

COVID VACCINES AND INTELLECTUAL PROPERTY RIGHTS: EVALUATING THE POTENTIAL FOR NATIONAL LEGISLATION IMPLEMENTING GLOBAL PATENT WAIVERS

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ABSTRACT

Debates over the proper scope of intellectual property protections during the COVID-19 pandemic have occupied newspaper headlines since the first vaccines were developed nearly three years ago. Scholars and key politicians from several nations considered the implementation of a global patent waiver in an effort to make the vaccines more widely available in developing parts of the world. Although the question of whether such a waiver would fulfill this goal remains empirically unanswered and up for debate, the legal structure of United States patent law would make its implementation by Congress difficult given the value placed on intellectual property protections since America's birth. If lawmakers wish to consider limiting patent rights in an inevitable future pandemic or other national emergency, they would be wise to consider these legal issues ex ante by revising the Bayh-Dole Act and the existing patent law takings provision.

INTRODUCTION

In December 2019, news broke about the discovery of a respiratory disease outbreak in Wuhan, China.¹ The disease was caused by a coronavirus known as SARS-CoV-2, which quickly became known as COVID-19 as it spread rapidly around the world.² By February 2020, the virus had infected hundreds of people in South Korea and Italy.³ The World Health Organization officially declared COVID-19 a global pandemic on

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¹ Div. of Viral Diseases, Nat'l Ctr. for Immunization and Respiratory Diseases, Ctrs. for Disease Control and Prevention, *Basics of COVID-19*, CDC (Nov. 4, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html>.

² *Id.*

³ Jason Horowitz & Elisabetta Povoledo, *Europe Confronts Coronavirus as Italy Battles an Eruption of Cases*, N.Y. TIMES (Feb. 27, 2020), <https://www.nytimes.com/2020/02/23/world/europe/italy-coronavirus.html>.

March 11, 2020,⁴ and by the end of that month, the virus had spread to six continents, including North America.⁵ Nearly three years later, the consequences of the pandemic are still felt by millions, although significant progress has been made in worldwide vaccination status.⁶ As of the date of this publication in November of 2022, over 6.6 million lives have been lost due to COVID-19 and more than 637 million cases have been officially reported around the globe.⁷

Since the start of the pandemic, politicians voiced the need for a safe and effective vaccine to prevent serious illness and death resulting from COVID-19, despite warnings from scientists that politicization could discourage the public from getting the vaccine once developed.⁸ In November 2020, just ten months after the first COVID-19 cases were reported, news that Pfizer and Moderna had both created a vaccine with ninety percent effectiveness created a flurry of excitement in the media.⁹ Of particular importance, both pharmaceutical companies achieved this success by using novel messenger ribonucleic acid (mRNA) technology.¹⁰ The Food

⁴ David J. Cennimo, *How Did the Coronavirus Outbreak Start?*, MEDSCAPE (Jun. 25, 2021), <https://www.medscape.com/answers/2500114-197402/how-did-the-coronavirus-outbreak-start#:~:text=On%20March%2011%2C%202020,a%20pandemic%20in%202009>.

⁵ *Id.*

⁶ See *Understanding Vaccination Progress*, JOHNS HOPKINS UNIV., <https://coronavirus.jhu.edu/vaccines/international> (last visited Nov. 18, 2022, 4:22 PM). However, note that many developing countries still trail behind developed countries in terms of percentage of the population vaccinated.

⁷ *Coronavirus Resource Ctr.*, JOHNS HOPKINS UNIV., <https://coronavirus.jhu.edu> (last visited Nov. 18, 2022, 4:18 PM).

⁸ Sarah Kreps & Douglas L. Kriner, *Will Americans Trust a COVID-19 Vaccine? Not if Politicians Tell Them to*, BROOKINGS (Oct. 30, 2020), <https://www.brookings.edu/techstream/will-americans-trust-a-covid-19-vaccine-not-if-politicians-tell-them-to/>.

⁹ See, e.g., Sarah Zhang, *The End of the Pandemic Is Now in Sight*, THE ATLANTIC (Nov. 18, 2020), <https://www.theatlantic.com/health/archive/2020/11/vaccines-end-covid-19-pandemic-sight/617141/> (“The most tenuous moment is over: The scientific uncertainty at the heart of COVID-19 vaccines is resolved. Vaccines work. And for that, we can breathe a collective sigh of relief.”). Several additional vaccines against COVID-19 have been invented by other manufacturers within the United States and around the world. However, this article will specifically focus on the intellectual property rights of the two most popular vaccines in the United States that have used the mRNA technology specifically, which were invented by Pfizer and Moderna.

¹⁰ *Id.*

and Drug Administration (FDA) gave emergency use authorization for both vaccines in December 2020.¹¹ Many, perhaps naively, believed the discovery of the resulting vaccines was a light at the end of the tunnel that would bring an end to the pandemic.¹² However, logistical challenges, both domestically and internationally, acted as a barrier to achieving this optimistic goal.¹³

In an effort to remove some of these prohibitive barriers that stand in the way of spreading the benefits of the vaccine globally, world leaders discussed the potential of a global waiver of patent rights associated with the COVID-19 vaccines.¹⁴ Theoretically, such a patent waiver could be accomplished through amendments to the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) vis-à-vis proposals to the World Trade Organization (WTO).¹⁵ Researchers opine that patents are a barrier to a proposed three-step plan that could achieve a more equitable distribution of vaccines because they prevent knowledge on how to manufacture vaccines from being used by other pharmaceutical companies around the world.¹⁶

¹¹ The Pfizer vaccine was later fully approved for adults in August 2021. Press Release, U.S. Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021) (on file with author). The Moderna vaccine was fully approved by the FDA in January 2022 and is now marketed as Spikevax. *Moderna COVID-19 Vaccines*, U.S. FOOD & DRUG ADMIN. (Nov. 7, 2022), <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>.

¹² See, e.g., Zhang, *supra* note 9 (hypothesizing the end of the COVID-19 pandemic was near upon the discovery of coronavirus vaccines).

¹³ See Understanding Vaccination Progress, *supra* note 6. As of November 2022, the map generally shows the densest locations of vaccine administration as being in the United States, Western Europe, Australia, and parts of South America and Eastern Asia. The concentration of doses administered shows a sparser pattern across the entire continent of Africa, as well as throughout parts of the Middle East and Eastern Europe.

¹⁴ See, e.g., Amy Maxmen, *In Shock Move, US Backs Waiving Patents on COVID Vaccines*, NATURE (May 6, 2021), <https://www.nature.com/articles/d41586-021-01224-3> (reporting on the announcement by the United States government agreeing to support patent waivers for COVID-19 vaccines).

¹⁵ Anthony D. So, *WTO TRIPS Waiver for COVID-19 Vaccines*, JOHN HOPKINS BLOOMBERG SCH OF PUBLIC HEALTH (May 10, 2021), <https://publichealth.jhu.edu/2021/wto-trips-waiver-for-covid-19-vaccines>.

¹⁶ *Id.* The three-step plan consists of (1) removing the patent barriers, (2) providing pharmaceutical manufacturers around the world with knowledge on how to make the vaccines, and (3) investing in manufacturing capabilities to ensure proper infrastructure is developed to allow for vaccine production.

The pharmaceutical industry and several developed nations, including the United States and countries throughout the European Union, initially opposed the waiver of such patent rights.¹⁷ The Biden Administration ultimately changed positions, endorsing the proposed waiver in May 2021.¹⁸ However, even if passed by all member states of the WTO, Congress would still have to implement the waiver with domestic legislation for it to become effective in the United States.¹⁹ Since the beneficiaries of the waiver would predominantly be residents of developing nations, as opposed to domestic citizens and entities, such legislation would prove difficult under existing patent laws.²⁰

This Note focuses on the legal mechanisms of two key domestic patent laws that would require amendments to allow for the implementation of a global patent waiver by Congress. Regardless of the decision reached by the TRIPS Council in relation to the COVID-19 vaccine patent waivers, this Note is intended to provide an overview of the potential of global patent waivers in their entirety. This discussion is critical as global inequities continue to grow while developed nations harbor most of the talents and resources, in the form of domestic pharmaceutical companies and drug manufacturers, which are necessary to develop new healthcare technologies.²¹

The United States patent laws are primarily designed to encourage and incentivize innovations by granting economic protections, a concept that the Constitution itself recognizes.²² However, global patent waivers on pharmaceutical products, which tend to be viewed as altruistic in nature,²³ may be inconsistent with these fundamental goals and purposes. Such

¹⁷ Maxmen, *supra* note 14.

¹⁸ SHAYERAH I. AKHTAR & IAN FERGUSON, CONG. RSCH. SERV., IF11858, POTENTIAL WTO TRIPS WAIVER AND COVID-19 1 (2021), <https://crsreports.congress.gov/product/pdf/IF/IF11858>.

¹⁹ Hans Sauer, *Waiving IP Rights During Times of COVID: A 'False Good Idea'*, IP WATCHDOG (Apr. 19, 2021), <https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/>.

²⁰ *Id.*

²¹ *Id.*

²² See U.S. CONST. art. I, § 8, cl. 8 (“[The Congress shall have power] [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”)

²³ James Roberts, *Biden's Wink at Global Theft of U.S. Vaccine Patents Is Bad for America and the World*, HERITAGE FOUND. (Jun. 9, 2021), <https://www.heritage.org/economic-and-property-rights/report/bidens-wink-global-theft-us-vaccine-patents-bad-america-and-the>.

inconsistency will lead to tensions between existing patent legislation and the amendments that would be required to implement a global patent waiver domestically. Thus, on the world stage, WTO member states may symbolically agree to waive patent rights protections for new technologies, like the COVID-19 mRNA vaccines, by amending the TRIPS Agreement. However, at home in the United States, significant legal barriers inherent in American patent legislation would make it difficult to implement national legislation to give patent waivers their full, extraterritorial effect. Such difficulties would be most prominent in the case of patent rights that have already been granted.

I. BACKGROUND

A. *The TRIPS Agreement and the WTO Doha Declaration*

The TRIPS Agreement was negotiated during the Uruguay Rounds²⁴ and has been in effect since January 1, 1995.²⁵ Its predecessor, the General Agreement on Tariffs and Trade (“GATT”), contained little explicitly on international protections of intellectual property, instead only prohibiting member states from discriminating against and between goods imported from other nations.²⁶ Importantly, with the limited protections provided in the GATT alone, the United States felt as though its domestic companies did not have adequate intellectual property protections.²⁷ Consequently, to ensure American industries were more competitive on a global scale and to protect its trade interests, the United States encouraged the inclusion of more protective international intellectual property rights during the Uruguay Rounds.²⁸

In relation to patents specifically, the TRIPS Agreement sets several minimum standards for patent legislation in its member states.²⁹ First, Article 27.1 requires all member states to make patents available for all inventions, regardless of where the product or process is invented or manufactured, unless the invention falls under one of the three categories of

²⁴ Adrian Otten, *The Trips Negotiations: An Overview in THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUNDS* 55, 59 (Jayashree Watal & Antony Taubman eds., 2015) (ebook).

²⁵ *Overview: The TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Feb. 18, 2022).

²⁶ Otten, *supra* note 24, at 59.

²⁷ *Id.* at 58.

²⁸ *Id.*

²⁹ WORLD TRADE ORG., *supra* note 25.

exceptions.³⁰ Second, in the cases of patents for products, Article 28 requires member states to confer several basic, exclusive rights to all patent holders, such as the right to offer the product for sale, the right to sell it, and the right to import it.³¹ In the cases of patents for processes, it requires all patent holders be given the exclusive right to use the process as well as the products resulting from that use.³² Third, Article 33 of the TRIPS Agreement requires member states to provide protection for a total of twenty years from the filing date of the patent application,³³ but Article 30 allows limited exceptions to the exclusive rights granted under specific circumstances.³⁴ Lastly, Article 31 of the TRIPS Agreement contains an article for compulsory licensing.³⁵ Initially, this allowed a member state's government or a government-authorized third party to use patented subject matter without authorization from the patent holder when a voluntary license could not be obtained, but only to supply the domestic market of that state.³⁶

The TRIPS Agreement originally contained several mechanisms intended to prevent patent rights from interfering with individual member states' unique public health needs, especially for those in the developing world dealing with the HIV/AIDS pandemic.³⁷ However, the attempted

³⁰ *Id.* The three categories of inventions that are unpatentable are (1) inventions contrary to public order or morality, such as those dangerous to human life or health, Article 27.2, (2) diagnostic, therapeutic, and surgical methods, Article 27.3(a), and (3) plants, animals, and biological processes for their production, Article 27.3(b).

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.* For the exceptions to be granted, they must not unreasonably conflict with the patent's normal exploitation, and the legitimate interests of the patent holder must not be unreasonably prejudiced when weighed against the legitimate interests of third parties.

³⁵ *Id.*

³⁶ *Id.* In the case of a national emergency or in "other circumstances of extreme urgency," the government need not attempt to obtain a voluntary license from the patent holder.

³⁷ SOUTHCENTRE, *THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH TEN YEARS LATER: THE STATE OF IMPLEMENTATION*, SOUTHCENTRE POLICY BRIEF No. 7, 1-2 (Nov. 1, 2011), https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf. These measures included compulsory licenses, parallel imports, and exceptions to patent rights. The goal of these mechanisms was to increase competition and allow for the introduction of generics to drive down drug prices for patients. Such flexibilities of the TRIPS Agreement were particularly critical for developing states to adjust to

invocation of such mechanisms resulted in considerable pushback from global pharmaceutical companies and developed nations.³⁸ Additionally, because of the requirement that products manufactured under a compulsory license could only be used to supply the domestic market of the manufacturing state, developing member states that depended on imports from developed member states were limited in realizing the benefits of a compulsory license.³⁹ As a result, the African Group of the TRIPS Council proposed several provisions to reaffirm the flexibilities of the TRIPS Agreement while ensuring developing member states could protect public health needs and domestic access to drugs.⁴⁰ The result of this proposal was the Doha Declaration, which was agreed upon by member states in 2001.⁴¹

Of particular relevance, the Doha Declaration set forth modifications to the compulsory licensing article in the TRIPS Agreement, which went into force as an amendment in 2017.⁴² Known as the Paragraph 6 system, the purpose of the amendment was to ensure developing member states could actualize the benefits of the compulsory licensing article, since they often did not have pharmaceutical manufacturing facilities of their own that could supply their domestic markets.⁴³ Under this amendment, developed member states with the capacity to manufacture pharmaceutical products could grant compulsory licenses to their governments or government-authorized third parties for manufacturing purposes and export the resulting products to eligible developing member states.⁴⁴

their newly required patent systems, many of which did not previously allow product patents on drugs. *Id.* at 2.

³⁸ *Id.* at 2.

³⁹ *Guide to Notifications*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm (last visited Feb. 18, 2022).

⁴⁰ SOUTH CENTRE, *supra* note 37, at 3–4.

⁴¹ *TRIPS and Public Health*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (last visited Feb. 18, 2022).

⁴² *Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm (last visited Feb. 18, 2022).

⁴³ *Id.*

⁴⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement art. 31bis, Dec. 6, 2005, https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm (entered into force Jan. 23, 2017).

B. COVID-19 Patent Waiver Proposals

The first patent waiver proposal related to COVID-19 came from draft text submitted to the WTO in October 2020 by South Africa and India.⁴⁵ The proposal reasoned that the pandemic had caused significant shortages of medical products around the world,⁴⁶ leading several member states to initiate domestic production of medical products to meet growing demands,⁴⁷ and that intellectual property rights could prevent affordable medical products from reaching patients in a timely manner.⁴⁸ The proposal emphasized that developing member states were particularly at risk for legal challenges arising from their use of the flexibilities in the TRIPS Agreement.⁴⁹ Specifically, despite the newly amended compulsory licensing article, the proposal expressed concern that developing states still would not receive sufficient medical products quickly enough when they relied heavily on imports from developed states.⁵⁰

Accordingly, the draft text proposed waiving the requirements of member states in the TRIPS Agreement to grant and enforce patents⁵¹ related to the “prevention, containment or treatment of COVID-19.”⁵² Although the draft text did not state a time limit for the waiver,⁵³ the proposal specified that “the waiver should continue until widespread

⁴⁵ AKHTAR & FERGUSON, *supra* note 18, at 1.

⁴⁶ Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa*, WTO Doc. IP/C/W/669 (October 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ The draft text also proposed waiving obligations of member states to grant and enforce copyrights, industrial designs, and trade secrets. However, this Note focuses on the proposed patent waivers.

⁵² Council for Trade-Related Aspects of Intellectual Prop. Rights, *Draft Decision Text: Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19*, WTO Doc. IP/C/W/669 (October 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

⁵³ *See id.* (stating the waiver shall apply “for [X] years from the decision of the General Council”).

vaccination is in place globally.”⁵⁴ Although developing states largely supported the proposal, it was met with resistance from many developed and high-income states due to its broad scope.⁵⁵ In response to the opposition, India, South Africa, and several other states with lower per capita wealth submitted a revised proposal with a narrower scope.⁵⁶ Notably, the revised proposal narrowed the waiver to “health products and technologies including . . . vaccines . . . their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.”⁵⁷ Additionally, the revised proposal set the waiver to be in effect for at least three years, subject to termination after such period by the General Council of the WTO if the “[exceptional] circumstances cease to exist.”⁵⁸

Despite this narrowed proposal, critics still argue such a waiver is unnecessary and would be particularly unhelpful to developing states that do not have their own manufacturing capacities.⁵⁹ These critics emphasize that the key to widespread vaccination globally will depend on increased manufacturing capacity, not on intellectual property which has not yet proven to be a barrier.⁶⁰

⁵⁴ Council for Trade-Related Aspects of Intellectual Prop. Rights, *supra* note 46, at 2.

⁵⁵ AKHTAR & FERGUSON, *supra* note 18, at 1.

⁵⁶ *Id.*

⁵⁷ Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.

⁵⁸ *Id.*

⁵⁹ See, e.g., Weinian Hu, *Is the proposed IP waiver to help combat Covid-19 all it seems?*, CTR. FOR EUROPEAN POLICY STUDIES (Aug. 31, 2021), <https://www.ceps.eu/is-the-proposed-ip-waiver-to-help-combat-covid-19-all-it-seems/> (arguing in favor of the improved potential for compulsory licensing, given the 2017 amendment, and emphasizing the current lack of enforcement of IP rights for COVID-19-related patents already, since several of the developing states that signed on to the proposal are not yet required to enforce intellectual property rights under the TRIPS Agreement).

⁶⁰ *Id.*

C. Current Status of Vaccine Patents and Funding

The web of COVID-19 vaccine patents and licenses involving mRNA technology has already become highly complex.⁶¹ In addition to trade secrets and confidential know-how, BioNTech, which partnered with Pfizer to co-develop the COVID-19 vaccine,⁶² has approximately three patents that have already been granted by the United States and are related to the mRNA technology used in the vaccines, as well as ten relevant patent applications still pending in the United States, three of which have already been published.⁶³ Moderna has identified eight patents that have already been granted by the United States and that are linked to its COVID-19 vaccine.⁶⁴ According to the U.S. Patent and Trademark Office, the company has dozens more that are still pending.⁶⁵

Both Moderna and the Pfizer-BioNTech joint venture have received billions of dollars from the federal government for purposes related to their COVID-19 vaccines.⁶⁶ The Biomedical Advanced Research and Development Authority (BARDA), a group within the U.S. Department of Health and Human Services (HHS), has funded Moderna with nearly a

⁶¹ See Mario Gaviria & Burcu Kilic, *A network analysis of COVID-19 mRNA vaccine patents*, NATURE (May 12, 2021), <https://www.nature.com/articles/s41587-021-00912-9> (detailing in Figure 1 the multiple patents, licenses, and sub-licenses existing between entities considered to have developed some type of mRNA-based vaccine candidate that uses a lipid nanoparticle to deliver mRNA to target cells, leading to the production of a SARS-COV-2 spike protein and a corresponding immune response).

⁶² See *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine*, PFIZER, INC., (Mar. 17, 2020, 2:00 AM), [https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-co-develop-potential-covid-19-vaccine#:~:text=\(NYSE%3A%20PFE%2C%20%E2%80%9CPfizer,at%20preventing%20COVID%2D19%20infection.](https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-co-develop-potential-covid-19-vaccine#:~:text=(NYSE%3A%20PFE%2C%20%E2%80%9CPfizer,at%20preventing%20COVID%2D19%20infection.)

⁶³ See Mario Gaviria & Burcu Kilic, *BioNTech and Pfizer's BNT162 Vaccine Patent Landscape*, PUBLIC CITIZEN (Nov. 16, 2020), <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>.

⁶⁴ *Program Patents*, MODERNA, INC., <https://www.modernatx.com/patents>, (last visited Jan. 3, 2021).

⁶⁵ U.S. PATENT AND TRADEMARK OFFICE, PATENT APPLICATION FULL TEXT AND IMAGE DATABASE (database last visited January 2022), <https://appft1.uspto.gov/netacgi/nphParser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.html&r=0&p=1&f=S&l=50&Query=an%2Fmoderna&d=PG01.>

⁶⁶ SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 2 (2021), <https://crsreports.congress.gov/product/pdf/IN/IN11560>.

billion dollars for its research and development of the vaccine.⁶⁷ An additional five billion dollars was paid by the federal government to Moderna in exchange for three hundred million doses of the vaccine.⁶⁸ In its contract to supply the vaccine doses, Moderna did not expressly waive government rights to the vaccine.⁶⁹ Unlike Moderna, Pfizer did not receive federal funding for the research and development of its COVID-19 vaccine.⁷⁰ However, the federal government paid nearly six billion dollars in exchange for three hundred million doses of the vaccine.⁷¹ In the contract for this deal, Pfizer-BioNTech expressly retained all of its intellectual property rights in its inventions and did not grant any license to practice its inventions to the federal government.⁷²

II. RELEVANT EXISTING DOMESTIC STATUSES AND PROVISIONS

As provided by the Treaty Clause of the United States Constitution,⁷³ the executive branch, often the President, acts on the world stage as the nation's authorized representative⁷⁴ who can sign onto an amendment to an international treaty, such as the TRIPS Agreement.⁷⁵ However, even after the nation agrees to be bound by a treaty through the executive branch, its terms still must be approved by Congress.⁷⁶ This may require passing new domestic legislation or amending existing provisions.⁷⁷ Several aspects of existing legislation stand in the way of domestically

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ See DEPARTMENT OF HEALTH & HUMAN SERVICES, CONTRACT FOR OPERATION WARP SPEED WITH MODERNA, INC. (2020), <https://www.hhs.gov/sites/default/files/moderna-large-scale-production-sars-cov-2-vaccine.pdf>, at 44 (stating vaguely that “background intellectual property . . . assertions have been made” and leaving room for the parties to “reevaluate said assertions as necessary in the future”).

⁷⁰ Sydney Lupkin, *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NPR (Nov. 24, 2020, 4:46 PM), <https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections>.

⁷¹ SIDDALINGAIAH, *supra* note 66, at 2.

⁷² See DEPARTMENT OF THE ARMY U.S. ARMY CONTRACTING COMMAND—NEW JERSEY, TECHNICAL DIRECTION LETTER FOR MEDICAL CRBN DEFENSE CONSORTIUM (MCDC), REQUEST FOR PROTOTYPE PROPOSALS (2020), <https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf>, at 17.

⁷³ U.S. CONST. art. 2, § 2, cl. 2.

⁷⁴ See SEAN D. MURPHY, PRINCIPLES OF INTERNATIONAL LAW 266–67 (3rd ed. 2018).

⁷⁵ Vienna Convention on the Law of Treaties art. 12, May 23, 1969.

⁷⁶ U.S. CONST. art. 2, § 2, cl. 2.

⁷⁷ MURPHY, *supra* note 74, at 86.

implementing a patent waiver such as the one proposed in May 2021 for COVID-19 technologies, where the primary benefits, as well as acts that would normally constitute infringement, would be directed and performed extraterritorially.

This section highlights relevant provisions of the Bayh-Dole Act as well as the takings provision under 28 U.S.C. § 1498. Each of these pieces of existing patent legislation contains language that would prevent the federal government from taking away patent rights from domestic inventors to benefit extraterritorial recipients.

A. Bayh-Dole Act

The Bayh-Dole Act was passed in 1980 with the purpose of encouraging small businesses and research universities to put their federally-funded inventions into commercial use.⁷⁸ It generally allows any small business or nonprofit organization receiving federal funding to elect to retain title to the subject matter of their inventions, unless the funding agreement provides otherwise.⁷⁹ To retain title, the entity must disclose the invention to the federal government within a reasonable time after its development.⁸⁰

Although the Bayh-Dole Act grants substantial rights to federally funded inventors, it also was intended “to ensure that the Government obtain[ed] sufficient rights in federally supported inventions” in order to comply with governmental obligations,⁸¹ such as international agreements or treaties.⁸² Thus, the funding agreement must contain a provision to allow the federal agency providing the funding “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced [the invention] *for or on behalf of the United States . . . throughout the world.*”⁸³ If such a

⁷⁸ See 35 U.S.C. § 200.

⁷⁹ See 35 U.S.C. § 202(a). The Government may include a provision in the contract preventing a federally-funded entity from retaining title if foreign intelligence activities reveal that elimination of the right is necessary to protect the security of such activities. Here, since the Moderna funding agreement has not been publicly disclosed, it is unclear exactly which provisions have been added to the agreement. However, such a provision could theoretically be used in the event of a public health crisis, for example, if a communicable disease threatened foreign intelligence activities.

⁸⁰ 35 U.S.C. § 202(c)(1).

⁸¹ 35 U.S.C. § 200.

⁸² See 35 U.S.C. § 202(c)(4).

⁸³ 35 U.S.C. § 202(c)(4) (emphasis added). See also *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 611 (M.D.N.C. 2006) (finding the creation of a license by statute that allows the federal agency to practice the invention, in addition to the

provision is acted upon, it gives the federal agency providing the funding an affirmative defense in the case of claims of infringement that are raised because of the federal government's use of the invention.⁸⁴

The Bayh-Dole Act also contains a provision for march-in rights, which allows the federal agency providing the funding “the right . . . to require the [funded entity] to grant a nonexclusive, partially exclusive, or exclusive license . . . to a responsible applicant.”⁸⁵ In theory, this provision could be used if a pharmaceutical company that received federal funding for the development of a lifesaving drug later refused to make the drug available to the general public at a reasonable price.⁸⁶ However, for the federal government to exercise this right, at least one of four specific, enumerated circumstances must be met.⁸⁷ These circumstances include the federal agency's determination that the action is necessary because (1) the federally funded entity has not taken steps to put its invention into practical use within a reasonable time, (2) health or safety needs are not being reasonably satisfied by the federally funded entity, (3) federal regulations require public use of the invention and are not being reasonably met by the federally funded entity's actions, or (4) the third party originally licensed by the federally funded entity to use or sell the invention in the United States has breached or waived the agreement.⁸⁸ Although this provision has been in effect for over forty years, federal agencies have never exercised this power, despite several petitions made to the National Institute of Health to do so.⁸⁹

Nothing in the provision authorizing march-in rights explicitly states the federal agency must act to benefit the United States,⁹⁰ but the fourth circumstance is particularly telling. Its reference is to a later provision that explicitly requires federally funded inventors to give

creation of a license through the contractual provision in the funding agreement).

⁸⁴ *Madey*, 413 F. Supp. 2d at 611–12.

⁸⁵ 35 U.S.C. § 203(a).

⁸⁶ *See, e.g.*, Letter from Alex M. Azar, Secretary, U.S. Department of Health & Human Services, to Francis S. Collins, Director, Nat'l Inst. of Health (Aug. 4, 2020) (on file with the State of California Department of Justice) (urging the federal government to exercise their march-in rights to make Gilead's blockbuster drug, remdesivir, more accessible and affordable to the public during the COVID-19 pandemic).

⁸⁷ *See* 35 U.S.C. § 203(a).

⁸⁸ 35 U.S.C. § 203(a)(1)-(4).

⁸⁹ JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 1 (2016) <https://sgp.fas.org/crs/misc/R44597.pdf>.

⁹⁰ *See* 35 U.S.C. § 203(a)(3) (specifying only that the “public” should benefit from the government's exercise of its march-in rights without language to limit the beneficiary to the public in the United States).

preference to manufacturers based in the United States when granting licenses to exclusively use or sell the invention in the United States.⁹¹ Since the federal agency can exercise its march-in rights in the event that an exclusive licensee does not substantially manufacture its product domestically,⁹² there exists a presumption that at least United States manufacturers are intended to benefit from exclusive licenses granted for the use of inventions developed from federal funds.⁹³

B. Takings Provision

In cases where the invention was not federally funded, 28 U.S.C. § 1498 requires that the federal government pay “reasonable and entire compensation” for the government’s use and manufacture of the invention when it takes patent rights that have already been granted.⁹⁴ This concept reflects the longstanding belief in American property law that, in cases of eminent domain, the federal government may manufacture or use the patent, but only if it pays compensation to the patent holder.⁹⁵ However, similar to the Bayh-Dole Act, action can only be taken against the federal government when the patented invention is “*used or manufactured* by or for the United States.”⁹⁶ Additionally, § 1498(c) explicitly states that the takings provision does not apply “to any claim arising in a foreign country.”⁹⁷ This provision has been interpreted to offer an affirmative defense for the federal government.⁹⁸ Additionally, the federal government is exempted from suit if only one part of the invention is practiced extraterritorially.⁹⁹

⁹¹ 35 U.S.C. § 204.

⁹² *Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614, 629 (D.N.J. 1992).

⁹³ *See Applying for a Waiver From U.S. Manufacturing Requirements For Federally Funded Intellectual Property*, BLOOMBERG LAW (Aug. 18, 2015, 5:51 PM), <https://news.bloomberglaw.com/pharma-and-life-sciences/applying-for-a-waiver-from-us-manufacturing-requirements-for-federally-funded-intellectual-property>; *see also* Daniel J. Hemel and Lisa L. Ouellette, *Bayh-Dole Beyond Borders*, 4 J. LAW BIOSCI., 282, 293 (2017) (emphasizing the benefit to profits in the United States that stems from requiring international consumers to purchase inventions federally funded by the United States government from United States manufacturers).

⁹⁴ 28 U.S.C. § 1498(a).

⁹⁵ *Irving Air Chute Co. v. United States*, 93 F. Supp 633, 635 (Ct. Cl. 1950) (approving the Government’s argument that successful invocation of eminent domain entitles the Government to “manufacture or use a patented article” so long as it reasonably compensates the patent holder).

⁹⁶ 28 U.S.C. § 1498(a) (emphasis added).

⁹⁷ 28 U.S.C. § 1498(c).

⁹⁸ *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 833 (Ct. Cl. 2002) (explaining that § 1498(c) was intended to be an affirmative defense for the government

Further, the takings provision has not generally been interpreted to apply to all forms of direct infringement that apply to private parties.¹⁰⁰ For instance, because the statute only mentions that the federal government must compensate the patent holder if it uses or manufactures a patented invention, it has not been interpreted to also require compensation if the federal government merely sells the invention.¹⁰¹ The Court of Federal Claims has reasoned that Congress must take action to require the federal government to pay compensation for all modes of direct infringement currently recognized under patent laws.¹⁰² For instance, Congress would need to clearly show it intended the takings clause to “change in congruence” with any conduct later recognized as constituting infringement.¹⁰³

III. ARGUMENTS AND RECOMMENDATIONS

As highlighted above, both the Bayh-Dole Act and the existing patent law takings provision provide mechanisms that could give the federal government more control over a specific technology, like the COVID-19 vaccines. However, each mechanism would require revision for a global patent waiver to be implemented into the domestic patent legal system. This Section proposes an Amendment that would remove the existing legal barriers in the mechanisms set forth by the Bayh-Dole Act and patent law’s existing takings provision. Importantly, to ensure global patent waivers are only allowed in the most exigent of circumstances, the Amendment should contain language to prevent it from being applied in a more far-reaching manner.

Unquestionably, prosperous pharmaceutical companies have continued to profit significantly from the high demand for medical products that resulted from the COVID-19 pandemic.¹⁰⁴ However, when revising the

rather than an additional element that the plaintiff needs to prove to establish its case and that therefore even if the plaintiff establishes all elements of its case, if the government can show that the claim originated in a foreign country then the takings provision does not apply).

⁹⁹ *Id.* at 836.

¹⁰⁰ *Id.* at 836–37. *See generally* 35 U.S.C. § 271 (codifying direct infringement to encompass any party that “makes, uses, offers to sell, or sells any patented invention, within the United States) (emphasis added).

¹⁰¹ *Zoltek Corp.*, 51 Fed. Cl. at 837.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ For a particularly condemnatory view on the profits gained by pharmaceutical companies during the pandemic, allegedly because of laws like the Bayh-Dole Act, see Judy Stone, *The People’s Vaccine—Moderna’s Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars*, FORBES (Dec. 3, 2020, 11:00 AM), <https://www.forbes.com/sites/judystone/2020/12/03/the->

above laws to create the Amendment, Congress must consider the purpose of its constitutional grant of power to create a patent system, which is to continue to “promote the progress of science and useful arts.”¹⁰⁵ In considering this constitutional purpose, Congress should not forego consideration of the economic incentives granted to pharmaceutical companies through the issuance of patents.¹⁰⁶ Thus, when structuring the Amendment for a domestic waiver of specific patent rights, Congress should ensure inventors continue to receive just compensation.¹⁰⁷

A. Proposed Revisions to the Bayh-Dole Act

This Section primarily applies to the patents granted to Moderna’s COVID-19 vaccine that used federal funding for its research and development.¹⁰⁸ Theoretically, the Bayh-Dole Act sets forth the necessary groundwork to allow the federal government sufficient rights to a federally-funded invention to use it to uphold its obligations.¹⁰⁹ Empirically, however, the federal government can only exercise its march-in rights under a highly

peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/.

¹⁰⁵ U.S. CONST. art. 1, § 8, cl. 8.

¹⁰⁶ See Henry G. Grabowski et. al., *The Roles of Patents and Research and Development Incentives In Biopharmaceutical Innovation*, 34 HEALTH AFFAIRS 302, 303 (2015). The research and development process required to invent new drugs comes with a high risk of failure. As few as one in every eight candidates pass the clinical testing phase. Trials often last several years and require billions of dollars in upfront investments. Patents play a key role in providing a high reward to compensate for the high risks taken by pharmaceutical companies.

¹⁰⁷ Another issue arises when attempting to put a monetary value on a patent for the COVID-19 vaccine, when it is unclear how much a lifesaving vaccine would be worth in WTO member states with a wide range of national economic situations. However, for the purposes of this Note, it will be assumed that such a monetary value can be placed on the vaccine, based on existing case law surrounding the definition of just compensation.

¹⁰⁸ See Letter from James Love, Knowledge Ecology International, to Mark T. Esper, Sec. of Def., Dep’t of Def. (August 27, 2020) (on file with Knowledge Ecology International). It is currently unclear exactly which of Moderna’s patents for the COVID-19 vaccine technology used federal funding. A third party has asked the U.S. Department of Defense to investigate Moderna’s failure to disclose the use of federal funding on several patent applications believed to be related to the mRNA technology used in the COVID-19 vaccine.

¹⁰⁹ See 37 C.F.R. § 401.5(d)(1) (allowing federal agencies to acquire a right to license federally funded technology to foreign governments at the time of contracting, which provides a mechanism for the federal government to uphold its obligations under international treaty agreements).

specific set of circumstances.¹¹⁰ Additionally, the mandatory statutory grant of the irrevocable license given to the federal government in the funding agreement does not clearly allow the federal government to use the invention to primarily benefit those outside domestic borders.¹¹¹ Both march-in rights and an irrevocable license would grant the federal government greater control over the use of the invention,¹¹² allowing for an effect similar to a complete global patent waiver on the world stage. Thus, to allow for the effect that implementation of a global patent waiver would have in the specific instance of an international public health emergency, the Amendment should expand the federal government's ability to effectively use the Bayh-Dole Act in practice.

First, the Amendment should explicitly allow the federal government to exercise march-in rights in the case of a public health emergency involving a communicable disease. Currently, the Bayh-Dole Act prevents the federal government from forcing a funded entity to grant a "responsible applicant" a license unless one of four extremely narrow circumstances are met.¹¹³ This large amount of discretion granted to a federally-funded entity leaves a wide range of decision-making about licenses to use critical technology out of the federal government's hands.

In particular, Congress should set a specific standard for measuring whether health or safety needs are being "reasonably satisfied"¹¹⁴ and allow the measure to consider the health or safety needs of those abroad. As seen in the disparities in vaccine distribution during the COVID-19 pandemic, health and safety needs can be met domestically through the widespread

¹¹⁰ Letter from Sylvia M. Burwell, Sec. of Health & Hum. Svcs., to The Honorable Lloyd Doggett, U.S. House of Representatives (Mar. 2, 2016).

¹¹¹ See 35 U.S.C. § 202(c)(4) (requiring that the irrevocable license be used by the Federal agency "to practice or have practiced for or on behalf of the United States.").

¹¹² U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-742, FEDERAL RESEARCH: INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS, at 2 (2009).

¹¹³ 35 U.S.C. § 203(a)(1)-(4). As previously stated, the four circumstances in which the federal government can exercise its march-in rights occur when (1) the federally funded entity has not taken steps to put its invention into practical use within a reasonable time, (2) health or safety needs are not being reasonably satisfied by the federally funded entity, (3) federal regulations require public use of the invention and are not being reasonably met by the federally funded entity's actions, or (4) the third party originally licensed by the federally funded entity to use or sell the invention in the United States has breached or waived the agreement.

¹¹⁴ 35 U.S.C. § 203(a)(2).

availability of technologies and wealth available in the United States.¹¹⁵ However, globalization mixed with the growing threat of a highly contagious disease abroad that has not been contained can easily spread to those living within domestic borders.¹¹⁶ Thus, to allow for implementation of a global patent waiver, Congress should ensure the Amendment contains language to expand the definition of health or safety needs to include the needs of those living extraterritorially.

Second, the Amendment should provide clarity on what it takes for an entity to be considered a “responsible applicant”¹¹⁷ when the federal government utilizes its march-in rights. Currently, a federally-funded entity must give preference to domestic manufacturers when granting licenses¹¹⁸ and the federal government can exercise its march-in rights if an exclusive licensee no longer manufactures the invention primarily in the United States.¹¹⁹ These provisions are problematic for granting international entities licenses to use federally-funded inventions because they prevent international manufacturers from being granted licenses by the federal government.¹²⁰ The federal government would be directly counteracting these provisions if it granted exclusive licenses to international manufacturers. Thus, Congress should more generally define a “responsible applicant” in the Amendment as being an entity, domestic *or* international, that uses the invention to further the specific purpose established by the federal government in exercising its march-in rights.

Notably, in clarifying its language, Congress should not expand a federal agency’s ability to exercise its march-in rights solely because an invention was researched and developed by the federal government. The Amendment should retain the overall purpose of the Bayh-Dole Act of incentivizing small inventors and start-ups to invent and innovate using

¹¹⁵ See *The Development Podcast: 'Absolutely Unacceptable' COVID-19 Vaccination Rates in Developing Countries*, THE WORLD BANK (Aug. 3, 2021), at 00:03:57 (“Many wealthy countries actually preordered far more vaccine doses than they even needed to vaccinate their populations . . . [T]he U.S. paid for enough vaccines for twice its population.”).

¹¹⁶ See Horowitz & Poveldo, *supra* note 3 (describing contemporaneously the rapid spread of COVID-19 throughout the globe as people continued travelling in the beginning parts of the pandemic).

¹¹⁷ 35 U.S.C. § 203(a).

¹¹⁸ 35 U.S.C. § 204.

¹¹⁹ 35 U.S.C. § 203(a)(4).

¹²⁰ See Hemel & Ouellette, *supra* note 93, at 293 (explaining the theory posed by economist Suzanne Scotchmer that the preference for United States manufacturers will lead to supracompetitive prices for international consumers).

federal funds.¹²¹ In addition to clarifying the definition of a “responsible applicant” and the “reasonably satisfied” health and safety needs of the public,¹²² Congress should create a fifth circumstance in the Amendment. This circumstance would specifically allow the federal government to exercise its march-in rights when a communicable global disease creates an exigent need for a technology that has been researched and developed using federal funds provided by a United States federal agency. Such a clause would ensure small inventors are still provided legal protection to control the use of their invention even if they receive federal funding, while allowing the federal government to step in when a rare public health emergency occurs.

Third, the Amendment should create the mandatory statutory grant of an irrevocable license in the funding agreement to explicitly allow for the practice of the invention by the governments of other WTO member states or on their behalf. Since the language in 35 U.S.C. §202(c)(4) currently only allows the federal agency to retain a license, and such licensed invention must be practiced “for or on the behalf of the United States,”¹²³ other member states who need to practice the federally-funded invention themselves would not necessarily have any means to do so without the United States government stepping in as an intermediary. To make a license as effective as a global patent waiver, the cumbersome technical and nationalistic requirement that the invention be practiced “for or on the behalf of the United States”¹²⁴ should be removed to allow the invention to be more easily practiced by international governments in emergency situations. However, to protect federally-funded inventions from being open to legally accepted infringement by international governments in non-emergency situations, the Amendment should also set forth an efficient authorization process requiring the United States to formally transfer the license to other governments of WTO member states.

B. Proposed Revisions to Patent Law’s Existing Takings Provision

This Section applies more generally to inventions that did not receive federal funding for their research and development, as was the case for the Pfizer-BioNTech COVID-19 vaccine. To ensure pharmaceutical companies are compensated upon the federal government’s revocation of their patent rights, the Amendment should explicitly provide that the federal government will provide the pharmaceutical companies manufacturing

¹²¹ 35 U.S.C. § 202(a).

¹²² 35 U.S.C. § 203(a).

¹²³ 35 U.S.C. § 202(c)(4).

¹²⁴ *Id.*

COVID-19 vaccines with “reasonable and entire compensation.”¹²⁵ This provision is critical to the Amendment to ensure pharmaceutical companies remain compensated for their loss of property, reducing the likelihood that a suit is brought against the Amendment for violating due process.¹²⁶

First, the current takings provision will likely not apply to a situation where the federal government takes patent rights for the primary benefit of extraterritorial entities who use, make, or sell the invention outside the domestic borders of the United States. This conclusion arises from the historical interpretation of the takings provision because it bars suit against the United States federal government if the takings claim did not arise entirely in the United States.¹²⁷ Additionally, the takings provision currently only applies if the patented invention is “used or manufactured by or for the United States.”¹²⁸ However, a global patent waiver could involve a claim of infringement arising outside the borders of the United States. Moreover, taking patent rights for a global patent waiver may not primarily benefit the United States in the most direct sense, because of the widespread availability of vaccines already present in the United States compared to other parts of the globe.¹²⁹ Accordingly, to ensure patentees are provided reasonable and entire compensation for the loss of the patent right in accordance with section 1498, the Amendment should open up the possibility of suit against the United States in the event that a global patent waiver is implemented to uphold international obligations of the federal government. Such liability could arise if the federal government signed a treaty, such as an amendment to the TRIPS Agreement, without consultation with the patentees whose patent rights are lost as a result.

¹²⁵ See 28 U.S.C. § 1498 (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his *reasonable and entire compensation* for such use and manufacture.”) (emphasis added).

¹²⁶ Although this section focuses on a taking by the federal government under § 1498, it is important to note that state governments are still immune to suit for infringing a patent. For an interesting perspective on the Eleventh Amendment and intellectual property rights, see Collin Hong, *The Eleventh Amendment and Nondiverse Suits Against States*, 92 U. CINCINNATI L. REV. (forthcoming 2023).

¹²⁷ *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 835 (Ct. Cl. 2002).

¹²⁸ 28 U.S.C. § 1498(a) (emphasis added).

¹²⁹ See Understanding Vaccination Progress, *supra* note 6 (detailing the wide disparity between high-income and low-income countries in the number of doses of vaccines administered).

Second, the Amendment should also be clarified to include “offering to sell” or “selling” as a mechanism of taking by the federal government to match current conduct in patent law that constitutes infringement.¹³⁰ A global patent waiver would allow the United States federal government to sell the vaccines directly to other WTO member states.¹³¹ As is, this conduct would not fall under the takings provision as requiring compensation.¹³² However, since such conduct would otherwise constitute infringement,¹³³ a manufacturer of the vaccine could become liable to the patentee for contributory infringement for selling it to another.¹³⁴ Even an international healthcare supplier merely purchasing the vaccine from a manufacturer not licensed to sell it could be liable to the patentee for direct infringement for using the vaccine.¹³⁵ Thus, to prevent lawsuits against international downstream consumers from the pharmaceutical companies being undercompensated by the federal government, the Amendment should make “selling” or “offering to sell” a mechanism of taking by the United States federal government.

CONCLUSION

We live in a global society with advancing technology that rapidly allows us to travel from one hemisphere to another in only a few short hours. Although this relatively newfound freedom provides a multitude of conveniences, it also gives infectious diseases a significant opportunity to spread quickly and internationally. In short, another global pandemic is likely inevitable.¹³⁶ COVID-19 has illustrated the need for achieving

¹³⁰ *Zoltek Corp.*, 51 Fed. Cl. at 836–37.

¹³¹ Harvey Rubin & Nicholas Saidel, *Innovation Beyond Patent Waivers: Achieving Global Vaccination Goals Through Public-Private Partnerships*, THE BROOKINGS INSTITUTION (Aug. 31, 2021).

¹³² *See Zoltek Corp.*, 51 Fed. Cl. at 837 (noting the exclusion of selling from § 1498)

¹³³ *See* 35 U.S.C. § 271 (including selling as a form of infringement).

¹³⁴ *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 485 (1964) (finding contributory infringement on the part of unlicensed manufacturers who sold a patented product without a license to purchasers who directly infringed the patent by using the product).

¹³⁵ *See id.* at 480 (finding the purchasers of the unlicensed patented product committed direct infringement by using the product that was sold to them by the unlicensed manufacturer).

¹³⁶ Importantly, as biotechnologies like CRISPR become increasingly advanced, the infliction of bioterrorism from an artificially modified virus is also becoming more possible. Thus, rapid global vaccination against a deadly infectious disease may not only be necessary in the case of a naturally occurring disease but could be critical in stopping an intentional and artificially created bioterrorism apocalypse. *See* Pin Lean Lau, *How gene editing could be used as a weapon, and what to do about it*, PHYS (Nov. 15, 2021), <https://phys.org/news/2021-11->

widespread global vaccination in both developing and developed nations alike. A global patent waiver may have increased the accessibility of highly effective mRNA vaccines around the world. However, parts of the patent legal system of the United States, home to some of the world's most advanced pharmaceutical inventors, would require modification to give a symbolic gesture on the world stage empirical effect. Given the current polarized nature of American politics, passing such a compromise to amend existing legislation may prove difficult. However, a successfully modified Bayh-Dole Act and takings provision would set forth legal mechanisms that could aid in implementing a global patent waiver for specific technologies under certain conditions.

gene-weapon.html. For a scientific perspective, see Margaret E. Kosal, *Emerging Life Sciences and Possible Threats to International Security*, 64 ORBIS 599 (2020).