage.

If this happens, such legislation could require a coerced tech transfer of the valuable technical know-how by the innovators who have worked for decades to create the mRNA platform as a means to create medical treatments and vaccines for diseases like the COVID-19 virus. The precise language of the IP waiver has yet to be settled upon, given the ongoing negotiations in the WTO. As currently worded, however, the proposal has at least two results that would kill the technical innovations that have driven the U.S. innovation economy and given the U.S. a competitive advantage in the global economy in both biotech and high-tech—as well as imperil its national security.

Coerced Disclosure: Constitutional and Policy Concerns. First, the coerced disclosure of technical know-how to foreign companies (and even to foreign governments) requires violating the rights of American IP owners far beyond anything previously imagined. If the WTO adopts the proposed IP waiver currently under consideration, this would simply set aside the TRIPS agreement and the enforcement mechanism at the WTO to uphold in the international arena the multilateral respect among different countries for IP rights. Each country would then choose if—and how—to adopt in its own domestic laws the “moral imperative” imposed by the IP waiver, in Speaker Pelosi’s words.

According to those arguing that the IP waiver imposes this moral mandate, legislation to implement the IP waiver in the United States would have to do more than just prohibit U.S. patent owners from enforcing their patents under U.S. law—such as filing lawsuits in court to prevent unauthorized imports of infringing products or services or seeking exclusion orders against infringing imports in the U.S. International Trade Commission. To truly implement domestically the IP waiver, at least as it is currently worded,

this legislation would require *coerced disclosure* of the valuable trade secrets necessary to develop the facilities and to manufacture billions of doses of mRNA vaccines that are consistently safe and effective in preventing COVID-19 infections.

Coerced Disclosure and Obamacare. It is not impossible for the federal government to do this, such as through regulatory mandates and tax incentives. Unfortunately, the Obama Administration provided the Biden Administration with a road map of how to accomplish this goal with the Obamacare tax incentives in the regulatory mandate to adopt health care insurance. Unfortunately, the Supreme Court confirmed this road map when it refused to strike down Obamacare as unconstitutional in 2012.³³

Nonetheless, there are other constitutional hurdles that would need to be overcome by Congress and the Biden Administration in implementing a coerced disclosure of trade secrets. The Supreme Court has expressly recognized that trade secrets are protected property rights under the Fifth Amendment.³⁴ As such, trade secrets cannot be coercively disclosed through regulatory mandates without triggering the requirement that the owner be paid “just compensation.”³⁵

Unfortunately, this “regulatory takings” doctrine known as the “Penn Central inquiry” has proven to provide little to no protection for U.S. landowners who have suffered deprivations of economic value in their real estate resulting from regulations.³⁶ This legal doctrine is infamously problematic; the Supreme Court admits that it is “ad hoc” and that it is uncertain and unpredictable, except perhaps for the safe prediction based on case outcomes that the government always wins.³⁷

The Supreme Court and Regulatory Takings. Given the nature of the regulatory-takings doctrine and the consistent outcomes in cases, it is easy to predict that the Supreme Court would find a coerced disclosure of a trade secret by regulatory decree, especially if accompanied by some form of “reasonable compensation,” to pass constitutional muster. If implementing legislation of the IP waiver functions through something like tax penalties or incentives, it is even harder to see the Supreme Court finding a constitutional quailm in this legislation: Again, think Obamacare. At the very least, it is always a big risk to pass legislation assuming a court will strike it down, especially when it comes to regulatory takings.

It is therefore incumbent on Congress to *refuse to enact this legislation* in the first place. If it chooses to address concerns about global vaccine distribution invoked by the IP waiver’s advocates, Congress should create international relief programs to help construct infrastructure to distribute vaccines or eliminate the prohibitions on international exports of vaccines,

personal protective equipment (PPE), and other pandemic-related goods. Congress should not enact any legislation that violates the rights of American IP owners.

Hands-On Technical Know-How. There is another fundamental constitutional concern beyond ostensive regulatory takings concerns with the coerced disclosure of the trade secrets in mass producing safe and effective mRNA vaccines. As noted, the technical know-how in mass producing mRNA vaccines represents more than just the information itself. It cannot be taught abstractly through reading documents or online lectures. It requires trial-and-error practice and experiential learning.

It requires the active, in-person teaching of the technical skills, which means operational oversight of an expert to guide the many attempts by students who are learning this practical knowledge. Teaching this technical know-how is not like teaching mathematics. It represents the acquisition of practical skills, like the training of an Olympic athlete, a professional athlete, a medical intern in a hospital, or a junior associate in a law firm.

Legislation implementing requirements of the IP waiver that require disclosure of the technical know-how necessary to mass produce mRNA vaccines might mandate that U.S. scientists and engineers teach foreign scientists or government officials how to mass produce safe and effective mRNA vaccine doses. It is one thing to deny patent owners the legal right to sue for patent infringement or to compel a compulsory license in which the government imposes price controls via a “reasonable royalty” for this coerced transfer of the patented invention (as would occur under Article 31 of TRIPS). It is quite another to mandate that a U.S. company like Moderna actively ensure the transfer of its technical know-how to foreign scientists or government officials so that these foreign actors can effectively manufacture and distribute mRNA vaccines in those countries.

Some argue that the IP waiver will require—or at least should be interpreted to require—the transfer of technical know-how.³⁸ As the Moderna CEO put it so well, this information—which is currently protected as a trade secret—cannot simply be acquired by others from reading a patent or technical manual. This raises a whole new level of constitutional and policy concerns about how the U.S. government will achieve *effective* transfer of technical know-how under the IP waiver. Congressional Democrats, international activists, scholars, and even foreign governments will expect the U.S. to do so, given the Biden Administration’s express support for the IP waiver.

IP Waiver: Undermining Innovation, Subsidizing Chinese and Russian R&D. In addition to the legal and policy concerns of how the U.S.

government might seek to implement the IP waiver in compelling disclosure of the trade secrets representing the technical know-how in producing mRNA vaccines, there is a broader concern about the countries benefiting from this coerced scientific and technical training. Implementing the goals of an IP waiver would require more than surrendering patents, disclosing trade secrets, and training scientists in Brazil, India, or South Africa: *Any* member state of the WTO would no longer be required to honor its commitments to protect the waived IP rights. This could mean that Russia and China might seek to compel disclosure or demand the active transfer of the technical know-how or training.

This leads to the second innovation policy concern raised by the IP waiver's goal to surrender patents, disclose trade secrets, and transfer technical know-how necessary to effectively respond to COVID-19. As noted earlier, once a trade secret is disclosed, the value of the information is lost. More precisely, the competitive advantage in the information as a commercial asset is lost because it is now available to anyone in the world who wishes to learn it and act on it.

A patent is an exclusive property right for 20 years, but the information is already public through the patent document itself, which is what prompts follow-on innovations during the term of the patent and further innovation once the invention falls into the public domain. The trade secret—the “secret sauce” in a company's business model—is only valuable so long as it is kept secret.

This year, the federal government began actively seeking to promote the growth of its innovation economy to ensure the continuation of the comparative advantages long enjoyed by the U.S. against the rising challenge represented by China. The U.S. Innovation and Competitiveness Act of 2021 (USICA) is a prime example of this concern. The USICA was approved by the Senate on June 8, 2021, and is awaiting a vote in the House, authorizing \$250 billion in funding for research and development (R&D) in artificial intelligence and other new technologies, as well as in semiconductor chip production.³⁹ Regardless of whether one agrees with the creation of federal industrial policy in the USICA, it represents a response to a mounting concern that the U.S. must focus more on promoting the innovation that grows the U.S. economy, creates jobs, and increases quality of life for all Americans—especially in the face of global economic and strategic competition from China.⁴⁰

The Biden Administration's support for the IP waiver at the WTO contradicts these innovation policy concerns that are prompting the USICA, which the Biden Administration also claims to support, albeit

without much regard for coherence in innovation policy.⁴¹ For at least two decades, China has actively engaged in various forms of “tech transfer” to steal U.S. IP, such as engaging in outright industrial espionage or simply mandating under Chinese law that foreign companies engaged in economic activities in China turn over IP and other valuable know-how to Chinese companies or to the government.⁴² In a recent Senate hearing, William Evanina, the former director of the National Counterintelligence and Security Center, testified that the Chinese Communist Party was responsible for stealing between \$300 billion and \$600 billion in U.S. intellectual property and trade secrets in just 2020.⁴³ Federal Bureau of Investigation Director Chris Wray stated last year that China’s concerted campaign of theft of American IP represented “one of the largest transfers of wealth in human history.”⁴⁴

The IP waiver would effectively transfer to China valuable patents, trade secrets, and tech know-how created through billions in investments and decades of labor by U.S. innovators. What China has only been able to steal or otherwise obtain through other improper methods over the years, the IP waiver would achieve under a U.S. law enacted to implement the perceived moral mandate of the IP waiver. Such a law would do the same for other global competitors of the U.S. who are member states of the WTO, such as Russia.

This will not only massively harm the incentives to innovate in the U.S., it would also result in a multi-billion-dollar subsidy of basic research and development in China, Russia, and other countries who would immediately benefit from the technical know-how produced by the productive labors of the scientists and businesspersons in the biopharmaceutical sector during the past decades.

The IP waiver strikes at the heart of the IP-based labors that are the principal drivers of the U.S. innovation economy, killing the incentives to create the technologies that create jobs, grow the economy, and, in the context of the life sciences, save lives and increase quality of life. In doing this—by anticipating forced disclosure of valuable technical know-how acquired from decades of R&D—the waiver could effectuate a massive tech transfer to other countries that did not invest in this R&D, nor create the valuable scientific insights and technological innovations that have produced modern medical miracles, such as mRNA vaccines. The forced waiver would kill the comparative advantage of the U.S. innovation economy, and further undermine U.S. competitiveness in the global economy at a time when the U.S. is just waking up to the challenge represented by economic and national competitors like China.

The Economic and National Security Concerns About the IP Waiver

Last, the waiver's policy concerns go far beyond the subsidization of tens of thousands of labor hours and billions in investments to create the knowledge necessary to produce safe and effective mRNA vaccines. The mRNA technology is a *platform technology*—a technological discovery that has applications that go far beyond the current COVID-19 pandemic. Companies have begun investigating how to develop more mRNA vaccines to address viral scourges that have killed millions of humans around the globe.⁴⁵ With incredible medical cures ranging from cancer to HIV to malaria, the mRNA platform is the invention that may fulfill the full promise of the biotech revolution that began in the U.S. almost four decades ago.⁴⁶

Unauthorized Use by Global Competitors. If implemented domestically to the degree demanded by its advocates, the IP waiver would promote the disclosure of technical know-how in the mRNA platform to countries throughout the globe, including to China and Russia. As economic and strategic competitors—expressed in both words and deeds over many years—it is highly unlikely that China or Russia would respect the requirement in the IP waiver that these trade secrets be used *only* for COVID-19 medical treatments and *only* for three years or the length of the pandemic, whichever is longer.

Unauthorized Transfer to Global Competitors. Even if China or Russia are prohibited somehow from directly receiving the technical know-how, there is nothing that would stop other countries or individuals in other countries from transferring the information to them after the direct disclosure and training by U.S. scientists in the technical know-how of how to produce mRNA vaccines. Again, once a trade secret is disclosed, it is lost by its owner to the world; information is transmissible as easily as it takes for digital signals to traverse the cables that carry international Internet traffic or as easily as it is for people with the knowledge in their heads to travel from one country to another country.

Preventing trade secret misappropriation is a difficult endeavor within a single jurisdiction, and identifying or tracking information back to the original act of misappropriation can be onerous and costly for private companies seeking remuneration or other legal relief. On an international scale between nation-states, even with the threat of WTO trade sanctions, it may prove nearly impossible to catch malefactors—or even simply prove the unauthorized transfer by any reasonable measure of evidence.

Any prohibitions or sanctions for unauthorized transfers of technical know-how in implementing U.S. legislation would represent oratory proclamations at best, tantamount to the Biden Administration's demand in August 2021 that the Taliban create a "united, inclusive and representative" government in Afghanistan.⁴⁷ Simply put, U.S. laws have no control over actions undertaken in foreign jurisdictions by foreign citizens. Ultimately, any forced disclosure of the technical know-how in the mRNA biotech platform simply requires that Congress and U.S. officials have blind faith that China, Russia, or other countries will use these disclosed trade secrets solely for purposes of producing only vaccines and other medical treatments only for COVID-19. This reflects an astonishing level of naïveté in international politics—especially when dealing with a well-established economic and strategic competitor like China that has blatantly stolen hundreds in billions in U.S. IP or a country like Russia that has engaged in cyberattacks on U.S. institutions, illegally invaded Ukraine, and annexed the Crimea in 2014.⁴⁸

National Security Implications. Beyond the obvious economic benefits of this massive tech transfer to these economic and strategic competitors—and the direct harm done to U.S. innovators—the national security concerns are equally palpable. The concern that COVID-19 was leaked from a government lab in Wuhan, China, experimenting with coronaviruses is still being investigated.⁴⁹ There is also intelligence information that this government lab was working on "classified research for the Chinese military."⁵⁰ There are many reasons why the lab leak theory remains very much in play. Unlike prior global disease outbreaks in recent years, the world still does not know—almost two years after the inception of a worldwide viral pandemic—where COVID-19 came from or who was Patient Zero.

The reason is simple: China has obstructed international efforts to obtain the necessary information to answer these vital questions in better understanding and responding to COVID-19.⁵¹ In fact, China has actively *deleted* publicly available data about COVID-19, such as removing gene data on COVID-19 from a National Institutes of Health database in June 2020.⁵²

Given China's pattern of obstruction during the course of almost two years in uncovering necessary information about the origin and first human cases of COVID-19, it is clear that China *cannot be trusted* with a powerful biotechnology platform like mRNA. As a strategic competitor, China has in fact already stolen innumerable military secrets in addition to its economic espionage.⁵³ Thus, the U.S. should refuse to turn over to China the technical know-how in using the mRNA platform—either directly to China or indirectly through disclosures to other countries that might then leak, sell, or simply trade this information to China in exchange for other strategic benefits.

Recommendations

In sum, the U.S. should stand fast in defense of the rights of American innovators, its innovation economy, and its national security interests.

- The Biden Administration should immediately withdraw support for the IP waiver at the World Trade Organization.
- Failing this, Congress should reject any attempt by the Biden Administration or congressional Democrats to use the IP waiver to eliminate or weaken IP rights under U.S. law.

This is especially pressing when any IP transfers or disclosures would be made to an economic and strategic competitor like China that has already stolen hundreds of billions in U.S. IP—and which can easily use the biotech platform to fulfill its own economic or military goals. The IP waiver threatens the foundations of the U.S. innovation economy, as well as risks U.S. companies giving away biotech know-how to countries like China and Russia that could undermine U.S. economic and national security interests.⁵⁴ The IP waiver should *not* be adopted by the WTO, and, if it is, the U.S. should refuse to adopt it in any form in domestic legislation.

If the advocates for the IP waiver are truly concerned about promoting global distribution of vaccines, drugs, and other medical treatments or supplies in response to the COVID-19 pandemic, there are numerous actions the U.S. could take that would achieve these goals.

Instead of supporting the IP waiver at the WTO, the U.S. should consider alternative measures to protect U.S. technological innovation, stimulate economic growth, and preserve national security. Therefore, the Biden Administration should:

- **Eliminate trade barriers** that have prevented international exports of vaccines and other health care materials such as PPE—as the *Wall Street Journal* recognized in its own critique of the IP waiver.⁵⁵
- **Release for use in other countries the stockpile** of *tens of millions of doses* of the AstraZeneca vaccine that are not being administered in the U.S. but has been approved for use in 70 other countries.⁵⁶
- **Marshal international support for investment in developing countries** to create the necessary commercial distribution chains and

physical infrastructure to facilitate distribution of the more than *12 billion* doses of vaccines that will be produced by the end of 2021.⁵⁷

Conclusion

The IP waiver is an example of a solution in search of a problem. There is zero evidence that IP rights have impeded or otherwise hampered the distribution of any vaccines. The evidence is to the contrary: IP rights prompted the investment of billions of dollars over several decades in research and development, encouraged the creation of a knowledge infrastructure within the biopharmaceutical sector, and served as the foundation for innumerable commercial and information-sharing agreements that made possible an unprecedented health care response to the COVID-19 pandemic.⁵⁸

By wiping out international commitments to the protection of IP rights, including patents and trade secrets, the IP waiver violates the primary maxim in healthcare, “first, do no harm.” The best way to end the COVID-19 pandemic, as well as other scourges and future pandemics, is to continue recognizing, supporting, and respecting IP rights like patents and trade secrets—the legal engines that have driven medical innovations for the past century.

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Endnotes

1. See, for example, Adam Mossoff, *Waiving Vaccine Patents Would Imperil Public Health*, VIRGINIAN-PILOT (Apr. 13, 2021), <https://www.pilotonline.com/opinion/columns/vp-ed-column-mossoff-0414-20210413-krqjhk7zhfgyxjm4kyvjvitym-story.html>; *Biden's Vaccine IP Debacle*, WALL STREET J. (May 6, 2021), <https://www.wsj.com/articles/bidens-vaccine-ip-debacle-11620341686?mod=e2two>.
2. See James M. Roberts, *Biden's Wink at Global Theft of U.S. Vaccine Patents Is Bad for America and the World*, HERITAGE FOUND. BACKGROUND No. 3628 (June 8, 2021), <https://www.heritage.org/economic-and-property-rights/report/bidens-wink-global-theft-us-vaccine-patents-bad-america-and-the>; see also Adam Mossoff, *Pandemics, Patents, and Price Controls*, HERITAGE FOUND. LEGAL MEMORANDUM No. 285 (May 13, 2021), <https://www.heritage.org/economic-and-property-rights/report/pandemics-patents-and-price-controls> (detailing the unprecedented response by the biopharmaceutical sector to the COVID-19 pandemic and how this was made possible by the reliable and effective patent rights secured in biotechnology during the past four decades).
3. See *id.*
4. See *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver* (May 5, 2021), U.S. Trade Representative, <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.
5. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299 (hereafter TRIPS).
6. See TRIPS, art. 31, https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.
7. See TRIPS, art. 8, https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm.
8. TRIPS, art. 31(h).
9. TRIPS, art. 31(b).
10. Strictly speaking, the IP waiver applies to patents, copyrights, industrial designs, and confidential know-how required for making and using medical treatments and other technologies necessary to respond to the COVID-19 pandemic, and thus it does not apply to trademarks, geographical indications, layout designs, or the performance rights of musicians and firms working in the creative industries that distribute sound recordings.
11. 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>.
12. 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>.
13. *Id.*
14. See *WTO Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and Exceptions* (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (discussing the 2003 agreement approving compulsory licensing as “contain[ing] three waivers”).
15. See Mossoff, *supra* note 1; Roberts, *supra* note 2.
16. See James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines 2*, CATO INSTITUTE FREE TRADE BULLETIN No. 70 (Dec. 2020), <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>.
17. See Mossoff, *supra* note 1; Doug Badger, Adam Mossoff, Peter Pitts, & Marie Fishpaw, *What You Need to Know About President Biden's Prescription Drug Agenda*, HERITAGE FOUND. LECTURE No. 1324 (July 21, 2020), <https://www.heritage.org/health-care-reform/lecture/what-you-need-know-about-president-bidens-prescription-drug-agenda>.
18. See Mossoff, *supra* note 1; Roberts, *supra* note 2. See also Jonathan M. Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (Oxford University Press, 2020); Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016).
19. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is the *quid pro quo* of the right to exclude.”); Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J. L. & TECH. 321, 366 (2009) (“By the late eighteenth century, courts had altered the *quid pro quo* of the patent from an affirmative duty to work the patented manufacture to a disclosure of the invention in the patent document.”).
20. See TRIPS, art. 33; the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat. 4809, § 532(a)(1) (1994), amending 35 U.S.C. § 154(a)(2) (changing the U.S. patent term from 17 years from date of issuance of the patent to 20 years from date of filing of patent application).
21. See James Pooley, *Secrets: Managing Information Assets in the Age of Cyberespionage* 21–36 (Verus Press, 2015).
22. See Eric R. Claeys, *Use at Common Law and Under the Uniform Trade Secrets Act*, 33 HAMLINE L. REV. 583, 586 (2010).
23. See Eric R. Claeys, *Intellectual Usufructs: Trade Secrets, Hot News, and the Usufructuary Paradigm at Common Law*, in *Intellectual Property and the Common Law* (ed. Shyam Balganes, Cambridge University Press, 2013).
24. See Public Law 114–153, 130 Stat. 376 (2016).
25. See Katy Stech Ferek, *Legislation Aimed at China Seeks to Expedite Probes of Trade-Secret Thefts*, WALL ST. J. (June 15, 2021), <https://www.wsj.com/articles/legislation-aimed-at-china-seeks-to-expedite-probes-of-trade-secret-thefts-11623786088>.

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28. See Adam Mossoff, *US Should Not Confiscate Gilead's Remdesivir Patent*, LAW360 (Aug. 21, 2020), <https://www.law360.com/articles/1303214/us-should-not-confiscate-gilead-s-remdesivir-patent>.
29. See *supra* notes 13 and 15, and accompanying text.
30. See *Members of Congress That Led Push for TRIPS Waiver Applaud Biden Administration Announcement* (May 5, 2021), <https://schakowsky.house.gov/media/press-releases/members-congress-led-push-trips-waiver-applaud-biden-administration>.
31. See *Pelosi Statement on Biden Administration Support for Vaccine Patents Waiver at WTO* (May 5, 2021), <https://www.speaker.gov/newsroom/5521-3>.
32. See Justin Hughes, *Biden Decision on COVID Vaccine Patent Waivers Is More About Global Leadership Than IP*, USA TODAY (May 6, 2021), <https://www.usatoday.com/story/opinion/2021/05/06/covid-vaccine-patents-biden-boosts-american-leadership-column/4932766001/>.
33. See *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012).
34. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984).
35. See *id.* at 1011 (holding that a regulation that discloses a trade secret is a taking because “the right to exclude others is central to the very definition of the property interest.”).
36. In all cases brought before the Supreme Court, landowners have never won when the Supreme Court has applied the legal test for regulatory takings doctrine—known as the *Penn Central* inquiry. See *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978).
37. *Penn Central*, 438 U.S. at 124 (observing that regulatory takings doctrine comprises “essentially ad hoc, factual inquiries” and that it “depends largely upon the particular circumstances” in each case).
38. See *Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal 3* (July 13, 2021), <https://dx.doi.org/10.2139/ssrn.3885568> (“Governments must work with IP holders to make available and incentivise the disclosure of information held as trade secrets (and other undisclosed information). . . .”); *The IP Waiver at the WTO: A Discussion of the Implications for IP, Innovation, and Public Health* (June 23, 2021), <https://www.youtube.com/watch?v=nJ5EdykoB58> (statements by Professor Joshua Sarnoff on the moral obligation and legal mandate to share all information covered by the IP waiver).
39. See S. 1260, 117th Cong. (2021).
40. See Patricia Zengerle & David Shepardson, *Sweeping Bill to Address China Tech Threat Likely to Take Weeks in U.S. House* (June 16, 2021), <https://www.reuters.com/world/us/sweeping-bill-address-china-tech-threat-likely-take-weeks-us-house-2021-06-15/>.
41. See *Statement of President Joe Biden on Senate Passage of the U.S. Innovation and Competition Act* (June 8, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/08/statement-of-president-joe-biden-on-senate-passage-of-the-u-s-innovation-and-competition-act/>.
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44. See Russell Flannery, *China Theft Of U.S. Information, IP One Of Largest Wealth Transfers In History: FBI Chief*, FORBES (July 7, 2020), <https://www.forbes.com/sites/russellflannery/2020/07/07/china-theft-of-us-information-ip-one-of-largest-wealth-transfers-in-history-fbi-chief/?sh=3b99c0cf4440>.
45. See Joanne Kenen, *Welcome to the New Era of Vaccines*, POLITICO (Apr. 16, 2021), <https://www.politico.com/newsletters/politico-nightly/2021/04/16/welcome-to-the-new-era-of-vaccines-492493>.
46. See Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 943–944 (2017) (discussing birth of biotech revolution in U.S.).
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54. In addition to China, Russia and Iran are very real security threats, as evidenced in the recent COVID-19 pandemic. See Volz, *supra* note 55 (“The NSA has previously implicated the Russian government in efforts to exploit one of the flaws to steal coronavirus vaccine research, for example, and private-sector researchers have said suspected Iranian hackers have attempted to breach systems using some of the bugs.”).
55. See *Biden’s Vaccine IP Debacle*, *supra* note 1.
56. See Noah Weiland & Rebecca Robbins, *The U.S. Is Sitting on Tens of Millions of Vaccine Doses the World Needs*, N.Y. Times (Mar. 11, 2021), <https://www.nytimes.com/2021/03/11/us/politics/coronavirus-astrazeneca-united-states.html>.
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