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The Inherent Monetary Incentive of Intellectual Property Rights and the Failure of Intellectual Property Waivers to Recognize This Motive

Ellaheh D. Sims

THE INHERENT MONETARY INCENTIVE OF INTELLECTUAL PROPERTY RIGHTS AND THE FAILURE OF INTELLECTUAL PROPERTY WAIVERS TO RECOGNIZE THIS MOTIVE

Ellaheh D. Sims[*]

Table of Contents

[*] J.D., *summa cum laude*, Valedictorian, 2022, Dwayne O. Andreas Barry School of Law; M.Sc. (Medical Science Research Thesis), McMaster University; H.B.Sc. (Biomedical Physics and Economics), *high distinction*, University of Toronto. I would like to thank my husband, Michael, and family for their continuous support and encouragement.

INTRODUCTION

With the emergence of the Coronavirus Disease 2019 (COVID-19) pandemic came a race to develop the first effective vaccine. However, now that the vaccines are here, countries have begun to debate the merits of an intellectual property waiver for the COVID-19 vaccines.[1] Proponents of a vaccine intellectual property waiver believe it allows for "fair global distribution" to support developing countries.[2] In opposition, opponents believe such a waiver will fail to address the shortage of vaccines in underdeveloped countries while causing lasting consequences.[3] This article discusses the influence that capitalism has on innovation and particularly in addressing international critical diseases and medical conditions.

Intellectual property rights include patents, copyrights, trademarks, and trade secrets.[4] The Framers of the Constitution of the United States recognized the importance of intellectual property and granted Congress the 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."[5] In 1790, under this authority, Congress enacted the Patent Act of 1790 and the Copyright Act of 1790[6] as the first federal patent and copyright law.[7] Today, the United States Patent Act[8] governs patent law, and the Copyright Act of 1976[9] governs copyright law. The Lanham (Trademark) Act [10] and the Defend Trade Secrets Act of 2016 (DTSA)[11] govern trademarks and trade secrets, respectively.

Patents protect inventions and discoveries that are useful,[12] novel,[13] and non-obvious[14] by providing a property right to the inventor to protect his or her invention.[15] Trade secrets complement patents by protecting information that has or may have independent economic value from not being known where reasonable efforts have been made to maintain its secrecy.[16] In contrast, copyright law protects only *expressions* of ideas, not ideas themselves.[17] Lastly,

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[1] *See* Anita Chakraverty, *Patent Waiver on Covid-19 Vaccines Splits Opinions in Biotech Industry*, LABIOTECH (June 15, 2021, 2:58 PM), https://www.labiotech.eu/trends-news/vaccine-patent-covid-19/; Steve Holland et al., *U.S. Urges All WTO Members to Support Intellectual Property Waiver for COVID-19 Vaccines*, REUTERS (Oct. 22, 2021, 7:23 AM), https://www.reuters.com/world/us/white-house-wto-members-must-support-intellectual-property-waiver-covid-vaccines-2021-10-21/.
[2] *See* Chakraverty, *supra* note 1.
[3] *See id.*
[4] NAVNEET NAGPAL ET AL., INTELLECTUAL PROPERTY RIGHT 1 (2017).
[5] U.S. CONST. art. I, § 8, cl. 8.
[6] Patent Act of 1790, 1 STAT. § 109 (1790); Copyright Act of 1790, 1 STAT. § 124 (1790).
[7] Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 228–29 (1964).
[8] *See* 35 U.S.C. §§ 1–390.
[9] *See* 17 U.S.C. §§ 101–1511.
[10] *See* 15 U.S.C. §§ 1051–1141.
[11] *See* 18 U.S.C. §§ 1836–1839.
[12] 35 U.S.C. § 101.
[13] *Id.* § 102.
[14] *Id.* § 103.
[15] *See id.* §§ 101, 154; *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (Feb. 14, 2018, 2:34 PM), https://www.uspto.gov/patents/basics/general-information-patents.
[16] *Trade Secrets / Regulatory Data Protection*, U.S. PAT. & TRADEMARK OFF. (July 18, 2022, 10:13 AM), https://www.uspto.gov/ip-policy/trade-secret-policy.
[17] Gal v. Viacom Int'l, Inc., 518 F. Supp. 2d 526, 536 (S.D.N.Y. 2007).

trademarks and service marks protect "source-identifying mark[s]"[18] that identify goods or services, respectively.[19]

With patents, part of the motivation for obtaining a patent is that it grants patent owners a "temporary monopoly," which is a property right.[20] This monopoly is crucial to companies looking to protect their invention from competitors.[21] A patent provides the patent owner with the security and protection necessary to be able to develop a product further without fear of duplication.[22]

Intellectual property, including patents, has become an increasingly important form of protection for innovators. Between 2009 and 2020, the annual number of patents granted in the United States doubled.[23] In 2020, the United States Patent and Trademark Office granted 388,900 patents.[24] Additionally, the annual number of copyright registrations has also increased from 382,086 in 2009[25] to 443,911 in 2020.[26] One of the main motivators in obtaining intellectual property rights is the monetary incentives offered through its protection.[27] This motivation coincides with the fact that the United States is arguably a capitalist country.[28]

An intellectual property waiver could eliminate this form of protection[29] and consequently impact the motivation level for inventors to enter the market in the first place. Therefore, when considering an intellectual property waiver, it is prudent to consider the potential long-term consequences that such a waiver may cause. This article posits that intellectual property waivers for international health crises, including the waiver for the COVID-19 vaccines, fail to recognize the monetary and protective incentives inherent in patents that encourage future groundbreaking innovation in the United States and across the world.

Section I of this article provides an overview of Article I, § 8, clause 8 of the Constitution of the United States, as well as patents and intellectual property rights generally and their importance. Section II discusses the inherent economic nature of patents and other intellectual

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[18] Viacom Int'l, Inc. v. IJR Cap. Invs., L.L.C., 891 F.3d 178, 186 (5th Cir. 2018).
[19] *What is a Trademark?*, U.S. PAT. & TRADEMARK OFF. (June 13, 2022, 5:30 PM), https://www.uspto.gov/trademarks/basics/what-trademark.
[20] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002).
[21] *See* Marcia Angell & Arnold Seymour Relman, *Patents, Profits & American Medicine: Conflicts of Interest in the Testing & Marketing of New Drugs*, J. AM. ACAD. ARTS & SCIS., Spring 2022, at 102, 103, https://www.amacad.org/sites/default/files/daedalus/downloads/Daedalus_Sp2002_On-Intellectual-Property.pdf.
[22] *Id.*
[23] *See U.S. Patent Statistics Chart Calendar Years 1963 – 2020*, U.S. PAT. & TRADEMARK OFF. (May 2021), https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.
[24] *Id*.
[25] *Annual Report of the Register of Copyrights: Fiscal Year Ending September 30, 2009*, U.S. COPYRIGHT OFF. 54 (2009), https://www.copyright.gov/reports/annual/2009/ar2009.pdf.
[26] *United States Copyright Office Annual Report: Fiscal 2020*, U.S. COPYRIGHT OFF. 11 (2020), https://www.copyright.gov/reports/annual/2020/ar2020.pdf.
[27] Jorge L. Contreras, *Expanding Access to Patents for COVID-19* 159–60 (U. Utah, S.J. Quinney Coll. L. Rsch. Paper, Paper No. 390, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3675857.
[28] *See* Edward A. Purcell, Jr., *Capitalism and Risk: Concepts, Consequences, and Ideologies*, 64 BUFF. L. REV. 23, 38 (2016).
[29] *See* Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT'L BUS. & L. 137, 141–42 (2009).

property, with an emphasis on the medical and pharmaceutical industries. Section III then explores the potential impacts an intellectual property waiver would have in a capitalist-driven society. Next, Section IV discusses the need for health-related intellectual property to be streamlined internationally to maintain a monetary motivation for innovators in critical health-related areas, as well as solutions that have been proposed by other commentators. Lastly, Section V proposes that the solution to addressing critical health conditions internationally requires a collaborative effort across countries globally that incorporates the monetary and protective incentives necessary, at least in today's current economy, to promote medical and pharmaceutical companies to address critical health conditions. The article then provides a brief conclusion.

I. A BRIEF OVERVIEW OF INTELLECTUAL PROPERTY LAW

At the time the Constitution of the United States was enacted, innovation was an active part of the lives of some of the Framers of the Constitution.[30] Benjamin Franklin was one such Framer.[31] In 1742, Franklin invented a wood-burning iron furnace.[32] He then went on to also invent a flexible urinary catheter and bifocals.[33] Similarly, in 1776, John Fitch developed the steamboat, which the constitutional committee viewed.[34] It is not surprising that the Framers incorporated intellectual property into the Constitution of the United States and "sought to create a patent system that would benefit and encourage independent inventors and small companies."[35]

Accordingly, the Constitution of the United States grants Congress the 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."[36] Pursuant to this power, Congress enacted the United States Patent Act[37] and the Copyright Act of 1976[38] to govern patents and copyrights, respectively. Separately, Congress has also enacted the Lanham (Trademark) Act[39] and the DTSA,[40] which govern trademarks and trade secrets, respectively.

Patents offer protection to inventions and discoveries by providing a property right to the inventor "to exclude others from making, using, offering for sale, or selling the invention in the United States or 'importing' the invention into the United States."[41] Particularly, patents are eligible for "invent[ions] or discover[ies] [of] any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[42] A

[30] David L. Newman et al., *Standing on the Shoulders of the Framers of the U.S. Constitution's Patent and Copyright Clause*, 31 WESTLAW J. COMPUT. & INTERNET, July 11, 2013, at 1.
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] U.S. CONST. art. I, § 8, cl. 8.
[37] *See* 35 U.S.C. §§ 1–390.
[38] *See* 17 U.S.C. §§ 101–1511.
[39] *See* 15 U.S.C. §§ 1051–1141.
[40] *See* 18 U.S.C. §§ 1836–1839.
[41] 35 U.S.C. § 154; *General Information Concerning Patents*, *supra* note 15.
[42] 35 U.S.C. § 101.

patentable discovery must be (1) useful,[43] (2) novel,[44] and (3) non-obvious.[45] An example of a patentable invention would be a "new type of hybrid engine."[46]

While patents require detailed disclosures about the invention to obtain the right to exclude others from the invention, trade secrets rely on secrecy to maintain their protection.[47] Therefore, trade secrets complement patents by protecting information that has or may have economic value from not being known.[48] A trade secret requires that (1) the information has actual or potential economic value in not being known; (2) the information is not readily ascertainable by competitors; and (3) the owner of the information has taken reasonable measures to maintain its secrecy.[49] For example, while a recipe may be a trade secret, if it has become commonly known in the industry, it is not protectable as a trade secret.[50]

On the other hand, copyright law protects only *expressions* of ideas and not ideas themselves.[51] Copyrights protect "authors of 'original works of authorship' fixed in any tangible medium of expression."[52] For example, song lyrics are copyrightable.[53]

Lastly, trademarks and service marks offer protection to "a source-identifying mark."[54] "Trademarks" generally refer to both "trademarks" and "service marks," which represent marks used for goods or services, respectively.[55] Trademarks encompass "any word, phrase, symbol, design, or a combination of these things that identifies . . . goods or services."[56] However, a trademark or service mark only protects how the word(s), phrase(s), design(s), or symbol(s) are used in relation to the owner's specific good(s) or services(s).[57] An example of a trademark is "Coca-Cola® for soft drinks."[58]

Importantly, in the pharmaceutical and medical industries, patents and trade secrets play an essential role. Patents provide a "temporary monopoly" to the patent owner.[59] In pharmaceuticals, this temporary monopoly is crucial in providing the company with protection from competitors.[60] On the other hand, trade secrets provide companies with protection of

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[43] *Id.*
[44] *Id.* § 102.
[45] *Id.* § 103.
[46] *Trademark, Patent, or Copyright*, U.S. PAT. & TRADEMARK OFF. (June 13, 2022, 5:32 PM), https://www.uspto.gov/trademarks/basics/trademark-patent-copyright.
[47] *Trade Secrets / Regulatory Data Protection*, *supra* note 16.
[48] *Id.*
[49] *Id.*; 18 U.S.C. § 1839(3).
[50] *In re* Parmalat Sec. Litig., 258 F.R.D. 236, 255 (S.D.N.Y. 2009).
[51] Gal v. Viacom Int'l, Inc., 518 F. Supp. 2d 526, 536 (S.D.N.Y. 2007).
[52] *Copyright Basics*, U.S. PAT. & TRADEMARK OFF. (July 22, 2022, 5:10 PM), https://www.uspto.gov/ip-policy/copyright-policy/copyright-basics.
[53] *Trademark, Patent, or Copyright*, *supra* note 46.
[54] Viacom Int'l, Inc. v. IJR Cap. Invs., L.L.C., 891 F.3d 178, 186 (5th Cir. 2018).
[55] *What is a Trademark?*, *supra* note 19.
[56] *Id.*
[57] *Id.*
[58] *Trademark, Patent, or Copyright*, *supra* note 46.
[59] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002).
[60] *See* Angell & Relman, *supra* note 21, at 102–03.

undisclosed knowledge.[61] Trade secrets are important to medical and pharmaceutical companies because they allow the company to protect their "'cook books' of [their] manufacturing processes."[62]

However, innovation has expanded worldwide, and therefore, international protection of intellectual property rights has become necessary.[63] Consequently, on January 1, 1995, the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect to provide a "comprehensive multilateral agreement on intellectual property."[64] The TRIPS Agreement encompasses copyrights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed information such as trade secrets.[65] The purpose of the TRIPS Agreement is to protect innovation through the establishment of minimum standards of protection for members of the WTO.[66] The WTO has 164 members as of July 29, 2016.[67] These members include, but are not limited to, the United States, the United Kingdom, China, Canada, and Australia.[68]

While the TRIPS Agreement offers minimum international protections for intellectual property, it also includes some limitations.[69] Specifically, under Article 31 of the TRIPS Agreement, the requirements for a member to obtain authorization for use from a patent holder may be waived in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."[70] This permissive compulsory license exception allows underdeveloped countries to be able to obtain patent licenses during national emergencies or exigent circumstances.[71] Consequently, Article 31 is particularly relevant to the world's recent COVID-19 pandemic.[72]

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[61] David Lawder et al., *U.S. Wants COVID Vaccine Patent Waiver to Benefit World, Not Boost China Biotech*, REUTERS (May 8, 2021, 4:29 PM), https://www.reuters.com/world/china/us-wants-covid-vaccine-patent-waiver-benefit-world-not-boost-china-biotech-2021-05-08/.
[62] *Id.*
[63] *See Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 6, 2023).
[64] *Overview: The TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 5, 2021).
[65] *Id.*
[66] *Intellectual Property: Protection and Enforcement*, *supra* note 63.
[67] *Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Nov. 5, 2021).
[68] *Amendment of the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Nov. 5, 2021).
[69] *See Part II—Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, WORLD TRADE ORG., https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Nov. 5, 2021).
[70] *See id.*; Alexandra H. Farquhar, *Redefining the TRIPS Agreement to Accommodate En Masse Compulsory Licensing of Vaccines & Other Pharmaceuticals for the Treatment of Covid-19*, 22 N.C. J. L. & TECH. 259, 262 (2020).
[71] Ann Marie Effingham, *TRIPS Agreement Article 31(B): The Need for Revision*, 46 SETON HALL L. REV. 883, 884 (2016).
[72] *See* Simon Lester & Huan Zhu, *The Trips Waiver and Covid-19 Vaccine Production*, LEXOLOGY (Oct. 13, 2021), https://www.lexology.com/library/detail.aspx?g=fe9b27fe-b945-4381-ab42-845d4c9d67df.

Furthermore, throughout the pandemic, there has been considerable debate regarding whether there should be an intellectual property waiver for the COVID-19 vaccines.[73] Proponents of the temporary waiver argue it will allow developing countries to produce vaccines themselves for wider distribution, whereas opponents argue distribution, and not production, is the issue and, therefore, the waiver will not solve the problem.[74] Furthermore, opponents express concern over the consequences to the companies who invested time and money into developing the vaccines.[75] The next section explores this monetary influence on intellectual property.

II. THE INHERENT ECONOMIC NATURE OF PATENTS AND INTELLECTUAL PROPERTY

Throughout the years, intellectual property rights have generated an economic motivation for innovators to invent or discover.[76] This section explores how monetary compensation acts as an enabler, inhibitor, and motivator in innovation. The Framers of the United States Constitution deemed the promotion of the sciences and arts to be sufficiently important to include in the Constitution.[77] Congress has exercised this power to develop and codify laws for patents[78] and copyrights.[79] Additionally, pursuant to other powers, Congress has enacted laws governing trademarks[80] and trade secrets.[81]

Throughout case law, the Supreme Court of the United States has defined patent laws as a property right that provides a temporary monopoly to the patent owner.[82] The Supreme Court has emphasized that the boundaries of this property right in the form of a temporary monopoly should be clear.[83] The Supreme Court noted: "This clarity is essential to promote progress, because it enables *efficient investment* in innovation. A patent holder should know what he owns, and the public should know what he does not."[84] This "efficient investment" language implicitly recognizes the monetary motivation present in many inventions and discoveries.[85] If patent owners do not know where the boundaries of their protection begin and end, they cannot invest their time and money into a project with the certainty of its protection.[86]

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[73] *Id.*
[74] Michael K. Jones et al., *What Is a 'Patent Waiver' Anyway? Zooming Out on the TRIPS COVID-19 IP Waiver Debate*, TROUTMAN PEPPER (Aug. 18, 2021), https://www.troutman.com/insights/what-is-a-patent-waiver-anyway-zooming-out-on-the-trips-covid-ip-waiver-debate.html.
[75] *Id.*
[76] *See generally* Allen N. Dixon, *Intellectual Property: Powerhouse for Innovation and Economic Growth*, INT'L CHAMBER COM. 12, https://iccwbo.org/content/uploads/sites/3/2011/02/Intellectual-Property-Powerhouse-for-Innovation-and-Economic-Growth.pdf.
[77] *See* Newman et al., *supra* note 30; U.S. CONST. art. I, § 8, cl. 8.
[78] *See* 35 U.S.C. §§ 1–390.
[79] *See* 17 U.S.C. §§ 101–1511.
[80] *See* 15 U.S.C. §§ 1051–1141.
[81] *See* 18 U.S.C. §§ 1836–1839.
[82] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002).
[83] *Id.*
[84] *Id.* at 730–31 (emphasis added).
[85] *See id.*
[86] *See id.* at 727.

The incentive to develop and discover is furthered because, as the Supreme Court of the United States notes, "patent laws . . . *reward*[] innovation with a temporary monopoly."[87] This temporary monopoly provides the patent owner with:

> [T]he right to exclude others from making, using, offering for sale, or selling the invention . . . and, if the invention is a process, of the right to exclude others from using, offering for sale or selling . . . products made by that process, referring to the specification for the particulars thereof.[88]

In other words, the patent allows its owner to exclude competitors from copying the invention and reproducing it. In effect, this exclusive right allows the patent owner to monopolize the market for the invention or discovery in question. This monopoly is imperative to providing market exclusivity and an economic advantage to the inventor. Furthermore, it ensures that the inventor's time, effort, and expenses incurred do not become valueless by a competitor simply copying the inventor's final result without expending the cost necessary in its development.

This economic advantage afforded by intellectual property rights is particularly important in industries that rely heavily on this protection to ensure there is an economic reward for their efforts and to cover their costs.[89] One such industry is pharmaceuticals.[90] Pharmaceutical companies invest a considerable amount of money into the research and clinical trials needed to develop their products.[91] For example, in 2000, the pharmaceutical industry expended approximately "$3.77 billion on grants for clinical trials, compared with $750 million spent by the federal government through the [National Institutes of Health]."[92]

Clearly, the majority of the funding for these clinical trials comes from the pharmaceutical company itself.[93] The source of funding is particularly important because the United States Food and Drug Administration (FDA) "usually require[s] that the effectiveness of a newly patented drug be demonstrated in clinical trials."[94] Due to these requirements, clinical trials are a critical and necessary step that pharmaceutical companies must allocate resources to when developing patentable drugs. It is estimated that in developing an epidemic infectious disease vaccine from preclinical trials to early clinical safety and efficacy, testing costs between $31 million and $68 million when it is assumed there is no risk of failure.[95] Because of the substantial cost associated with the pharmaceutical industry, a pharmaceutical company requires more than a mere possibility that it can recoup the money it invested into the extensive research,

[87] *Id.* at 730 (emphasis added).
[88] 35 U.S.C. § 154(a).
[89] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1583 (2003).
[90] *See id.* at 1616–17; Angell & Relman, *supra* note 21, at 103.
[91] *See* Angell & Relman, *supra* note 21, at 103.
[92] *Id.*
[93] *Id.* at 102.
[94] *Id.*
[95] Dimitrios Gouglas et al., *Estimating the Cost of Vaccine Development Against Epidemic Infectious Diseases: A Cost Minimisation Study*, 6 LANCET GLOB. HEALTH e1386, e1386 (2018).

development, and clinical trials to produce a drug or vaccine that is effective and useful to society.[96]

The temporary monopoly that a patent provides is crucial in ensuring that these time-consuming and costly efforts can be recuperated:

> Patents are the lifeblood of the drug industry. Without a patent, a company has no incentive to bring a drug to market. Patents . . . give a company a monopoly that protects them from competitors as they develop the product and carry out the clinical trials necessary for FDA approval. Once approved, the drug can be sold on the market for the remaining lifetime of the patent, without risk of duplication of competitors.[97]

Eliminating or limiting this benefit could disrupt the balance between the costs associated with developing novel pharmaceuticals and the incentive of profiting from that investment. In this sense, the monetary compensation generated from monopolizing the market acts as both an enabler and motivator for innovation.

The Honorable Gerald J. Mossinghoff identified at least five ways in which patents stimulate economic development:

> [i] Patents provide the incentives for existing companies to undertake very costly research and development;
> [ii] Patents facilitate technology transfer and foreign direct investment;
> [iii] Patents encourage [research and development] at universities and research centers;
> [iv] Patents are catalysts of new businesses; and
> [v] Businesses accumulate patents and use them to engage in licensing, joint ventures, and other revenue-generating transactions.[98]

It is apparent that pecuniary gain has become an inherent motivator and interwoven aspect of patents. The scope and duration of the patent can either act through favorable terms to the inventors to enable and motivate innovators to develop new patentable products or methods or through unfavorable terms to discourage and inhibit innovation. The rights granted to a patent owner need to be clearly defined to avoid uncertainty among innovators.

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[96] *See* Caroline Manne, *Pharmaceutical Patent Protection And Trips: The Countries That Cried Wolf And Why Defining "National Emergency" Will Save Them From Themselves*, 42 GEO. WASH. INT'L L. REV. 349, 349–50, 354–55 (2010); Angell & Relman, *supra* note 21, at 103.
[97] Angell & Relman, *supra* note 21, at 103.
[98] Hon. Gerald J. Mossinghoff, *Patent Harmonization Through The United Nations: International Progress Or Deadlock?*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 5, 6–7 (2004).

III. THE POTENTIAL IMPACTS OF AN INTELLECTUAL PROPERTY WAIVER

Before discussing proposals to grant intellectual property waivers in light of COVID-19, it is prudent to understand the potential impacts of such a waiver. Granting a waiver, temporary or permanent, to select intellectual property rights can have significant impacts on innovation. In granting Congress the power to establish patent and copyright laws, one of the core purposes of intellectual property rights is "[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."[99] A waiver would limit the protections normally offered to the owner of an intellectual property right.[100] As countries debate the merits of such a waiver for the COVID-19 vaccines,[101] it is important to consider the potential impacts of granting an intellectual property waiver.

At a general level, there are consequences impacting both monetary and exclusivity benefits, as well as future innovation, when granting an intellectual property waiver. Without the protection afforded by intellectual property rights, such as patents, owners lose the exclusivity of their inventions.[102] If other people or companies are able to access and utilize this information permissively under certain circumstances, the exclusivity normally benefited from patent protection, or the like, will be limited. Financially, this lack of exclusivity would also impact the owner's exclusive control of the market for that patent. As previously discussed, exclusive control of the market is key to the inventor or creator recouping his or her costs in developing the product.

Furthermore, a waiver or compulsory license can impact licensing opportunities for the owner. Patent owners may grant licenses in their patents.[103] In granting a patent license, the patent owner can allow a licensee to make, use, sell, or import the invention within the bounds of the license agreement.[104] However, mandated licenses and waivers may impact future innovation.[105] Imposing an intellectual property waiver or mandating licenses may diminish the intellectual property holders' ability to freely license their rights to other companies in exchange for a fee.[106] The motivation to negotiate with the owner may be obviated. Even if they are only granted for a temporary period, the potential for future license agreements may be weakened due to the demand for and exclusivity of the invention having been impacted by a waiver or compulsory license during the period when the invention was first released and considered groundbreaking and most useful. Together, these general impacts must be considered carefully when balancing the benefits of an intellectual property waiver against the future consequences as a result of the waiver.

In addition to these general consequences, an intellectual property waiver for the COVID-19 vaccines poses specific risks and long-term impacts on innovation in the

[99] U.S. CONST. art. I, § 8, cl. 8.
[100] *See* Jones et al., *supra* note 74.
[101] *See* Chakraverty, *supra* note 1; Holland et al., *supra* note 1.
[102] *See* Feldman, *supra* note 29.
[103] U.S. PAT. & TRADEMARK OFF., MANUAL PAT. EXAMINING PROC. § 301 (8th ed., rev. Feb. 2023).
[104] *Id.*
[105] Feldman, *supra* note 29, at 157.
[106] *See id.* at 157–58.

pharmaceutical and other critical healthcare industries.[107] In regard to intellectual property waivers for COVID-19 vaccines, the stakes are high for the pharmaceutical companies who developed the vaccine.[108] The two leading companies, Pfizer Inc. (Pfizer) and Moderna, Inc. (Moderna), utilized cutting-edge technology in developing their vaccines.[109] Both companies' vaccines implemented new messenger RNA (mRNA) biotechnology.[110] This novel approach is an important factor in considering the impact of any intellectual property waivers.[111] In granting such a waiver, this technology would lose some of its protection.[112] Even with a temporary waiver, some analysts suggest that once this technology has been released, it could become difficult to enforce any meaningful limitations on its use in the future.[113]

The consideration of exposing novel technology, such as the use of mRNA technology in vaccines, to competitors is critical because its impact runs beyond that of the present invention.[114] This biotechnology has taken several years for Pfizer and Moderna to research and develop, and its potential benefits are not confined to COVID-19 vaccines.[115] Importantly, this technology can be utilized in other medical treatments beyond the COVID-19 vaccines.[116]

The risk is further amplified in the case of trade secrets. Pfizer and Moderna's trade secrets, including their manufacturing processes, are not public, and these trade secrets are crucial in maintaining the companies' protection of their technology.[117] The potential for future uses and benefits generated from this technology is what makes waiving the intellectual property rights that protect it a delicate situation. Proponents of the waiver must carefully consider the long-term impact of a waiver beyond that of COVID-19.

The underlying consequence of these impacts, both generally and specifically to a COVID-19 vaccine waiver, is the potential to discourage pharmaceutical and medical companies from developing future novel technologies and treatments due to fear of losing it to an "emergency exception."[118] The next time there is a pandemic or critical disease, a pharmaceutical company may reevaluate its cost-incentive analysis and find that there are fewer pecuniary or exclusivity incentives for drugs, vaccines, or treatments relating to high-risk diseases. Instead, a pharmaceutical company may conclude that, in its cost analysis of the

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[107] *See* Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, PETRIE-FLOM CTR. HARV. L. (May 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/.
[108] *See* Lawder et al., *supra* note 61.
[109] *Id.*
[110] *Id.*
[111] *See* Ian Lopez, *WHO Vaccine Push Rattles Arguments Against Covid Patent Waiver*, BLOOMBERG L. (Mar. 16, 2022, 5:18 AM), https://news.bloomberglaw.com/health-law-and-business/who-vaccine-push-rattles-arguments-against-covid-patent-waiver.
[112] *See* Lawder et al., *supra* note 61.
[113] *Id.*
[114] *See* Feldman, *supra* note 29, at 141–42, 157.
[115] Lawder et al., *supra* note 61.
[116] *Id.*
[117] *Id.*
[118] *See* Reto M. Hilty et al., *Covid-19 and the Role of Intellectual Property*, MAX PLANCK INST. FOR INNOVATION & COMPETITION 3, 5–6 (May 7, 2021), https://abpi.org.br/wp-content/uploads/2021/05/2021_05_07_Position_statement_Covid_IP_waiver-3.pdf.

expenses to develop the product against the potential to recoup and profit from that investment, it is more economically prudent to invest in less critical diseases or conditions that would not rise to the level of an international emergency.

These considerations of both long- and short-term impacts of intellectual property waivers must be carefully weighed against the potential benefit that a waiver would provide. Because medicine, health, and diseases are continuously evolving,[119] it is important that the major innovators in the pharmaceutical and medical industries maintain motivation to invest their resources into treating health conditions, especially those that pose the greatest risk to society.

IV. THE NEED TO STREAMLINE HEALTH-RELATED INTELLECTUAL PROPERTY RIGHTS INTERNATIONALLY

In an effort to address intellectual property rights internationally, the WTO adopted the TRIPS Agreement as a multilateral agreement on intellectual property.[120] The United States is one of the members of the WTO.[121] Amongst other intellectual property, the TRIPS Agreement encompasses patents, copyrights, trademarks, and trade secrets.[122] The TRIPS Agreement protects innovation by establishing minimum international protections for intellectual property.[123]

One of the relevant articles of the TRIPS Agreement is Article 31.[124] Article 31 addresses the use of patents without the authorization of the rights holder.[125] In its pertinent part, Article 31 provides:

> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
>
> (a) authorization of such use shall be considered on its individual merits;
> (b) such use may only be permitted if, prior to such use, the proposed user has 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. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use . . .

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[119] *See generally* Konstantinos Dean Boudoulas et al., *The Endlessness Evolution of Medicine, Continuous Increase in Life Expectancy and Constatnt Role of the Physician*, 58 HELLENIC J. CARDIOLOGY 322, 323 (2017).
[120] *Overview: The TRIPS Agreement*, *supra* note 64.
[121] *Amendment of the TRIPS Agreement*, *supra* note 68.
[122] *Overview: The TRIPS Agreement*, *supra* note 64.
[123] *Intellectual Property: Protection and Enforcement*, *supra* note 63.
[124] General Agreement on Trade-Related Aspects of Intellectual Property art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter Marrakesh Agreement].
[125] *Id.*

> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . .
> (d) such use shall be non-exclusive;
> (e) such use shall be non-assignable . . .
> (f) any such use shall be authorized predominately for the supply of the domestic market of the Member authorizing such use;
> (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur . . .
> (h) the right holder shall be paid adequate remuneration in the circumstances of each case . . . .[126]

Article 31 permits "[c]ompulsory licensing [which] is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[127] Under Article 31, typically, the member applying for the *compulsory* license must have attempted to negotiate a *voluntary* license with the patent holder within a reasonable time under reasonable commercial terms prior to seeking the compulsory license.[128]

However, Article 31 also incorporates an important exception to these required prior negotiations: "national emergencies," "other circumstances of extreme urgency," and "in cases of public non-commercial use."[129] For such uses, the user may circumvent the initial requirement of attempting to negotiate a voluntary license and seek a compulsory license immediately.[130] One of the main purposes of this provision is to "save time"[131] in times such as an emergency when expedited action is vital to address the emergency. This section "covers pharmaceutical products, including medicines, vaccines and diagnostics, needed to fight an epidemic"[132] and is therefore especially relevant to the COVID-19 vaccines.

Furthermore, with the emergence of COVID-19 and the subsequent development of the COVID-19 vaccines, a debate commenced as to whether an intellectual property waiver should also be exercised in light of the global pandemic to help reduce barriers in production.[133] Proponents contend it will permit developing countries to produce vaccines domestically and increase distribution.[134] Opponents believe the problem stems from a distribution issue instead, and this waiver would not address that issue and instead harm the companies who invested in these products.[135] Nevertheless, a waiver had not materialized over a year after it was

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[126] *Id.*
[127] *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Feb. 4, 2022).
[128] *Id.*; Marrakesh Agreement, *supra* note 124.
[129] *Compulsory Licensing of Pharmaceuticals and TRIPS, supra* note 127.
[130] *Id.*
[131] *Id.*
[132] *Id.*
[133] Lester & Zhu, *supra* note 72.
[134] Jones et al., *supra* note 74.
[135] *Id.*

proposed,[136] and as of June 2022, members of the WTO had only agreed to a limited intellectual property waiver which was met with skepticism over its timing and efficacy.[137]

The COVID-19 pandemic has cast light on the weaknesses inherent in Article 31 of the TRIPS Agreement as it currently stands. The first of which is its purported purpose to "save time."[138] The proposal for an intellectual property waiver for the COVID-19 vaccines and the substantial delay of over a year in reaching a decision regarding the waiver[139] clearly establish that time is not necessarily saved during emergencies. This is not a new issue.[140] For example, it was only after four years that eligible member Rwanda was able to receive generic AIDS pharmaceuticals under Article 31, including a two-year delay from negotiations and over a year delay once the compulsory license was issued.[141]

The next weakness lies in the requirement for the patent holder to be paid "adequate remuneration" in exchange for the license.[142] While the patent holder is required to be paid compensation, the issuing member decides the "adequate remuneration," and review must be sought in the issuing member's jurisdiction, which may result in multiple forums for litigation.[143] In addition, there is an issue of adequate resources and technology to actually manufacture the product once the compulsory license is obtained.[144]

Furthermore, companies are hesitant to enter markets where their intellectual property is not guaranteed adequate and definitive protection.[145] For example, a survey revealed that "80% of chemical companies admitted they would not invest in India due to a general perceived lack of [intellectual property] protection."[146] As previously discussed in Section III, a compulsory license or intellectual property waiver poses significant long-term financial risks for pharmaceutical companies and may, in effect, act to discourage them from investing in certain technology that they know will become susceptible to an intellectual property waiver in countries that may not adequately protect their technology.[147] While the short-term effect of an intellectual property waiver may provide access to the COVID-19 vaccines, the long-term effect could result in lower-quality vaccines in future global health crises due to hesitancy to invest in this market area.[148]

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[136] Juhohn Lee, *Experts Seriously Doubt Whether Patent Waivers on Covid-19 Vaccines Will Ever Come to Be*, CNBC (Jan. 22, 2022), https://www.cnbc.com/2022/01/22/why-moderna-pfizer-and-the-nih-debate-who-owns-the-covid-vaccine.html.
[137] Rebecca Robbins, *W.T.O. Countries Agree to a Limited Relaxing of Patent Protections on Coronavirus Vaccines*, N.Y. TIMES (June 17, 2022), https://www.nytimes.com/2022/06/17/business/wto-covid-vaccine-patent.html; World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/W/15/Rev.2 (June 17, 2022).
[138] *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 127.
[139] Lee, *supra* note 136.
[140] Farquhar, *supra* note 70, at 272.
[141] *Id.* at 264.
[142] *Id.* at 265.
[143] *Id.*
[144] *Id.* at 263.
[145] Molly Jamison, *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHI. J. INT'L L. 688, 708 (2015).
[146] *Id.*
[147] *See* Feldman, *supra* note 29, at 158.
[148] *See id.*

For these reasons, it has been suggested that "Article 31 [is] well-intentioned but impractical in use."[149] To address these shortcomings, commentators and scholars have reevaluated the efficacy of the TRIPS Agreement and proposed alternate approaches when addressing health crises.[150] One suggested approach is to shift the focus from *compulsory* licenses to "more extensive and coordinate use of *voluntary* licensing [that] would provide a degree of certainty for patent holders that their rights would be protected, while also ensuring that patients in both developed and developing nations have access to biotechnology at a lower cost."[151] This approach contends that independent licensing agreements are more realistic compared to harmonizing patent regimes.[152] Under this method, the firms holding the patent would be able to assess the costs that need to be recouped, outline the terms of use, and request reasonable royalties.[153] However, voluntary licenses have the potential to result in refusals to grant the license.[154] Therefore, this approach emphasizes promoting and coordinating voluntary licenses while monitoring abusive restrictions in granting such licenses.[155]

An alternate method is using a prize-based system.[156] This system focuses on encouraging innovators to enter the market to offer drugs that address global health.[157] Under this approach, drug developers would receive a "prize" corresponding to the level of impact their invention has on global health.[158] However, in exchange for this prize, the developers "surrender their monopoly pricing flexibility, and drug prices are more closely linked to the cost of manufacture."[159] This system incorporates the monetary incentive that motivates many drug companies to enter the market.[160] This method would also help compensate for the loss of control over monopoly pricing by providing an alternate financial incentive in the form of a prize.[161] Such a process could assist in encouraging drug developers to invest time and money into less lucrative areas of health that, while they may not have a significant financial incentive, pose a significant risk to society.

Another very similar system is a reward-based system.[162] Under this approach, a government-financed reward fund would be established, and this fund would be used to pay pharmaceutical registrants who grant zero-priced licenses to make and sell the drug.[163] This

[149] Farquhar, *supra* note 70, at 264.
[150] *See* Jamison, *supra* note 145, at 711–20; Farquhar, *supra* note 70, at 273–74.
[151] Jamison, *supra* note 145, at 716 (emphasis added).
[152] *Id.*
[153] *Id.* at 716–17.
[154] *Id.* at 717.
[155] *Id.* at 720.
[156] Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, HEALTH & HUM. RTS. J. (Nov. 23, 2015), https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/.
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] *See* Aidan Hollis, An Efficient Reward System for Pharmaceutical Innovation 2 (Jan. 17, 2005) (unpublished working paper) (available at https://www.keionline.org/misc-docs/drugprizes.pdf).
[163] *Id.* at 7.

approach would place the burden on the government to provide the financial incentive for pharmaceutical companies to lower costs.[164]

Yet another suggestion is a form of an ultimatum.[165] An inventor must "choose either to avail themselves of protection in the rich countries or, alternatively, in the poor countries, but not in both, whenever a patented product is for a global disease."[166] The natural result would be that the inventor will almost always select the "rich" countries because the profit potential is higher.[167] The effect would then force the inventor to surrender their protection in the "poor" countries and consequently decrease drug prices for global diseases in poorer, developing countries.[168]

An alternative approach is to revise the TRIPS Agreement itself to rectify its deficiencies. One commentator suggests that (1) key terms in the TRIPS Agreement Article 31, including the scope, duration, and adequate remuneration, must be defined; (2) adequate remuneration should be codified in advance; and (3) third-party arbitration should be used to resolve compulsory systems instead of under the importing member's jurisdiction.[169] These suggested revisions focus on working with the existing TRIPS Agreement and adjusting it to address the weaknesses that have become apparent in its application.[170]

Each of these methods focuses on how to develop a practical solution to ensure access to groundbreaking drugs in times of global health crises. The current debates over the COVID-19 vaccines have highlighted the deficiencies in our current system.

V. A PROPOSED INTERNATIONALLY BASED STRATEGY TO PROMOTE INNOVATION GLOBALLY TO ADDRESS CRITICAL HEALTH DISEASES AND CONDITIONS

This section proposes that the TRIPS Agreement must be amended to continue to promote a collaborative effort across countries globally and incorporate the monetary and exclusivity incentives necessary, at least in today's current economy, to promote medical and pharmaceutical companies to still enter the market.

While Article 31 allows members to bypass mandatory negotiations with the patent holder to obtain a *voluntary* license and instead obtain a *compulsory* license in times of emergency and other limited circumstances,[171] patent laws still must play an important role in protecting the patent holder. Mandatory licenses would impact both the monetary and protective motivators inherent in patents that encourage inventors to invest the time and money required to

[164] *Id.* at 14–15.
[165] *See* Jean O. Lanjouw, *A Patent Policy Proposal for Global Diseases*, BROOKINGS (June 11, 2001), https://www.brookings.edu/research/a-patent-policy-proposal-for-global-diseases/.
[166] *Id.*
[167] *Id.*
[168] *Id.*
[169] Farquhar, *supra* note 70, at 273–74.
[170] *Id.* at 273.
[171] Marrakesh Agreement, *supra* note 124.

enter the market.[172] Removing the inventor's rights to permit or reject licenses and to determine its suitable terms may eliminate both of these motivating factors.[173] A compulsory license for cutting-edge mRNA vaccines may have significant future consequences beyond COVID-19.[174] Exposing this technology may diminish trust in the patent system and encourage inventors to avoid developing drugs or vaccines to address future health crises for fear of losing their protection of their innovative technology.[175] This result is not conducive to solving *future* international health concerns.

This article proposes a reformation of the TRIPS Agreement that combines elements from the suggestions outlined in Section IV. There are two primary health concerns for which an international intellectual property agreement must account.

The first of which are health conditions or diseases that primarily concern developing countries.[176] These areas of health are often neglected by major pharmaceutical companies.[177] In 2018, it was estimated that pharmaceutical companies had not developed "91 of 139 urgently needed drugs, vaccines, diagnostic tests or devices identified by the World Health Organization . . . and 16 prioritised diseases [had] no projects at all."[178] It is evident that these areas of health are less marketable to pharmaceutical firms.[179] Therefore, to address this problem, provisions should focus on promoting future innovation in this sector by incentivizing major pharmaceutical companies to prioritize these conditions. Because many pharmaceutical companies are driven by economic motivations,[180] monetary and protective incentives should be utilized to encourage companies to enter the market. One system that may accomplish this goal is the use of the government-funded, prized-based systems previously discussed.[181] Creating a monetary "prize" for pharmaceutical companies who invest in these areas may generate the necessary motivation for these companies to invest their time and money into these projects.

The second area of concern is health conditions or diseases that pose a national or international emergency, such as COVID-19.[182] As evidenced by the proposed need for a COVID-19 vaccine intellectual property waiver and its long-lasting debate, the current TRIPS Agreement has not necessarily "saved time" through its licensing scheme.[183] For these cases, voluntary licenses should continue to be encouraged. To promote voluntary licenses, the TRIPS Agreement should be amended to set a time limit to negotiate a licensing agreement voluntarily for intellectual property concerning critical and urgent health crises. If these negotiations are unsuccessful within this defined time period, the pharmaceutical company would become

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[172] *See* Feldman, *supra* note 29, at 140–42.
[173] *See id.* at 140.
[174] *See id.* at 141–42; Lawder et al., *supra* note 61.
[175] Feldman, *supra* note 29, at 140–42, 158.
[176] Julia Kollewe, *Big Pharma 'Failing to Develop Urgent Drugs for Poorest Countries'*, GUARDIAN (Nov. 20, 2018, 8:00 AM), https://www.theguardian.com/business/2018/nov/20/big-pharma-who-failing-to-develop-urgent-drugs-for-poorest-countries.
[177] *Id.*
[178] *Id*.
[179] *Id*.
[180] Angell & Relman, *supra* note 21, at 103; Feldman *supra* note 29, at 140.
[181] *See* discussion *supra* Section IV.
[182] *See* Farquhar, *supra* note 70, at 265–66.
[183] *See id.*

susceptible to a compulsory license. This time limit should be codified for different general types of health conditions or diseases to account for the time demands inherent in each type. For example, a highly infectious disease with a high transmission rate may require a short time limit to encourage efficiency. Adding a time limitation to negotiate the license under the company's own terms may incentivize pharmaceutical companies to open themselves up to negotiations they might have otherwise outright refused. Establishing clear time limitations will also provide a definitive period and notice to the company.

If the company refuses to enter negotiations or fails to reach a resolution within the time limit stipulated, then compulsory licenses may be used to address these health conditions that pose an emergency. However, any compulsory licensing must have pre-defined terms and constraints to it. These terms must also be clearly set forth to ensure that the intellectual property holder is protected and that future innovation in this sector is not avoided for fear of compulsory licensing or an intellectual property waiver. As suggested by one commentator, codifying what "adequate remuneration" requires will guarantee patent holders' compensation and minimize litigation.[184] In addition, the patent holder must still have access to protections and the right to bring infringement actions. These rights are particularly important when a voluntary or compulsory license is authorized.[185] Because companies are hesitant to invest in countries that lack the same intellectual property rights as their home country,[186] the rights granted to the patent holder must be clearly defined. Therefore, to minimize the need for additional intellectual property waivers, it may also be necessary to provide a timely and clear procedure to address any obstacles that may arise during production once the license is granted. Furthermore, there should be mandated, defined, and substantial consequences in place if a member exceeds the scope of its limited authorization. For example, members who abuse this limited privilege could become ineligible for compulsory licenses for a set period of time in the future. However, this type of consequence would have to be carefully structured so that it would not harm the citizens of the country.

It is important that the TRIPS Agreement be supplemented by additional clarifications and codifications so that it can be implemented in a more effective manner for future global health crises. It is also critical that the terms of the TRIPS Agreement carefully offset any burden imposed on the inventor by supplying rewards in the form of monetary or intellectual property protection so as not to discourage future innovation, particularly in areas such as international health crises that require fast and cutting-edge innovation.

CONCLUSION

The emergence of COVID-19 has highlighted the existing deficiencies in the TRIPS Agreement to handle increased access to life-saving drugs or vaccines globally. Despite the idea for an intellectual property waiver being proposed over a year ago, a waiver had still not materialized for the COVID-19 vaccines as of January 2022,[187] and by June 2022, only a limited

[184] *Id.* at 273–74.
[185] *See id.* at 265, 268, 273–74; Jones et al., *supra* note 74.
[186] *See* Jamison, *supra* note 145, at 708.
[187] Lee, *supra* note 136.

waiver had been recognized.[188] For better or for worse, the United States and pharmaceutical companies are driven by capitalism.[189] This article analyzed the role that pecuniary gain has on innovation in addressing international critical diseases and medical conditions. Intellectual property waivers pose a significant risk to the economic protection the temporary monopoly granted by patents and other intellectual property rights provides.[190] Furthermore, if compulsory patent licenses create significant economic loss for inventors, an inventor may be discouraged from entering the market again in the future.[191]

This article posits that intellectual property waivers for international health crises, including the waiver for the COVID-19 vaccines, fail to recognize the monetary and protective incentives inherent in patents that encourage future groundbreaking innovation in the United States and across the world. This article contends that two systems should be used to encourage innovation in critical health areas. First, previously suggested rewards-based systems should be utilized to encourage inventors to invest in developing solutions to critical health conditions or diseases in developing countries. Second, for global health emergencies, such as COVID-19, an extensive revision to the TRIPS Agreement is required to provide greater clarity in ambiguous areas and to codify terms and restrictions when encouraging voluntary licenses or mandating compulsory licenses.

It is prudent for frameworks that address intellectual property protection related to critical health issues to incorporate both the monetary and protective incentives necessary to incentivize medical and pharmaceutical companies to invest the substantial resources needed for research and development in these areas.

[188] Robbins, *supra* note 137.
[189] *See* Purcell, *supra* note 28, at 38.
[190] Farquhar, *supra* note 70, at 271.
[191] *See id.* at 271 n.26; Feldman, *supra* note 29.