IP Waivers in a Pandemic:

Great in Theory, Wrong in Practice

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I. INTRODUCTION

The damage caused by the COVID-19 pandemic has been far-reaching and devastating.[1] Not long after the first U.S. cases were reported, it quickly became apparent that this pandemic was deadlier and more contagious than originally thought.[2] On May 15, 2020, a partnership was formed between the Department of Health and Human Services and the Department of Defense to help accelerate COVID-19 vaccine research and development.[3] This partnership, aptly coined "Operation Warp Speed" (OWS), awarded

1. As of this writing, COVID-19 has taken 1,112,792 American lives and 6.7 million lives worldwide. *COVID-19 Coronavirus Pandemic*, WORLDOMETER, https://www.worldometers.info/coronavirus/ [https://perma.cc/QFB4-JLR5] (last visited Dec. 16, 2022).

2. At the outset of the pandemic, COVID-19's predicted R_o—the number of people, on average, that one infected person will subsequently infect—was thought to be two or three. Jonathan Shaw, *COVID-19 May Be Much More Contagious Than We Thought*, HARV. MAG. (May 13, 2020), https://www.harvardmagazine.com/2020/05/r-nought [https://perma.cc/RC7N-CNX5]. After contact tracing data became available, however, many epidemiologists predicted that the R_o was much closer to five or six. *Id.* The Omicron variant of COVID-19 has an approximate R_o of 7. Ashley Boarman, *Omicron is the Dominant COVID Variant for Two Reasons*, VITALS (Dec. 28, 2021), https://vitals.sutterhealth.org/omicron-is-the-us-dominant-covid-variant-for-two-reasons/ [https://perma.cc/MZ2V-PW5M].

3. U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-319, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES 2 (2021).

contracts to six pharmaceutical companies to develop and manufacture vaccine doses.[4] While researchers were racing to develop a safe and effective vaccine, the virus continued to spread at an alarming rate. There were worries that, even if a vaccine were developed, lower-middle-income countries (LMICs) would not have the same access to doses as wealthier countries.[5]

In an attempt to provide global access, World Trade Organization (WTO) members India and South Africa proposed a temporary waiver of certain Trade-Related Aspects of Intellectual Property (TRIPS) obligations in October 2020.[6] Specifically, these members sought to waive all IP rights that relate to the "prevention, containment or treatment of COVID-19."[7] Despite garnering considerable attention and support from the United States and 104 other countries,[8] several months went by without a decision as to whether the proposal should take effect. In June 2022, however, the WTO members finally reached a decision to pass a limited TRIPS waiver.[9]

Unlike the original proposal—which calls for a stay on IP rights pertaining to preventing, containing, and diagnosing COVID-19—this drafted agreement suspends only patent protections for COVID-19 vaccines.[10] Unsurprisingly, biopharmaceutical firms have been its most fervent opponents, as the waiver effectively strips them of the very benefits that led them to patent their treatments in the first place.[11] Many proponents of the IP waiver, on the other hand, feel that the limited June 2022 Ministerial Decision falls flat

4. *Id.* at 6. The initial six companies awarded contracts were Pfizer/BioNTech, Moderna, Janssen (Johnson & Johnson), AstraZeneca, Sanofi/GSK, and Novavax. *Id.* at 13–16. The government negotiated terms with each company to reach an agreement. Four firms—Moderna, Janssen, AstraZeneca, and Sanofi/GSK—received federal funding to support vaccine development. SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., IN11560, CRS INSIGHT: OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 1–2 (2021). The other two firms—Pfizer/BioNTech and Novavax—participated in Operation Warp Speed via advance purchase contracts for vaccine doses with the federal government. *Id.*

5. *See generally* Edward M. Choi, *COVID-19 Vaccines for Low-and Middle-Income Countries*, 115 TRANSACTIONS ROYAL SOC'Y TROPICAL MED. HYGIENE 447, 447 (2021) ("LMICs are in urgent need of COVID-19 vaccines to avert a global catastrophe.").

6. Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020).

7. *Id.* ¶ 12.

8. *See* Press Release, Covid-19: One Year Since Call for Vaccine Tech to be Shared, Amnesty Int'l U.K. (Oct. 1, 2021), https://www.amnesty.org.uk/press-releases/covid-19-one-year-call-vaccine-tech-be-shared [https://perma.cc/5LDG-UCFE].

9. World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/W/15/Rev.2 (June 17, 2022).

10. *See id.* ¶ 1 ("Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement . . . by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic . . . ."). Notably, the ministerial decision states that "no later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics." *Id.* ¶ 8. Thus, WTO members have until December 2022 to decide whether to extend the stay on IP rights regarding COVID-19-related diagnostics and therapeutics.

11. Press Release, Pharm. Rsch. & Mfrs. of Am., PhRMA Statement on WTO TRIPS Intellectual Property Waiver (May 5, 2021), https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver [https://perma.cc/7JFC-E2FS]. Additionally, proponents of the original TRIPS waiver have also expressed disappointment in this drafted agreement.

of making a considerable impact in combatting the global pandemic.[12]

Although the TRIPS waiver was proposed with the right goal in mind—i.e., to expand global access to COVID-19 treatments, diagnostics, and therapeutics[13]—this Note contends that an IP waiver is not the solution, especially when there are other, less harmful options available. Part II provides background information on intellectual property (IP) law and its significance in the biopharmaceutical industry.[14] Part III argues that the United States should not grant IP waivers by providing two rationales.[15] First, it contends that IP waivers will not actually lead to widespread global vaccination in a pandemic because there are severe barriers to entry in the biologics industry, supply chain shortages, and quality control concerns that IP access cannot resolve. Second, granting sweeping IP waivers can ultimately impede incentivization in a time where such innovation is needed most. Part IV then recommends solutions that are better suited to fight global vaccine inequality while supporting future biopharmaceutical innovation;[16] and, finally, Part V concludes.[17]

II. BACKGROUND

IP encompasses all original creations of the human intellect, ranging from art and literature to scientific discovery and technological advancement.[18] For centuries, nations have fostered such innovation by allocating exclusive intellectual property rights (IPRs) to inventors and creators for specified periods.[19] This concept is hardly new—for example, the United States has expressly supported the use of IPRs to encourage innovation since its founding.[20] Counterintuitively, these government-granted monopolies, if balanced with antitrust law, can promote competition.[21] This enigma can be understood by considering

12. *See, e.g.*, Andrew Green, *WTO Finally Agrees on a TRIPS Deal. But Not Everyone Is Happy*, DEVEX (June 17, 2022), https://www.devex.com/news/wto-finally-agrees-on-a-trips-deal-but-not-everyone-is-happy-103476 [https://perma.cc/W6KM-FMSA].

13. Council for Trade-Related Aspects of Intell. Prop. Rts., *supra* note 7, ¶ 3 ("[I]t is important for WTO Members to work together to ensure that intellectual property rights . . . do not create barriers to the timely access to affordable medical products including vaccines . . . or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19.").

14. *See infra* Part II.

15. *See infra* Part III.

16. *See infra* Part IV.

17. *See infra* Part V.

18. *See What Is Intellectual Property?*, WORLD INTELL. PROP. ORG., https://www.wipo.int/about-ip/en/ [https://perma.cc/DQP8-QJN9].

19. *See* Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry*, 2 J. ADVANCED PHARM. TECH. & RSCH. 88, 88 (2011) ("Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property.").

20. U.S. CONST. art. I, § 8, cl. 8 ("To 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.") (emphasis added); *see also* THE FEDERALIST NO. 43, at 222 (James Madison) (George W. Carey & James McClellan eds., Liberty Fund, Inc. 2001) (maintaining that the "public good" coincides with giving inventors exclusive ownership over their useful inventions).

21. *See* GESNER OLIVEIRA & THOMAS FUJIWARA, WORLD INTELL. PROP. ORG., INTELLECTUAL PROPERTY AND COMPETITION AS COMPLEMENTARY POLICIES: A TEST USING AN ORDERED PROBIT MODEL 2 (2007), https://www.wipo.int/export/sites/www/ip-competition/en/studies/study_ip_competition_oliveira.pdf [https://perma.cc/6HE7-M5SS] ("As the objective of IP is to induce innovations that will ultimately provide better conditions for price, quality and diversity of products available to consumers, it possesses the same final goal as

what would happen in a nation without IP protections. In such an environment, an innovative firm that takes on the economic risks of developing a novel product may never regain its losses because other, less innovative firms could lure consumers away by copying the product and selling it at a lower cost.[22] Even if the innovating firm managed to survive the lost returns, it would likely forego the opportunity to invent in the future.[23] While this example is overly simplified,[24] it illustrates that, without IP protection, markets would favor those firms who "sit and wait."[25] And, as a result, innovation would slow, and consumers would suffer. Thus, it is no wonder why governments can—and often do—effectively promote innovation through IPRs.[26]

A. IP and International Law

As advancements in transportation made it possible to export and import goods outside one's own country, the need for a multilateral IP treaty became necessary to protect IPRs across borders. Thus, on March 20, 1883, the Paris Convention for the Protection of Industrial Property was formed.[27] While it has been revised many times since its formation, the treaty's objective has remained unchanged: to harmonize how each nation treated other nations when seeking protection for their industrial property.[28] Only five years after the Paris Convention, the Berne Convention for the Protection of Literary and Artistic Works

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competition policy, which is to promote welfare.").

22. *IP and Competition Policy*, WORLD INTELL. PROP. ORG., https://www.wipo.int/ip-competition/en/ [https://perma.cc/QAZ6-TENN].

23. *Id.*

24. For example, a company may still be inclined to innovate in a market where the end-product could not be reverse-engineered without considerable resources.

25. This situation describes what economists call "the free-rider problem." *See* VAN LINDBERG, INTELLECTUAL PROPERTY AND OPEN SOURCE 12 (Andy Oram ed., O'Reilly Media, Inc. 2008). In describing the free-rider problem, Van Lindberg points to the example from which the term gets its name:

> Imagine that each day there are many city buses available to take people where they need to go. There is a catch, however: the first person to get on the bus pays $10,000, covering the fares for everybody else. . . . [A]ll others getting on the bus get to ride for free.
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> In this situation, there is a high cost for being the first person to get on the bus, but a low cost for everybody else. The incentive is for everybody to hang back; nobody wants to be the first person who pays the fare. Once somebody has paid the fare, however, everybody crowds on. After all, the ride is free—it has been paid for by someone else.

Id.

26. Empirical research has consistently demonstrated that countries with more robust IP rights have benefitted from increased innovation. *See, e.g.*, Cassandra Mehlig Sweet & Dalibor Sacha Eterovic Maggio, *Do Stronger Intellectual Property Rights Increase Innovation?*, 66 WORLD DEV. 665 (2015); Chih-Hai Yang, Yi-Ju Huang, & Hsuan-Yu Lin, *Do Stronger Intellectual Property Rights Induce More Innovations? A Cross-Country Analysis*, 55 HITOTSUBASHI J. ECON. 167 (2014).

27. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T 1583, 828 U.N.T.S. 305 (last revised at the Stockholm Revision Conference on July 14, 1967).

28. *See id.* at 2 ("Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.").

was formed.[29] Like the Paris Convention, the Berne Convention focuses on international harmonization, but goes a step further by providing minimum standards for copyright law.[30] However, because the Paris and Berne Conventions are both non-self-executing treaties,[31] they only have legal effects within a member state if, and when, countries implemented them through their own laws.[32] As a result, adoption of the two treaties was slow, and their effects less profound. That changed on January 1, 1995, when over 120 nations participated in multilateral trade negotiations in Punta del Este, Uruguay, leading to the creation of the WTO, the largest international economic trade organization in the world.[33] All WTO member countries receive benefits from other members, meaning membership is contingent on "a balance of rights and obligations."[34] Unlike the Berne and Paris treaties, the WTO has mechanisms for dispute resolution and consequences for violations of the agreements it oversees.[35] Disputes are settled by an ad hoc "quasi-judicial" panel and an "Appellate Body," which "issue reports with findings and recommendations."[36]

One of the most central trade agreements that the WTO governs is TRIPS.[37] "TRIPS establishes minimum standards for the availability, scope, and use of seven forms of intellectual property: copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets)."[38] Unlike the prior Berne and Paris treaties, TRIPS is unique because WTO membership is a "package deal," meaning that members cannot just selectively choose

29. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, S. TREATY DOC. NO. 99-27, 1161 U.N.T.S. 31 (as last revised in Paris on July 24, 1971, and amended Sept. 28, 1979).

30. Peter Burger, *The Berne Convention: Its History and Its Key Role in the Future*, 3 J.L. & TECH. 1, 16–17 (1988).

31. "A non-self-executing treaty, by definition, is one that was ratified with the understanding that it is not to have domestic effect of its own force." Medellín v. Texas, 552 U.S. 491, 527 (2008).

32. *See* Ahmad Takouche, *Well-Known, or Not Well-Known? That Is the Question. The Paris Convention for the Protection of Industrial Property's Article* 6bis *in the Context of American Trademark Law*, 9 U.C. IRVINE L. REV. 495, 518 (2019) (applying the two-prong self-executing analysis from *Medellín v. Texas* to the Paris Convention and finding that it is not self-executing); *see also* Berne Convention Implementation Act of 1988, Pub L. No. 100–568, § 2, 102 Stat. 2853, 2853 (1988) (noting that Congress had to pass this legislation to effectuate the terms agreed to in the Berne Convention).

33. Kym Anderson, *World Trade Organization*, ENCYC. BRITANNICA, https://www.britannica.com/topic/World-Trade-Organization [https://perma.cc/5JMC-7GYG]. Today, there are 164 members, representing 98% of world trade. *The WTO in Brief*, WTO, https://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr_e.htm [https://perma.cc/PX9R-R4QA].

34. *Membership, Alliances and Bureaucracy*, WTO, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org3_e.htm [https://perma.cc/LU59-FQMM].

35. .*See, e.g.*, Joost Pauwelyn, *Enforcement and Countermeasures in the WTO: Rules are Rules—Toward a More Collective Approach*, 94 AM. J. INT'L L. 335, 336 (2000) ("WTO rules are enforced through a WTO-specific dispute settlement system.").

36. *Id.* The Appellate Body can then use its discretion to impose trade sanctions on the member-state that was not compliant with the provisions of the WTO Agreement. *Id.*

37. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994). General Agreement on Trade-Related Aspects of Intellectual Property, Jan. 1, 1995, 1869 U.N.T.S. 183, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

38. *Trade-Related Aspect of Intellectual Property*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/ip-policy/patent-policy/trade-related-aspects-ip-rights [https://perma.cc/4HFZ-WKCM].

which agreements to implement and which to ignore.[39]

B. TRIPS and the Pharmaceutical Industry

Tensions have long existed between IPRs in the biopharmaceutical industry and public health concerns in LMICs.[40] Before TRIPS, some countries, such as India and Brazil, did not permit patents on medicine; rather, they only permitted drug companies to patent the processes used to create them.[41] This meant generic alternatives could enter the market right away, keeping prices affordable for consumers.[42] After TRIPS was formed, WTO member states were required to provide IPRs to innovators for product patents[43] with a minimum term length of 20 years.[44] This was necessary because it allowed biopharmaceutical companies to recover many of the R&D costs they would otherwise lose to generic companies.[45] And, as technology has advanced, R&D costs have only skyrocketed.[46] Between 2009 and 2018, the estimated median R&D cost per individual drug was $985 million.[47] However, giving the pharmaceutical industry blanket monopolies for every patented drug would exacerbate the lack of access in LMICs, as name brand drugs—without generic alternatives—can be priced at monopolistic price points.[48] Thus, in an attempt to find the right balance between promoting R&D into new drugs and furthering access to existing drugs, the TRIPS agreement includes two exceptions outlined in Articles 30 and 31.

Article 30 (Exceptions to the Rights Conferred) provides that certain activities, such as using the patented process or product for research purposes, can be defined under national law as exceptions to an inventor's IPRs.[49] In other words, these excepted activities

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39. *Id.* Importantly, the TRIPS Agreement includes many of the same provisions as those in the Paris and Berne Conventions, but now—through the WTO—mechanisms are in place to ensure their enforcement. *See* JASON RANTANEN, INTRODUCTION TO INTELLECTUAL PROPERTY 64 (2021).

40. *See, e.g.*, Marion Motari et al., *The Role of Intellectual Property Rights on Access to Medicines in the WHO African Region: 25 Years After the TRIPS Agreement*, BMC PUB. HEALTH (Mar. 11, 2021), https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/s12889-021-10374-y.pdf [https://perma.cc/X5P8-R8DF] (discussing how intellectual property protections interferes with access to medicine in LMICs).

41. Hillary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1, 1–2 (2020).

42. *Id.*

43. *Id.* at 2.

44. *Overview: The TRIPS Agreement*, WTO, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm [https://perma.cc/MSN3-D3EY].

45. *See* Wong, *supra* note 41, at 2.

46. *See* CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 1 (2021) ("The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. . . . That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.").

47. .Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimating Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 J. AM. MED. ASSOC. 844, 845 (2020) (using data collected from "63 of 355 new therapeutic drugs and biologic agents approved by the US Federal Drug Administration between 2009 and 2018").

48. Mark S. Levy, *Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged*, 66 AM. U. L. REV. 247, 247 (2017) ("Without generic competition, no watchdog exists to curb big pharma's prohibitive prices.").

49. TRIPS Agreement, *supra* note 37, art. 30. The "rights conferred" to a patent holder to which Article 31 is excepting are outlined in Article 28. *See id.* arts. 28, 30–31. Article 28(1)(a) provides that a *product* patent must confer to the patent holder the exclusive right to exclude a third party from "making, using, offering for sale,

do not require the patent holder's permission before proceeding with the use of the patented invention.[50] The Article 31 exception, on the other hand, has been understood to permit member governments the right to grant compulsory licenses in limited situations.[51] A compulsory license is essentially a means by which a government can license a patent owner's product or process to a third party without the patent owner's consent.[52] As one might expect, this exceptional measure is not without guidelines for how it may be used. Notably, if a government issues a compulsory license to a third party, the authorization of use "shall be considered on the merits,"[53] "the scope and duration shall be limited to the purpose for which it was authorized,"[54] it shall be non-exclusive (i.e., the patent holder cannot be excluded from practicing their own patent or vesting a non-exclusive license to another),[55] and the patent holder "shall be paid adequate remuneration in the circumstances of each case."[56]

In 2001, as the HIV/AIDS epidemic led to grossly disproportionate deaths in Africa,[57] it became clear that the WTO needed to provide TRIPS members with the flexibility to circumvent the IPRs of essential medications in addition to the exceptions provided for in Articles 30 and 31.[58] The WTO thus adopted the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), which eventually was amended into the TRIPS Agreement as Article 31bis.[59] This amendment clarifies that, in situations of "national emergencies", TRIPS members may grant compulsory licenses without the normal requirements (such as first trying to obtain a voluntary license from the patent

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selling, or importing for these purposes that product" without the owner's consent. *Id.* art. 28(1)(a). Article 28(1)(b) provides the equivalent rights, but for a *process* patent. *See id.* art. 28(1)(b).

50. *See* Chris Dent, *The TRIPS Agreement and an Experimental Use Exception for Research Tools*, 44 AUSTRALIAN ECON. REV. 73, 77 (2011). Other than experimental use, another common immunity is the "Bolar" exception, which permits countries with generic drug manufacturers to grant the use of a patented medication to obtain marketing approval without the patent holder's permission. Motari et al., *supra* note 40, at 5. This provides a method by which governments can "facilitate[] market entry by competitors immediately after the patent term expires hence ensuring early access to generic medicines." *Id.*

51. *See* TRIPS Agreement, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197, art. 31. Article 31 does not explicitly use "compulsory license" in its provisional language. "Instead, the phrase 'other use without authorization of the right holder' appears in the title of Article 31. Compulsory licensing is only part of this since 'other use' includes use by governments for their own purposes." *Fact Sheet: TRIPS and Pharmaceutical Patents*, WTO (Sept. 2003), https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf [https://perma.cc/6Q8B-X786].

52. *See* Eduardo Urias & Shyama V. Ramani, *Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence*, 3 J. INT'L BUS. POL'Y 1, 2 (2020).

53. TRIPS Agreement, *supra* note 37, art. 31(a).

54. *Id.* art. 31(c).

55. .*Id.* art. 31(d).

56. *Id.* art. 31(h).

57. *See generally* Thomas Goliber, *The Status of the HIV/AIDS Epidemic in Sub-Saharan Africa*, POPULATION REFERENCE BUREAU (July 2, 2002), https://www.prb.org/resources/the-status-of-the-hiv-aids-epidemic-in-sub-saharan-africa/ [https://perma.cc/7879-QT25] ("Three million people died from AIDS-related causes in 2001, and 2.2 million of these deaths were among sub-Saharan Africans.").

58. WTO, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

59. TRIPS Agreement, *supra* note 37, art. 31*bis*. There are also provisions that cover the patent-related standards of the TRIPS Agreement. *See id.* art. 27–34.

holder).[60] It further gives member states the ability to decide what qualifies as a national emergency.[61]

C. Vaccine Waivers in the Global Context

Generally speaking, a patent waiver is "a mechanism to overcome [the] exclusionary ability that traditionally inheres a patent."[62] The rationale for promoting an IP waiver in a global health crisis is to "replicate existing vaccines" or treatment practices and "manufacture at a scale so that considerably more doses will start flowing towards populations" in LMICs.[63]

As millions of people were suffering the impacts of the COVID-19 pandemic worldwide, India and South Africa proposed a WTO waiver from IP protections for COVID-19-related medical technologies, including vaccines.[64] In the original proposal, the duration of the waiver was open-ended.[65] It simply said "the waiver should continue until widespread vaccination is in place globally."[66] To garner more support, sixty LMICs in support of the waiver submitted a revised proposal[67] that would "limit the waiver" for an initial three-year period.[68] In a surprise move, the highest-grossing nation in the world—the United States—announced its plan to back the waiver.[69] Then, after months of negotiations, all WTO members reached a consensus on a limited waiver on COVID-19-related IPRs on June 17, 2022.[70] Unlike the original proposal—which calls for a stay on IP rights pertaining to preventing, containing, and diagnosing COVID-19—this drafted agreement waives only patent protections for COVID-19 vaccines.[71] The drafted decision did not, however, outright reject expanding the waiver to COVID-19 treatments and

60. *Fact Sheet: TRIPS and Pharmaceutical Patents*, WTO (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm [https://perma.cc/XCA9-KART].

61. *See id.*

62. Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, PETRIE-FLOM CTR. AT HARVARD L. SCH. (May 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/ [https://perma.cc/BUC2-4PWA].

63. *Id.*

64. Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO (Oct. 2, 2020) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True [https://perma.cc/HFD2-XRRM].

65. *Id.*

66. *Id.* at 2.

67. Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO (revised on May 21, 2021) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True [https://perma.cc/Q9EM-8Q2P] [hereinafter Revised TRIPS Waiver].

68. *See id.* at 3 ("This waiver shall be in force for at least 3 years from the date of this decision.").

69. *See* Emma Bowman & Ashish Valentine, *Biden Backs Waiving International Protections for COVID-19 Vaccines*, NPR (May 5, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/05/05/993998745/biden-backs-waiving-international-patent-protections-for-covid-19-vaccines [https://perma.cc/4LNN-EDL8]. However, the Biden Administration "voiced support for a narrower concept of a TRIPS waiver than contemplated" in the waiver's revised form. *See* SHAYER I. AKHTAR, CONG. RSCH. SERV., IF11858, POTENTIAL WTO TRIPS WAIVER AND COVID-19 2 (2021).

70. Draft Ministerial Decision on the TRIPS Agreement, *supra* note 9.

71. *See supra* note 10 and accompanying text.

diagnostics. Rather, it postponed the discussions on such an expansion by six months.[72]

An IP waiver, unlike a license, relinquishes the exclusivity component of IPRs. In other words, a waiver would mean that "a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver."[73] Proponents argue that an IP waiver solves widespread vaccine inequality in LMICs because generic pharmaceutical companies can start producing the vaccines immediately.[74] Critics of the waiver, on the other hand, assert that an IP waiver will not resolve global vaccine inequality because IP alone does not provide generic pharmaceutical companies with the know-how needed to reproduce complex biologics.[75]

III. ANALYSIS

An IP waiver (such as the TRIPS waiver for the COVID-19 pandemic) is not the proper vehicle for solving global vaccine inequality in LMICs.[76] Subpart A discusses that mere access to information does not help the vast majority of LMICs without the resources, advanced technology, and specialized labs and technicians needed to effectuate such an operation. Subpart B considers the substantial impact of IP waivers on the pharmaceutical industry. Specifically, it contends that when a new infectious disease leads to a global pandemic, the individuals and firms most equipped to develop a lifesaving antidote will be less inclined to put forth the labor and considerable investment to do so.

A. IP Waivers are Unlikely to Solve the Global Vaccine Shortage

IP waivers are unlikely to be a successful solution to vaccine inequality because a "recipe" for a vaccine does not resolve or address the issues and complexities that arise

72. Draft Ministerial Decision on the TRIPS Agreement, *supra* note 9, ¶ 1.

73. Bryan Mercurio, Editorial, *The IP Waiver for COVID-19: Bad Policy, Bad Precedent*, 52 INT'L REV. INTELL. PROP. & COMPETITION L. (IIC) 983, 986 (2021).

74. *See, e.g.*, Katarina Foss-Solbrekk, *The IP Waiver and COVID-19: Reasons for Unwavering Support*, 16 J. INTELL. PROP. L. & PRAC. 1347 (2021); Press Release, Katherine Tai, Ambassador, Off. U.S. Trade Rep., Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver [https://perma.cc/RQA5-XFRD]; Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic* (L., Soc'y & Econ., Working Paper No. 06/2021, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737 [https://perma.cc/YP9J-JT2R].

75. *See, e.g.*, Rutschman & Barnes-Weise, *supra* note 62; Tamara Kay, Adnan Naseemullah & Susan Ostermann, *Waiving Patents Isn't Enough —We Need Technology Transfer to Defeat COVID*, HILL (May 13, 2021), https://thehill.com/opinion/healthcare/553368-waiving-patents-isnt-enough-we-need-technology-transfer-to-defeat-covid [https://perma.cc/WJE2-5QYM] (arguing that the complex nature of vaccines necessitates the push of technology transfers and supply-line coordination); Harry G. Broadman, *The Cynicism of Biden's High-Risk, Low-Reward Vaccine Patent Waiver*, FORBES (May 31, 2021), https://www.forbes.com/sites/harrybroadman/2021/05/31/the-cynicism-of-bidens-high-risk-low-reward-vaccine-patent-waiver/?sh=1e17bcff2849 [https://perma.cc/8J42-T88N] (contending that President Biden could conceivably use the U.S. Defense Production Act to require pharmaceutical "companies to make the needed vaccines under the guise of protecting U.S. national security").

76. Although the scope of this Note is focused on the effects of IP waivers in the pharmaceutical industry, it is important to acknowledge that it does not seek to diminish the devastation caused by global vaccine inequality. Rather, this Note hypothesizes that the TRIPS waiver will not provide greater access to COVID-19 treatments in LMICs.

from large-scale production of novel, complex biologics.[77] Patent disclosures often leave out the specific manufacturing processes and procedures that the invention heavily depends on.[78] This ambiguity in the disclosures is sometimes just the consequence of language being inherently imprecise.[79] More often, in the biopharmaceutical context, the firm's decision to keep the specifics about their manufacturing processes secret is intentional.[80]

A global IP waiver will not resolve the infrastructure limitations that coincide with mass-producing and storing vaccines. Creating a safe and effective vaccine is only the first of many hurdles a pharmaceutical company must overcome before doses are administered to the public. After a vaccine receives regulatory approval, pharmaceutical companies must find a safe and effective way to produce and store the vaccine doses on an enormous scale, ensuring that the quality is maintained throughout.[81]

Using COVID-19 vaccines as an illustration, which has gone from zero to billions of doses in record time,[82] manufacturers have unsurprisingly encountered bottlenecking of raw materials and equipment.[83] While efforts have been made to combat this,[84] only so many individuals and firms have the equipment and know-how to develop many of these raw materials. Pfizer has managed to abate resource shortages by creating its own manufacturing facility to produce an essential lipid for COVID-19 vaccines.[85] Still, it is

77. Like a recipe, a patent's disclosure provides an informational function. Just as a recipe does not provide the chef with ingredients, tools, or appliances to prepare and cook the described dish, a patent does not provide the necessary resources, facilities, or manufacturing capabilities to bring the invention to fruition. However, unlike a recipe, which might be tailored for beginners, a patent's disclosure must only enable a person of ordinary skill *in the art* to recreate the invention or process. 35 U.S.C. § 112(a) (2018).

78. *See* Christopher Jordan & Daniel Ovanezian, *Keeping Trade Secrets Out of Patents*, CORP. COUNS. (Oct. 20, 2017), https://plus.lexis.com/api/permalink/b1248cc7-6925-4498-9f80-ce8b75f44c26/?context=1530671 [https://perma.cc/5ZE3-MBBR] ("[I]f the details of the manufacturing process are not pertinent to what will be claimed in the patent application, those details can be left out of the patent application to be maintained as a trade secret.").

79. *See, e.g.*, Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 899 (2014) ("Section 112's definiteness requirement must take into account the inherent limitations of language.").

80. *See* Tara Nealey, Ronald M. Daignault & Yu Cai, *Trade Secrets in Life Science and Pharmaceutical Companies*, 5 COLD SPRING HARBOR PERSPS. MED. 1, 3 (2015) (detailing that many pharmaceutical companies choose to protect their "manufacturing processes, formulas, and development research, including preclinical data" via trade secret laws).

81. *See generally* U.S. DEP'T HEALTH & HUM. SERVS., VACCINE STORAGE AND HANDLING TOOLKIT (2022) (discussing the storage requirements necessary for maintaining the efficacy of the vaccines).

82. As of October 6, 2022, over 612 million COVID-19 vaccine doses have been administered in the United States, and nearly 13 billion doses have been administered worldwide. Tom Ranall et al., *More than 12.7 Billion Shots Given: Covid-19 Tracker*, BLOOMBERG VACCINE TRACKER, https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ [https://perma.cc/HTP4-XHCZ].

83. *See* Lucy Rodgers, *Covid Vaccines: Why a Giant Plastic Bag Shortage is Slowing the Rollout*, BBC NEWS (July 24, 2021), https://www.bbc.com/news/health-57024322 [https://perma.cc/A2V3-FP2A].

84. *See, e.g.*, *The COVAX Marketplace*, COAL. FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI), https://cepi.net/the-covax-marketplace/ [https://perma.cc/R5FF-9QBE] (outlining a plan by CEPI to combat the bottlenecking of materials and resources). CEPI established the COVAX Marketplace to facilitate access to supplies for manufacturers of COVID-19 vaccines. *Id.* The Marketplace gives suppliers a platform to allocate and reallocate unused materials to maximize production capabilities. *Id.*

85. Kate Silver, *Shot of a Lifetime: How Pfizer Developed Its Own Raw Materials to Ensure a Steady Supply for the COVID-19 Vaccine*, PFIZER, https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_pfizer_developed_its_own_raw_materials_to_ensure_a_steady_supply_for_the_covid_19_vaccine [https://perma.cc/84M4-XFVJ]. It could only do this,

unlikely Pfizer could have accomplished this feat without the help of a tech transfer, a highly-skilled team, and the significant capital needed to purchase a facility and the specialized equipment,[86] all of which would be hard to come by in an LMIC. Indeed, even though Moderna announced that it would not be enforcing any of its patents related to its mRNA vaccine during the pandemic,[87] no other company has stepped up to manufacture it.[88] Commentators have made sense of this by attributing it to the lack of raw materials.[89] Thus, even if all IP restrictions were waived, limited resources or lack of industry expertise still pose the largest (and perhaps insurmountable) barrier to LMICs.

Apart from resource limitations, IP waivers also do not resolve the lack of adequate storage facilities in many LMICs.[90] For example, some vaccines must be stored in ultra-cold freezers to remain effective.[91] To many LMICs, where it is not uncommon for electricity supply to be interrupted often,[92] long-term storage of vaccines is of great

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however, because a third-party manufacturer agreed to a technology transfer. *See id.* ("[Pfizer] assembled a team . . . including operations, product technology, quality assurance, procurement, and planning, to prepare for . . . a "tech transfer" from the [third-party] facility."). A tech transfer enabled Pfizer to emulate "a comparable process and components—including equipment and ingredients" in its new facility without jeopardizing the quality of the lipids it was now producing. *Id.*

86. *See id.*

87. Eric Sagonowsky, *Moderna Won't Enforce COVID-19 Vaccine Patent During Pandemic*, FIERCE PHARMA (Oct. 8, 2020), https://www.fiercepharma.com/pharma/leading-vaccine-player-moderna-won-t-enforce-patents-against-other-companies-during-pandemic [https://perma.cc/27R5-GNZA]. However, countries considered "high-income" will have to pay Moderna to use its technology. *See* Kevin Dunleavy, *Moderna Will Provide Access to mRNA Tech, But High-Income Countries Will Have to Pay*, FIERCE PHARMA (Mar. 8, 2022), https://www.fiercepharma.com/pharma/moderna-will-provide-access-technology-spikevax-high-income-countries-will-have-pay [https://perma.cc/CT35-4CZS] (noting that Moderna would be willing to license with high-income countries under "commercially reasonable terms").

88. *See* Rachel Silverman, *Waiving Vaccine Patents Won't Help Inoculate Poorer Nations*, WASH. POST (Mar. 15, 2021), https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/ [https://perma.cc/5BEB-PDDR].

89. *See, e.g.*, Delphine Knight Brown, *Will TRIPS Waiver of IP Protection for COVID-19 Vaccines Serve Global Needs?*, POWERHOUSE POINTS: A Q. LITIG. UPDATE, Summer 2021, at 9, 10 ("[D]espite Moderna's voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna vaccine. The most significant obstacle to COVID-19 vaccine supply is not just the IP rights that companies have obtained, or are pursuing, but rather the lack of raw materials and manufacturing facilities to produce the vaccines.").

90. Eunice Twumwaa Tagoe et al., *COVID-19 Vaccination in Lower-Middle Income Countries: National Stakeholder Views on Challenges, Barriers, and Potential Solutions*, 9 FRONTIERS PUB. HEALTH 1, 6 (2021).

91. *See, e.g.*, *Pfizer-BioNTech COVID-19 Vaccine: Storage and Handling Summary*, U.S. CTRS. DISEASE CONTROL & PREVENTION (CDC) (Oct. 03, 2022), https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf [https://perma.cc/P6ZG-GZXM] (recommending the Pfizer BioNTech mRNA vaccine be stored in "an ultra-cold freezer between -90 °C and -60 °C (-130 °F and -76 °F)"). To get a sense of just how cold that is, the lowest natural temperature ever recorded at ground level on Earth was -82.9 °C in Antarctica on July 21, 1983. John Turner et al., *Record Low Surface Air Temperature at Vostok Station, Antarctica*, 114 J. GEOPHYSICAL RSCH. 1, 1 (2009). Long-term storage of Moderna, another mRNA vaccine, only needs to be stored at standard freezer temperatures of -20 °C for up to six months. *Moderna COVID-19 Vaccine: Storage and Handling Summary*, CDC (Oct. 04, 2022), https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf [https://perma.cc/BR9S-9DFY]. For short-term storage (i.e., thirty days or less), the Moderna vaccine can be stored at standard refrigerator temperatures (2 °C to 8 °C (36 °F to 46 °F)). *Id.*

92. *See* NICHOLAS MOORE ET AL., ASIAN DEV. BANK, SYSTEMATIC REVIEW ON THE EFFECTS OF ACCESS TO ELECTRICITY INTERVENTION ON SOCIOECONOMIC OUTCOMES IN LOW- AND MIDDLE-INCOME COUNTRIES xi (Aug. 2020), https://www.adb.org/sites/default/files/evaluation-document/515326/files/in242-20.pdf

concern.[93] To remain safe and effective, "[v]accines must be continuously stored in a limited temperature range–from the time they are manufactured until the moment of vaccination."[94] The United Nations Children's Fund (UNICEF) is one agency that currently transports and administers vaccines in LMICs.[95] It accomplishes this through what is coined a "cold chain"—i.e., "a chain of precisely coordinated events in temperature-controlled environments to store, manage and transport these life-saving products."[96] Failure to follow a vaccine's cold chain may result in a loss in potency.[97] In other situations, broken cold chains can have more dire consequences. In 2017, for example, improper storage of a measles vaccine in South Sudan led to the deaths of fifteen children under the age of five.[98] Thus, before IP waivers can achieve their desired effect in LMICs, stable and reliable electricity is necessary to provide safe, consistent, and efficacious vaccine administration.

Finally, IP waivers are ineffective in their goal of global vaccination when there are not enough specialized personnel to develop the disclosed cutting-edge biologics.[99] One consequence of creating a vaccine using newly developed science is that there is often a shortage of trained personnel who know how to develop it.[100] An IP waiver is unlikely to help this because—even with the guidance of patents—one cannot just go through the disclosed steps and assume that they produced a vaccine.[101] As previously mentioned, many pharmaceutical companies opt to keep their manufacturing and quality-control processes trade secrets.[102] And although the TRIPS waiver proposes that trade secrets be freely shared,[103] it is hard to imagine how a government could compel involuntary

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[https://perma.cc/KQQ4-BW2E] ("While the proportion of the global population with electricity access increased from 78% to 89% between 2000 and 2017, an estimated 800 million people worldwide did not have any access to electricity in 2017. Access is still limited for [LMICs] (especially in sub-Saharan Africa) and rural communities."). According to 2019 data, approximately 60 percent of all health facilities in sub-Saharan Africa do not have access to electricity. *Power Africa: COVID-19 Response and Recovery*, U.S. AGENCY FOR INT'L DEV. (2020), https://2017-2020.usaid.gov/sites/default/files/documents/Power-Africa-COVID-19-response.pdf [https://perma.cc/2SGT-KJ5T]. Of the 40 percent who have electricity, "only 34 percent of hospitals and 28 percent of health facilities have reliable access." *Id.*

93. *See* Tagoe et al., *supra* note 90.

94. *What Is a Cold Chain?*, UNICEF, https://www.unicef.org/supply/what-cold-chain [https://perma.cc/8U9Q-JNVJ].

95. *See generally Vaccines for All*, UNICEF, https://www.unicef.org/immunization/vaccines-for-all [https://perma.cc/P9PF-9GEZ].

96. *What is a Cold Chain?*, *supra* note 94.

97. *Id.*

98. *See Statement Regarding Findings of Joint Investigation of 15 Deaths of Children in Nachodokopele Village, Kapoeta East County in South Sudan*, WORLD HEALTH ORG. (June 2, 2017), https://www.afro.who.int/news/statement-regarding-findings-joint-investigation-15-deaths-children-nachodokopele-village [https://perma.cc/U2K3-NV6E]. The vaccines became contaminated after they were stored in a building with no cold chain facilities for four days. *Id.*

99. Aisling Irwin, *What It Will Take to Vaccinate the World Against COVID-19*, NATURE (Apr. 8, 2021), https://www.nature.com/articles/d41586-021-00727-3 [https://perma.cc/3ZSJ-UV65].

100. *Id.*

101. *Id.* (quoting Jerome Kim, Director General of the International Vaccine Institute) ("The thing about vaccines is that, unlike a drug, you can't just [follow instructions] and assume that you've got a vaccine. This is a complex biological process that has multiple quality-control steps.").

102. *See* Jordan & Ovanezian, *supra* note 78.

103. *See* TRIPS Waiver, ¶ 3, WTO Doc. IP/C/W/669/Rev.1 (revised on Dec. 15, 2021) ("[I]t is important for WTO Members to work together to ensure that . . . patents, industrial designs, copyright and protection of

disclosure from private pharmaceutical companies without a legal battle.[104]

In conclusion, while IP waivers may appear, on their surface, to be an easy solution to global vaccine inequality, they are nevertheless improper and ineffective remediations, for they fail to address how LMICs will gain access to specialized raw materials, vaccine manufacturing facilities, temperature-controlled storage, and specialized personnel equipped to develop the vaccines. If an IP waiver were to take effect, many countries may be tempted to nonetheless try to develop the vaccine without quality control, oversight, or proper storage, which could potentially lead to a health crisis.

B. IP Waivers Are Likely to Impede Innovation in the Pharmaceutical Industry

As mentioned in Part II, government-granted IPRs have been a prevalent and largely effective mechanism to stimulate innovation.[105] They have been important for nearly every company involved in innovation and entrepreneurship; however, no one sector relies on IPRs more than the pharmaceutical industry.[106] This is unsurprising given the astronomical costs a pharmaceutical company must shoulder when bringing a new drug to the market.[107] Additionally, the liability risks accompanying novel pharmaceuticals often lead to massive settlements.[108] These settlements are paid by the pharmaceutical companies who produce the drugs. This Note contends that if a global IP waiver is instituted, it will disincentivize the pharmaceutical industry's drive to develop life-saving treatments for the global health crisis of tomorrow.

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undisclosed information do not create barriers to the timely access to affordable medical products including vaccines.").

104. *See* Brown, *supra* note 89, at 9–10 ("[T]here is no precedent for forcing pharmaceutical companies to involuntarily disclose trade secrets. Compulsory patent licenses were issued in the past to boost production of AIDS and HIV drugs, but even those licenses did not require disclosure of trade secrets."). Additionally, because trade secrets often relate to R&D pipelines (as opposed to the development of one single product), pharmaceutical companies will likely go to great lengths to protect them. *See id.*

105. *See supra* Part II.

106. *See* Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 EXPERT OP. ON THERAPEUTIC PATS. 739, 741 (2015) ("Since the 1980s, US-focused researchers have found patents to be relatively more important to R&D than other forms of IP protection . . . in biopharmaceuticals than in other industries. The most recent data from US government and annual US and Canada licensing professional surveys are consistent with these findings.").

107. *See supra* notes 46–47 and accompanying text.

108. *See, e.g.*, *10 Biggest Pharmaceutical Settlements in History*, ENJURIS, https://www.enjuris.com/blog/resources/largest-pharmaceutical-settlements-lawsuits/ [https://perma.cc/YF9F-ZLYB] (noting that in recent years, the negligent actions of pharmaceutical companies have led to massive criminal fines and civil settlements.). For example, in 2012, GlaxoSmithKline was responsible for a $3 billion settlement for promoting "off-label" uses (i.e., uses not approved by the U.S. Federal Drug Administration) for several of their medications. *Id.*; *see also* Press Release, U.S. Dep't of Justice, Off. of Public Affairs, Justice Department Recovers Over $2.2. Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020 [https://perma.cc/UYU6-MUCY] ("Of the more than $2.2 billion in settlements and judgments recovered by the Department of Justice this past fiscal year, over $1.8 billion relates to matters that involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.").

1. IP Waivers' Harm on Pharmaceutical Patents and Trade Secrets

IP waivers are antithetical to innovation as they punish the inventor for contributing to the public's wealth of knowledge.[109] In the pharmaceutical industry, generic companies pose the biggest threat to profits.[110] For consumers, of course, generic companies help lower the prices of various name-brand drugs.[111] But if generic companies were permitted to reverse engineer pharmaceuticals immediately, what firm would be driven to make a large capital investment in exchange for the uncertain, speculative opportunity to develop a new drug treatment option?[112] Knowing their novel treatment would be forthwith made by the generic companies at a lower price, few firms could justify the risk. This highlights the importance of IPRs in the pharmaceutical industry that IP waivers stand to threaten.

One major issue with the TRIPS waiver is that it does not mention any form of compensation for the minimum three years it would remain in effect.[113] This aspect of the proposal is the most likely to cause a lasting impact because profits—for better or worse—drive innovation in the pharmaceutical industry.[114] If the TRIPS waiver is implemented as it stands today, the race to develop life-saving drugs would almost certainly be less appealing to those who have the most to lose.

IP waivers are also harmful to the pharmaceutical industry because, for one vaccine, several (sometimes hundreds) patents interconnect with trade secrets and licensing deals to make a very complex network of ownership.[115] The race—and collaboration—between the major pharmaceutical companies to develop viable COVID-19 vaccines provides a perfect template to view this complexity. Figure 1, shown below, depicts the patent network for COVID-19 mRNA vaccine producers.[116] If a patent waiver is instituted, these pharmaceutical companies will not just lose exclusive IP rights over the vaccine itself, but

109. Because an IP waiver takes away the exclusivity rights of the inventor, it follows that it would be more fiscally advantageous to let another firm take on the risks and costs of development. *See generally* VAN LINDBERG, *supra* note 25 and accompanying text.

110. *See, e.g.*, Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff"*, 37 U.S. PHARM. 12 (2012) (reporting that "once drugs lose patent protection, lower-price generics quickly siphon off as much as 90% of their sales").

111. *See Generic Drugs: Questions & Answers*, U.S. FED. DRUG ADMIN. (Mar. 16, 2021), https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q3 [https://perma.cc/J6UG-533X] (finding that generic companies price drugs 80–85% less than the "name brand," in part because they incurred none of the R&D costs).

112. The idea that inventors should reap what they have sown has long been a policy objective in patent law. *See* Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988).

113. If the TRIPS waiver were enacted into U.S. law as it is proposed, pharmaceutical companies might be able to make a valid argument under the Takings Clause. *See* Adam Mossoff, *The COVID-19 Intellectual Property Waiver: Threats to U.S. Innovation, Economic Growth, and National Security*, HERITAGE FOUND. (Sept. 17, 2021), https://www.heritage.org/economic-and-property-rights/report/the-covid-19-intellectual-property-waiver-threats-us-innovation [https://perma.cc/4ZCB-NXDL].

114. *See, e.g.*, Standish Fleming, *Drug Prices and Innovation*, FORBES (June 20, 2019), https://www.forbes.com/sites/stanfleming/2019/06/20/the-relationship-between-drug-prices-and-innovation/?sh=362c77124b11 [https://perma.cc/U5MD-SV4D] ("Mega profits and dwindling productivity look bad to a public asked to pay high prices in the name of innovation. Yet those profits drive innovation throughout the industry.").

115. *See* Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, 546 (2020).

116. *Id.* at 546 fig.1.

also for the numerous patents, trade secrets, and licensing agreements that protect various processes and drug interactions.[117]

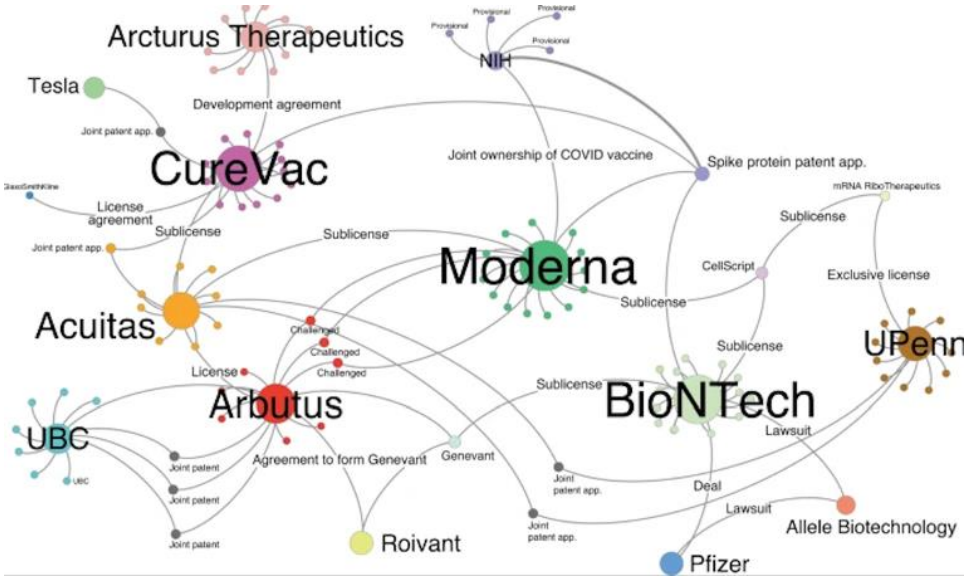

Figure 1*: The complex network of patents, licensing agreements, and lawsuits amongst the major pharmaceutical companies that led to the development of mRNA vaccines to treat COVID-19.*[118]

In conclusion, an IP waiver would effectively impact a pharmaceutical company's agreements and contracts with other manufacturing companies, expose previously undisclosed trade secrets, and give global competitors free access to dozens of patents.[119] In the following Part, this Note outlines three solutions that, when used in tandem, can more effectively provide widespread global vaccine equality, while also protecting the biopharmaceutical industry's IPRs.

IV. RECOMMENDATION

The above analysis explains that an IP waiver is not an appropriate remedy for global vaccine inequality. This Part now explores two alternatives—compulsory licensing and voluntary licensing—that, when combined, can be more effective at distributing vaccines

117. *See id.*

118. *Id.*

119. *See generally* Heidi Ledford, *What the Moderna-NIH COVID-19 Vaccine Patent Fight Means for Research*, NATURE (Nov. 30, 2021), https://www.nature.com/articles/d41586-021-03535-x [https://perma.cc/3QEM-8ZM2] (noting that pharmaceutical companies generally have dozens of patents over one vaccine); *The Deadly Side Effect of the COVID-19 IP Waiver on Trade Secrets*, PHARMALETTER (July 20, 2021), https://www.thepharmaletter.com/article/the-deadly-side-effect-of-the-covid-19-ip-waiver-on-trade-secrets [https://perma.cc/DT87-LNZM] (noting that once a trade secret is no longer a secret, all IP protection it had disintegrates).

to LMICs. Further, these options are much less likely to chill future innovation within the pharmaceutical industry.

A. Compulsory Licensing

Part II first introduced Article 31bis of the TRIPS Agreement, which provides that, in situations of "national emergencies," TRIPS members may grant compulsory licenses without first attempting to obtain a voluntary license from the patent holder.[120] Although the United States has been resistant to using TRIPS flexibilities to aid LMICs in the past,[121] the Biden administration's support for a narrower version of the COVID-19 TRIPS waiver signals a major departure. Assuming this positive shift continues, there are three motivations why compulsory licensing should be utilized in a future global health crisis.

First, because it is already part of the TRIPS Agreement, LMICs could propose that the WTO member-countries with the largest pharmaceutical industries use the national emergency exception under Article 31bis. Unlike the COVID-19 TRIPS waiver proposal—which has been stalled for months due to a lack of member support and disagreements over the waiver's broad terms[122]—governments can immediately act upon a compulsory licensing proposal.

Second, despite the pharmaceutical industry's aversion,[123] compulsory licenses are unlikely to have a long-lasting negative impact on innovation in the industry.[124] Because Article 31 has an "adequate remunerations" provision,[125] pharmaceutical companies may be reassured that they will enjoy some return on their investment. Additionally, any innovative harm is limited by the duration and scope requirements of compulsory licensing under Article 31.[126] Specifically, the license "must be limited to the purpose for which it was granted, it cannot be given exclusively to licensees (e.g., the patent-holder can continue to produce), and it should be subject to legal review."[127]

Third, compulsory licenses have "been reported as having resulted in substantially

120. TRIPS Agreement, *supra* note 37, art. 31*bis*.

121. *See* Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1, 2 (2012) ("At the height of the HIV/AIDS epidemic, US trade officials objected to drug licensing practices in South Africa and especially Brazil, against whom the US filed a complaint with the WTO Dispute Settlement Body (which it later withdrew).").

122. *See* Latha Jishnu, *The Fading Mirage of a TRIPS Waiver*, DOWNTOEARTH (Oct. 11, 2021), https://www.downtoearth.org.in/blog/health/the-fading-mirage-of-a-trips-waiver-79634 [https://perma.cc/TY53-5GDF] (stating that "a report by news agency Reuters from Geneva indicated the negotiations had hit a cul-de-sac, quoting trade sources who had attended a closed-door TRIPS Council meeting on October 4" and that "[t]he report said Norway's Dagfinn Sorli, chair of the Council, seemed frustrated on the way forward").

123. Of the twenty largest pharmaceutical companies, only four (Eisai, GSK, Johnson & Johnson, and Merck) publicly support the Doha Declaration (codified in the TRIPS Agreement as Article 31*bis*) on a consistent basis. *See* ALEX KONG ET AL., ACCESS TO MED. FOUND., FIRST INDEPENDENT TEN-YEAR ANALYSIS: ARE PHARMACEUTICAL COMPANIES MAKING PROGRESS WHEN IT COMES TO GLOBAL HEALTH? 1, 32 (May 2019).

124. *See* Rutschman & Barnes-Weise, *supra* note 62.

125. *See* TRIPS Agreement, *supra* note 37, art. 31(h). Importantly, the WTO has purposely left "adequate remuneration" undefined. *See Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/Q9QT-5C69]. What constitutes "adequate" compensation is a question for the authorities in the countries concerned to decide. *Id.*

126. *See* TRIPS Agreement, *supra* note 37, art. 31(c).

127. *See Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 125.

reduced prices of patented medicines during the patent term."[128] For more complex biologics, however, compulsory licensing alone may not be an effective solution. This Note thus recommends that, for complex biologics, compulsory licensing will be most effective when combined with incentivized voluntary licensing.

B. Incentivized Voluntary Licensing

In the pharmaceutical context, a voluntary license is generally considered an "arrangement in which developers enter into binding contractual agreements with generic producers."[129] While this may seem hard to legislate, governments should incentivize collaboration between pharmaceutical companies and manufacturers by offering tax breaks. One benefit of this method is that, unlike compulsory licenses (which only apply to licensing patents), voluntary licensing gives a pharmaceutical company the freedom to license both its patents and trade secrets to a third party.[130] Because complex biologics are not as easily reverse-engineered as their small-molecule counterparts,[131] access to trade-secret-protected manufacturing processes would give a generic company a complete blueprint to replicate the vaccine developed by the contracting pharmaceutical company.

Of course, pharmaceutical companies prefer this alternative to compulsory licensing, as it allows them to contract with generic companies and manufacturers that they believe can meet certain quality standards. From a public perception standpoint, it also looks much better for the pharmaceutical industry to work together voluntarily instead of government-forced collaboration amongst its players.[132] And, given the industry's notoriously bad image in recent years due to its role in the opioid crisis,[133] any opportunity to regain the public's trust might be just as valuable as profits. One financial analyst commented on Pfizer's role in the COVID-19 pandemic, stating that "[f]or Pfizer, this is as much public relations as it is a financial return—they very much want to be seen as part of the solution."[134] This Note contends that the threat of compulsory licensing can itself

128. WTO ET AL., PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 109 (2d ed. 2020). Ecuador, for example, procured a compulsory license over etoricoxib from India in 2014, which reportedly dropped the price "from US$ 0.84 per tablet to US$ 0.0084." *Id.* at 240.

129. Silverman, *supra* note 88.

130. WTO ET AL., *supra* note 128, at 109 (admitting that "compulsory licenses may have limited effectiveness for more complex technologies such as biotherapeutics, as they do not oblige the patent owners to cooperate in divulging trade secrets about production processes, transferring the additional know-how . . . that might be required."). This has prompted some legal scholars to advocate for an additional mechanism of compulsory licensing of trade secrets. *See* Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRAC. 1242 (2021).

131. WTO ET AL., *supra* note 128, at 108–09.

132. As noted in Part III.B, the pharmaceutical industry voluntarily collaborated to develop COVID-19 vaccines, despite competing against one another. *See supra* Part III.B. The pharmaceutical industry enjoyed a major surge in public opinion during this period. Marc Iskowitz, *Everybody Loves Pharma? Unexpected Reputational Gains Since COVID-19 Crisis*, THE HARRIS POLL, https://theharrispoll.com/everybody-loves-pharma-unexpected-reputational-gains-since-covid-19-crisis/ [https://perma.cc/3LH8-L28A].

133. *See, e.g.*, Jan Hoffman & Katie Benner, *Purdue Pharma Pleads Guilty to Charges for Opioid Sales*, N.Y. TIMES (Sept. 1, 2021), https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html [https://perma.cc/J3CS-XR9R].

134. Sharon LaFraniere et al., *Politics, Science and the Remarkable Race for a Corona Virus Vaccine*, N.Y. TIMES (Nov. 30, 2020), https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html [https://perma.cc/99WE-ZBBR].

incentivize pharmaceutical companies to seek out voluntary licensing arrangements. Indeed, the pharmaceutical industry has in the past used voluntary licensing as a "strategy" to mitigate the threat of compulsory licensing.[135]

V. CONCLUSION

COVID-19 was the first modern paradigm for the global pandemic response. While there were many triumphs—such as the heroic dedication of medical providers and rapid vaccine development—COVID-19 nevertheless cost millions of lives and underscored the disparate access to healthcare between developed nations and LMICs.[136] When—not if—the next global health crisis materializes, we must correct the faults from the COVID-19 response while maintaining or improving upon the triumphs. An IP waiver would not only fail in its aim to resolve global healthcare access, but it also would discourage pharmaceutical companies from undertaking the high risks and costs that accompany developing complex biologics.

Dampening the reward of innovation for the world's leading epidemiologists during a global pandemic is extremely unwise. For, without a viable vaccine, conversations about how it should be globally distributed are merely hypothetical. Sadly, even in a state of global emergency, it is improbable that a sense of moral duty alone will incentivize the pharmaceutical industry to bear the R&D costs and risks of vaccine development.

This Note recommends that when the next global health crisis occurs, high-income countries with strong pharmaceutical industries must be willing to issue compulsory licenses for life-saving vaccines. However, because compulsory licensing only pertains to patents, more is needed to ensure technology transfers occur between the producing pharmaceutical company and the generic company. Thus, high-income countries should also incentivize voluntary licensing in their pharmaceutical industries. This may require legislation to reward the pharmaceutical companies that voluntarily contract with generic brands in the form of tax breaks. The threat of compulsory licensing alone has also been documented as a strong incentive for pharmaceutical companies to license voluntarily.

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135. Daniel D. Kim, *Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing*, 8 AM. U. INTELL. PROP. BRIEF 63, 80 (2016).

136. *See, e.g.*, Anna Rouw et al., *Tracking Global COVID-19 Vaccine Equity*, KAISER FAM. FOUND. (July 21, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/tracking-global-covid-19-vaccine-equity/ [https://perma.cc/GZ6V-C3QW].