Patent Philanthropy

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As in previous global public health crises, such as the HIV epidemic, patents have presented a major obstacle to vaccine supply amid the devastating COVID-19 pandemic. Compulsory licensing and intellectual property waiver have been put forth as solutions. However, as this Article and other studies reveal, neither proposal alone can address global vaccine inequality with sufficient urgency. Nor would these measures significantly improve the capacity of developing countries to produce medicines and vaccines.

This Article proposes the establishment of a Patent Philanthropy Initiative (PPI) to overcome the inadequacies of compulsory licensing and intellectual property waiver and equip the global community with better preparedness for future public health crises. The United States Patent and Trademark Office (USPTO) would be called upon to administer the PPI. Pharmaceutical companies owning USPTO-granted medical patents would be required to contribute 1% of their annual post-tax profits accrued from their patented medicines to the PPI. Such financial contributions would then be deployed by pharmaceutical companies to promote public health in the United States and abroad through transferring knowledge, donating medical products, constructing facilities, training professionals, and facilitating public health education.

This Article defends the validity of the PPI against concerns that it would violate the TRIPS Agreement and the U.S. Constitution and discourage investment in medical innovation. It illustrates the PPI's economic and social functions in improving the capacity of developing countries to produce pharmaceuticals, and its ethical function in prompting pharmaceutical companies to accept greater responsibility for the protection of public health. These functions are discussed in the context of the COVID-19 pandemic and beyond.

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Introduction

The protection of patents can have fatal consequences for humans.[1] The coronavirus pandemic has claimed hundreds of thousands of lives in parts of the world where appropriate patented medicines and vaccines are severely lacking.[2] Amid this ongoing catastrophe, an intellectual property

1. *See* MADHAVI SUNDER, FROM GOODS TO A GOOD LIFE: INTELLECTUAL PROPERTY AND GLOBAL JUSTICE 177 (2012) ("Patents are a question of life *and death*.") (emphasis in original). Media have reported how patents hindered timely provisioning of affordable medical products to patients infected with coronavirus. *See* Morgan Watkins, *Kentucky Gov. Andy Beshear Calls on 3M to Release Patent for N95 Respirator Amid Pandemic*, LOUISVILLE COURIER J. (Apr. 3, 2020, 4:37 PM), https://www.courier-journal.com/story/news/2020/04/03/beshear-calls-3-m-release-patent-n-95-respirator-amid-pandemic/5112729002/ [https://perma.cc/S428-MAT7]; Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, 546 (2021), https://www.nature.com/articles/s41587-021-00912-9 [https://perma.cc/AEX8-823Y] ("[B]arriers such as the vaccine cold chain and multiple forms of intellectual property (IP) protection stand in the way of equitable access and fair allocation.").

2. *WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG. (Aug. 5, 2021, 6:08 PM CEST), https://covid19.who.int [https://perma.cc/ZR52-85QF] ("Globally, as of 6:08pm CEST, 5 August 2021, there have been 200,174,883 confirmed cases of COVID-19, including 4,255,892 deaths, reported to WHO.").

waiver has been proposed by certain countries and then negotiated under the auspices of the World Trade Organization (WTO).[3] Designed to temporarily lift patent protection for COVID-19-related medicines and vaccines, the waiver seeks to promote the expeditious scaling up of COVID-19 vaccine manufacture and distribution across the globe.[4]

World leaders including United States President Joe Biden, policymakers, and scholars have high hopes for this proposal.[5] Yet, as it stands, the intellectual property waiver is unlikely to deliver on its promise.[6] Worse still, some studies have presented a gloomy picture, predicting that "most people in low-income countries will be waiting until 2024 for COVID-19 vaccinations."[7]

What makes this "right and fair"[8] waiver proposal incapable of relieving pandemic suffering? First, profit-driven pharmaceutical companies vehemently oppose it and will not willingly transfer confidential COVID-19 vaccine manufacturing knowledge to developing countries.[9] Second, the proposal's prospects are further doomed by lack of raw materials and facilities necessary for manufacture of COVID-19 vaccines.[10] Even if the waiver were adopted tomorrow, developing countries' weak capacities in pharmaceutical manufacturing render any ramping up of COVID-19 vaccine production an impossibility in the short term.[11]

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3. *Members Approach Text-Based Discussions for an Urgent IP Response to COVID-19*, WORLD TRADE ORG. (June 9, 2021), https://www.wto.org/english/news_e/news21_e/trip_09jun21_e.htm [https://perma.cc/F666-J8YZ].

4. *See infra* Part I.B.

5. Max Bearak & Emily Rauhala, *Hopes Surge for Boosted vaccine Supply after U.S. Voices Support for Waiving Patents, Even as Uncertainty Remains*, WASH. POST (May 6, 2021, 5:02 PM) https://www.washingtonpost.com/world/2021/05/06/vaccine-intellectual-property-world-reaction/ [https://perma.cc/TLY3-DR57].

6. *See infra* Part I.B.

7. *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*, DUKE GLOB. HEALTH INST. (Nov. 9, 2020), https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive [https://perma.cc/Z694-CF7A]; Matthew Kavanagh & Madhavi Sunder, *Opinion: Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That.*, WASH. POST (Mar. 10, 2021, 5:01 PM), https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/ [https://perma.cc/AXJ8-JK7F] ("Indeed, experts say that without significant policy changes, poor countries may not be vaccinated against covid-19 until 2023 or 2024.").

8. *A Patent Waiver on COVID Vaccines is Right and Fair*, NATURE (May 25, 2021), https://www.nature.com/articles/d41586-021-01242-1 [https://perma.cc/J3VV-PKXW].

9. *See infra* Part I.B; Sarah Lazare, *Pfizer Helped Create the Global Patent Rules. Now it's Using Them to Undercut Access to the Covid Vaccine*, IN THESE TIMES (Dec. 17, 2020), https://inthesetimes.com/article/pfizer-covid-vaccine-world-trade-organization-intellectual-property-patent-access-medicines [https://perma.cc/2ZVK-FV2Z] ("Pfizer is not alone in staking out its opposition to pausing intellectual property rules. Pharmaceutical industry trade groups and individual companies . . . including Moderna, which is behind another leading Covid-19 vaccine . . . have all come out in full force against the proposal for reprieve from stringent intellectual property rules.").

10. *See infra* Part I.B.

11. *See infra* Part I.B. *See also*, William Fisher, Ruth Okediji, & Padmashree Gehl Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 MICH. J. INT'L L. (forthcoming 2021) (unpublished manuscript at 1), https://

The pandemic has exposed what could be described as moral and institutional comorbidities. Pharmaceutical companies continue to prioritize profits at the expense of human lives.[12] Yet, others still claim that the companies are socially responsible organizations.[13] However, how can we expect pharmaceutical companies to behave responsibly if they cannot even do so in a pandemic? What is more, death tolls have risen sharply in many developing countries due to a chronic failure of their institutions to build strong, local medicine and vaccine production capacities.[14]

In response, I propose that the United States Patent and Trademark Office (USPTO) establish and administer a Patent Philanthropy Initiative (PPI). Pharmaceutical companies owning medical patents granted by the USPTO would be required to contribute 1% of their annual post-tax profits from the sale of their patented pharmaceuticals to the PPI.[15] They should deploy these contributions to transfer knowledge, donate medical products, construct facilities, train professionals, and facilitate public health education, all in the service of promoting public health.[16] Approximately half of the funds would be devoted to carrying out these actions in the United States (U.S.) and the other half in developing or least-developed countries. This pilot program would be reviewed periodically so that proper adjustments can be introduced.[17] The USPTO's PPI will also encourage other countries to create PPIs through their patent offices.

As I discuss in this Article, the PPI will not bring the U.S. into noncompliance with the minimum intellectual property protection standards set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[18] Nor will the PPI violate the Property Takings Clause under the U.S. Constitution.[19] Further, participating pharmaceuti-

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papers.ssrn.com/sol3/papers.cfm?abstract_id=3825165 [https://perma.cc/MTV7-FCYH] ("As suggested by these debates, the problem of how best to facilitate access to medicines in developing countries is complex. What is clear, however, is that the existing system of pharmaceutical drug development and distribution is severely deficient with respect to the needs of developing countries.").

12. Press Release, Oxfam Int'l, *Vaccine Monopolies Make Cost of Vaccinating the World Against COVID at Least 5 Times More Expensive Than It Could Be* (July 29, 2021), https://www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more [https://perma.cc/UK8G-Q2FT] (citing the assertion that "[p]harmaceutical companies are holding the world to ransom at a time of unprecedented global crisis. This is perhaps one of the most lethal cases of profiteering in history.").

13. *See Global Report: Pfizer is a Socially Responsible Vaccine Producer*, THE CSR J. (June 1, 2021), https://thecsrjournal.in/pfizer-global-report-esg-pharma-vaccine-producer/ [https://perma.cc/Z3J3-4LB2].

14. *See infra* Part I.B.; *See also*, NATURE, *supra* note 8 ("The core problem is that vaccine manufacturing, research and development is too heavily concentrated in a small group of high- and middle-income countries.").

15. *See infra* Part II.A.2.

16. *See infra* Part II.A.1.

17. *See infra* Part II.A.3.

18. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 213999 [hereinafter TRIPS Agreement]. *See infra* Part III.A.1.

19. *See infra* Part III.A.2.

cal companies' surrender of 1% of their annual profits will not disrupt the patent law objective of incentivizing investment in innovation. Hence, the PPI will not affect medical innovation contributed by these companies.[20]

With those legal and policy concerns addressed, I demonstrate that the PPI can help alleviate the moral and institutional afflictions that weaken global society. The PPI is designed to achieve a moral awakening of pharmaceutical companies.[21] These companies have avoided their responsibilities by systematically abusing patent practices through insufficient disclosure of patent information, exaggerating their sole contributions to medical innovations, and failing to reciprocate for their publicly funded research.[22] Some of the PPI's purposes is to correct dishonest or bad-faith actions such as the aforementioned, to treat a pharmaceutical company's engagement in the PPI as a responsibility triggered by the grant of patent rights through the USPTO and to suggest charitable schemes through which these companies can translate their responsibilities on paper into real action.[23]

I also explore how the PPI can ameliorate the institutional failures that have made developing countries reliant on import or donation of patented medicines and vaccines during the COVID-19 pandemic. The PPI has five categories of charitable schemes through which it encourages an increased transfer of pharmaceutical production knowledge, more donations of medical products, enhanced contributions to the construction of research and manufacturing facilities, better training of medical professionals, and wider access to public health education. These efforts would incrementally improve local production capacities in developing countries.[24] The PPI would also benefit the U.S.—a country that has, so far, the highest COVID-19 infection rate and death toll—by devoting approximately half of all financial contributions to the implementation of these charitable schemes within the U.S.[25]

The PPI proposal provides three original contributions to patent law and public health scholarship. First, it offers a novel approach to reforming patent law to better promote public health. As shown in this Article, the PPI can help fix the problems associated with the compulsory licensing and intellectual property waiver proposals by enhancing their public health protection functions. Leading scholars have considered innovative means of improving developing countries' pharmaceutical production capacities.[26] The PPI offers a constructive, alternative approach that

20. *See infra* Part III.B.

21. SUNDER, *supra* note 1, at 187 (arguing that compulsory licensing is designed to "correct a moral failure, not a market failure"); Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicine Tool*, 102 MINN. L. REV. 2463, 2480–81 (2018).

22. *See infra* Part IV.B.

23. *See infra* Part IV.B.

24. *See infra* Part II.A.

25. *See infra* Part II.

26. *See, e.g.*, Fisher et al., *supra* note 11, at 29–30 (arguing the USTR should be involved in promoting local production of medicines and drugs in developing countries). SUNDER, *supra* note 1, at 189–97 (discussing tools to expand access to medicines

involves inducing more responsible involvement on the part of pharmaceutical companies and governmental institutions, such as, the USPTO.[27]

Second, the PPI proposal sheds new light on the nature and role of patents. Treating the patent as an absolute private property, conventional wisdom prioritizes private interests in the legal protection of patents.[28] Pharmaceutical companies routinely apply this private property notion to assert that their patent rights are derived solely from their own innovation and that any under-protection of these rights would harm medical innovation.[29] The PPI proposal defies this notion of patents. Drawing on the Supreme Court's definition of patents as "public franchises,"[30] it argues that patent protection should prioritize public interests and particularly those pertinent to public health. This new approach to patents would, this Article shows, prompt the USPTO to set up a pilot program for the PPI.[31]

Third, the PPI proposal offers a dynamic vision for pharmaceutical companies' responsibilities. Scholars have exposed and condemned as irresponsible these companies' exploitations of patent law through abusive measures that drive up prices of their products and fortify their control of the medical market.[32] But, what is lacking is an overarching justification for imposing responsibilities upon pharmaceutical companies that compel them to exercise their patent rights in better service of the public interest.[33] This Article fills this void in patent law literature. It considers why pharmaceutical companies should take more responsibility based on a synthe-

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in developing countries); W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-scale Vaccine Manufacturing*, 369 SC. MAG. 912, 912 (2020).

27. *See infra* Part IV.A.

28. *See* Ex parte Wood & Brundage, 22 U.S. 603, 608 (1824) (stating that patent law "intended to give [a patentee] the absolute enjoyment and possession"). Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. Rev. 689, 690–691 (2007).

29. *See infra* Part I.B (discussing pharmaceutical companies' arguments that the intellectual property waiver proposal will harm their innovation); *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 710 (2011) ("[T]he very theory of patent law is based on the idea that a lone genius can solve problems that stump the experts, and that the lone genius will do so only if properly incented by the lure of a patent."); *See* Christopher A. Cotropia, *The Individual Inventor Motif in the Age of the Patent Troll*, 12 YALE J.L. & TECH. 52, 55 (2009–2010) ("The patent system has traditionally taken the individual inventor motif to heart and seen patents as a vehicle to both fuel individual inventors and protect them from large corporations").

30. Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1374–1375 (2017).

31. *See infra* Part II.A.

32. *See* REP. OF THE U.N. SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 21 (2016) [hereinafter PANEL ON ACCESS] ("IP rights confer patent monopolies on the right holder, who in turn often charges whatever price the market will bear."). ROBIN FELDMAN, DRUGS, MONEY, & SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 1–3 (2019); ROBIN FELDMAN, DRUG WARS: HOW BIG PHARMA RAISES PRICES & KEEPS GENERICS OFF THE MARKET 2 (2017); Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 999–1000 (2012).

33. *See* Haochen Sun, *Corporate Fundamental Responsibility: What Do Technology Companies Owe the World?*, 74 U. MIA. L. REV. 898, 902, 904 (2020) (arguing that technology companies should take more responsibilities).

sis of public interest associated with sufficient disclosure of patent information and adequate reciprocation for another's research contributions and public funding.

The remainder of this Article is structured as follows. Part I examines the inadequacies of the compulsory licensing and intellectual property waiver proposals in generating effective pandemic relief actions for the global community. Part II presents the PPI as an alternative, or complement, to these proposals, detailing the structure of its USPTO-administered pilot program and its economic function in improving public health. Part III responds to concerns that the PPI may violate the TRIPS Agreement and the U.S. Constitution and disincentivize investment in medical innovation. Part VI explores the PPI's ethical functions in fostering responsible institutional actions that protect public health. To this end, Part VI considers why the USPTO should take responsibility for overseeing the PPI and pharmaceutical companies to better promote public health domestically and internationally.

I. Proposed Solutions

In this part, I examine how and why compulsory licensing and intellectual property waiver have been proposed as effective means of removing patent barriers amid the COVID-19 pandemic. Neither proposal, I argue, promotes the immediate scaling up of COVID-19 vaccine manufacture and distribution at a global level.

A. Compulsory Licensing

In a public health crisis, compulsory licensing empowers a government to authorize a third party to manufacture a patented medicine or practice a patented medical process without the patent holder's consent.[34] The government, meanwhile, guarantees that the patent holder will receive fair compensation.[35] In November 2001, the Doha Declaration on the TRIPS Agreement and Public Health[36] made clear that World Trade Organization (WTO) member states should enjoy sufficient latitude in granting

34. *See* TRIPS Agreement, *supra* note 18, art. 31. Creating compulsory licensing as a limitation on patent rights, Article 31 of the TRIPS Agreement stipulates some general compulsory licensing rules: (a) authorization shall be considered on its individual merits; (c) the scope and duration of licenses shall be limited to the purpose for which it was authorized; (d) licenses should be non-exclusive; (e) licenses should be non-assignable; and (f) licenses shall be issued predominantly for the supply of the WTO member's domestic market. However, Article 31(b) also establishes that the general requirement that compulsory licenses be preceded by efforts to obtain authorization from a right owner on reasonable commercial terms and conditions can be waived "in the case of *a national emergency* or other circumstances of *extreme urgency*" (emphases added).

35. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/5L2Z-8MLC]; Bagley, *supra* note 21, at 2465, 2466 (2018).

36. *Declaration on the TRIPS Agreement and Public Health*, Nov. 14, 2001, DOHA WORLD TRADE ORG, MINISTERIAL CONFERENCE, WT/MIN(01)/DEC/2 (2001) [hereinafter Doha Declaration].

compulsory licensing to alleviate public health crises such as the HIV/AIDS, tuberculosis, and malaria epidemics.[37]

Compulsory licensing allows the authorized third party to scale up its manufacturing capacity and lower prices, thereby increasing both availability and affordability of critical medicines.[38] In response to the HIV epidemic in Africa, for instance, South Africa has granted compulsory licenses to make generic HIV medicines available through importation.[39] The U.S. has used compulsory licensing as a bargaining tool in price negotiations for medicines. Facing the possibility of terrorists using anthrax as a biological weapon after the September 11 attacks in 2001, the U.S. sought to stockpile the antibiotic ciprofloxacin (Cipro). Patent owner Bayer initially resisted lowering prices or ramping up production, and it was only after the U.S. government threatened to invoke compulsory licensing that Bayer provided a 50% price discount and guaranteed adequate supply.[40]

Unsurprisingly, scholars and policymakers first proposed compulsory licensing as a means of addressing the global shortage of COVID-19 therapies and vaccines.[41] A government may take advantage of the TRIPS

37. *Id.* ¶5 (b) & (c) ("Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.").

38. Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of WTO Rules*, 37 J.L. MED. & ETHICS 222, 223 (2009) (arguing that compulsory licensing aims to provide an "efficient and straightforward means for developing countries to improve access to needed therapies through generic competition"); 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 367, 381 (2020) ("In our systematic review, we verified a mean price reduction between 66.2 and 73.9% for the 24 compulsory licensing events for which price data are available. Therefore, it would seem that compulsory licensing is indeed an effective mechanism for price reduction with increased availability.").

39. *See* Heinz Klug, *Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic*, 37 L. & SOC. INQUIRY 297, 314 (2012) (discussing the legislation); *See also The Price of Africa's Cheap Drugs*, THE ECONOMIST (Apr. 19, 2001), http://www.economist.com/node/578891 [https://perma.cc/2LMB-X9SN] (noting that South Africa was negotiating with an Indian generic manufacturer, Cipla, to cheaply obtain AIDS drugs).

40. Hannah Brennan, et. al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. TECH. 275, 303 (2016) ("Thompson's public discussion of importing generic versions of the antibiotic ciprofloxacin under § 1498 drove the relevant patent holder, Bayer, to cut its prices by half."); Gorik Ooms & Johanna Hanefield, *Threat of Compulsory Licences Could Increase Access to Essential Medicines*, BMJ (May 28, 2019), https://www.bmj.com/content/365/bmj.l2098, [https://perma.cc/R5GD-LSAH].

41. *See, e.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 CONN. L. REV. 57, 59–60 (2022); Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 VIEWPOINTS 1, 4 (2020) (arguing that compulsory licensing serves an important public health function by "alleviating insufficient supplies of necessary pharmaceuticals as well as mitigating prohibitively expensive drug prices").

Agreement and Doha Declaration to grant a compulsory license to allow a willing producer to make COVID-19 vaccines without the consent of the relevant patent holder. Afterwards, the government should provide the patent holder with fair compensation.[42]

Since the start of the COVID-19 pandemic, the European Union (E.U.) and its members have been strong supporters of compulsory licensing,[43] and therefore, have presented it to the WTO as a solution to the global vaccine inequality.[44] In March 2020, the governments of France and Germany passed emergency laws to make explicit their compulsory licensing power, and the E.U. officially embraced compulsory licensing as part of its IP Action Plan in November 2020.[45] This plan calls on member states to not only "pu[t] in place fast-track procedures for issuing compulsory licenses in emergency situations"[46] but also to support developing countries in doing the same to combat COVID-19.[47] Beyond the E.U., developed countries, including Canada and Israel, have also strongly supported compulsory licensing.[48] In March 2020, for example, Israel issued a compulsory license to import generic versions of AbbVie's antiretroviral drug, Kaletra, after the Ministry of Health determined it could be a possible treatment for patients with COVID-19.[49]

However, compulsory licensing will not increase availability of COVID-19 vaccines to an adequate extent in the short or immediate term.[50] There are several reasons for this. First, almost all developing countries lack capacity to manufacture vaccines. Many African countries,

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42. Kumar, *supra* note 41, at 66, 92.

43. *Questions and Answers: EU Communications to the WTO - EU Proposes a Strong Multilateral Trade Response to the COVID-19 Pandemic*, EUR. COMM'N (June 2, 2021), https://ec.europa.eu/commission/presscorner/detail/nl/qanda_21_2802 [https://perma.cc/9BRR-DH9C] ("In the absence of voluntary licences, compulsory licences are a legitimate tool to ensure that intellectual property rights do not hinder the expansion of production during the pandemic.").

44. Communication from the European Union to the Council for TRIPS: Urgent Trade Policy Responses to the COVID 19 Crisis: *Intellectual Property*, ¶ 11, WTO Doc. IP/C/W/680 (June 4, 2021) ("The EU proposes to clarify that in the circumstances of a pandemic, WTO Members can set the remuneration to the right holder at a level that reflects the price charged by the manufacturer of the vaccine or therapeutic under a compulsory licence. This would support production and supplies of vaccines and therapeutics at affordable prices to low and middle-income countries.").

45. *See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the Most of the EU's innovative potential: An intellectual property plan to support the EU's recovery and resilience*, at 12, COM (2020) 760 final (Nov. 11, 2020).

46. *Id.*

47. *See id.* at 17–18.

48. Kumar, *supra* note 41, at 86.

49. *AbbVie Drops Patent rights for Kaletra Antiviral Treatment*, FIN. TIMES (Mar. 23, 2020), https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b [https://perma.cc/9953-EK9B].

50. 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*, (LSE Law, Society and Economy Working Papers, Paper No. 06/2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737 [https://perma.cc/H5EL-R75C] (explaining "why the existing TRIPS flexibilities around compulsory licensing are incapable of addressing

with the possible exception of South Africa and Egypt, "lack even the capacity to produce formulations and only a few of these countries invest in research and development for new drugs or even conduct research in the pharmaceutical sector."[51] Zimbabwe faced this issue at the height of the HIV/AIDS crisis when, despite issuing compulsory licenses, local manufacturing deficiencies meant drug prices remained high and access low.[52] A report in October 2005 found that the prices of antiretroviral drugs had quadrupled in the previous three months, while another at the end of 2006 found that only about 52,000 people of the 350,000 who needed antiretroviral drugs were receiving them.[53]

Second, there are inherent deficiencies in developing and least developed countries that make compulsory licensing an inadequate mechanism for increasing access to medicine. For instance, taking advantage of TRIPS Article 31 requires "technical expertise, intergovernmental coordination, and legal sophistication, which are often lacking in developing governments."[54] Further, developing countries often lack the disease diagnosis capabilities necessary to properly assess needs and request adequate quantities of appropriate medicines in a compulsory license.[55] When addressing a problem as massive as COVID-19, the utility of Article 31 is not the same for all countries. While countries with manufacturing capacity can employ compulsory licenses effectively, developing countries most in need of assistance are disadvantaged.[56]

Third, Article 31*bis* of the TRIPS Agreement has been proven to be ineffective. Article 31*bis* allows a member state that lacks the capacity to manufacture a patented medicine under compulsory licensing to import it from another member state.[57] However, the Article 31*bis* mechanism remains in limbo because few countries have revised domestic laws to activate it.[58] In fact, since its introduction in 2003, the mechanism has only been used once.[59] That sole instance involved a collaboration between Rwanda as the importing country and Canada as the exporting country for

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the present pandemic context adequately, in terms of both procedure and legal substance.").

51. *See* Ebenezer Durojaye, *Compulsory Licensing and Access to Medicine in Post Doha Era: What Hope for Africa?*, 55 NETHERLANDS INT'L L. REV. 33, 49, 51 (2008).

52. *Id.* at 59.

53. *Id.*

54. *See* Dina Halajian, *Inadequacy of Trips & the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Program*, 38 BROOK. J. INT'L L. 1191, 1211 (2013).

55. *See id.*

56. *See* Prabhash Ranjan, *The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines*, 456 OBSERVER RSCH. FOUND. ISSUE BRIEF 1, 8 (2021).

57. *See* Halajian, *supra* note 54, at 1201.

58. *See* William Alan Reinsch, *Compulsory Licensing: A Cure for Distributing the Cure?*, CTR. FOR STRATEGIC & INT'L STUD. (May 8, 2020), https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure [https://perma.cc/28FV-9K8N] ("Many countries have not enacted domestic legislation to incorporate Article 31bis, making it non-operational.").

59. *See, e.g.*, Halajian, *supra* note 54, at 1204.

the antiretroviral drug Apo-TriAvir.[60] It took the Canadian generic company Apotex *three* years to supply the medicine.[61] Commentators have suggested that underuse of the Article 31*bis* system is not only due to the complexity, length, and cost of the undertaking process, but also the burdensome requirements, the challenge of recovering expenditure, and the resulting lack of incentives for generic manufacturers.[62] For example, the exporting country must ensure that the drugs are exported only to the importing country, are made as easily identifiable in color or shape as generic drugs, and are manufactured only in the specific amount necessary to meet the importing country's requirements.[63] The challenge of achieving economies of scale in countries with little manufacturing capacity presents further obstacles, as these countries are usually small in size.[64]

B. Intellectual Property Waiver

In October 2020, South Africa and India submitted an intellectual property waiver request through the WTO.[65] They argued that because the compulsory licensing process under the TRIPS Agreement is "cumbersome and lengthy,"[66] it cannot address the severe shortage of COVID-19 vaccines in developing countries.[67] Further, they argued that an unprecedented solution was needed to address the unprecedented trade impact of a pandemic that could not be effectively contained without expeditious access to affordable medical products, including diagnostic kits, personal protective equipment, ventilators, medicine, and vaccines.[68] While some countries are in a position to overcome supply issues by manufacturing their own medical products, many developing or least developed countries are not and, therefore, remain extremely vulnerable without a rapid scaling up of global production.[69]

In their submission, South Africa and India asserted that intellectual property rights are a major cause of manufacturing and supply problems, referring to reports suggesting that these rights are hindering, or potentially hindering, the "timely provisioning of affordable medical products."[70] South Africa and India noted that some WTO members had been

60. *See* Yahong Li, *Intellectual Property and Public Health: Two Side of the Same Coin*, 6 ASIAN J. WTO & INT'L HEALTH 389, 409–10 (2011).
61. *See id.* at 411.
62. *See* Halajian, *supra* note 54, at 1203.
63. *Id.* at 1211.
64. *See* Ranjan, *supra* note 56, at 9.
65. Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention and Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter *Waiver from Provisions*]. The request cited a WTO warning that the current COVID-19 pandemic represented an unprecedented disruption to the global economy and world trade and claimed that this had been realized through "a break down in global supply chains coupled with growing supply-demand gaps."; *See also id.* at 4.
66. Ranjan, *supra* note 56, at 10.
67. *See id.*
68. *Waiver from Provisions*, *supra* note 65.
69. *See id.*
70. *Id.*

forced to enact amendments to national patent laws to expedite the issue of compulsory licenses.[71]

In response to the need for global solidarity and sharing of technology, South Africa and India proposed waiving the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part 2 of the TRIPS Agreement.[72] These sections cover copyright and related rights, industrial designs, patents, and undisclosed information, respectively. The waiver, once adopted, should remain in place until widespread vaccination is in place globally and a majority of the world's population has developed COVID-19 immunity.[73]

This intellectual property waiver request is gaining increasing support. China has given its backing,[74] and President Joe Biden issued a statement outlining his support for the waiver in May 2021.[75] This represented a monumental shift in U.S. policy, breaking with decades of bipartisan support for strong protection of intellectual property rights.[76] The U.S. Trade Representative followed the President's indication of support with a statement declaring that the extraordinary circumstances of the COVID-19 pandemic required extraordinary measures.[77] However, this statement did not go so far as to back South Africa and India's specific waiver request, suggesting that there may need to be some further negotiation of the actual text of the waiver.[78] As of May 2021, over 120 countries have backed the intellectual property waiver proposal.[79]

Proponents of the waiver claim that it is a necessary response to the current crisis.[80] Just as the AIDS crisis prompted the Doha Declaration,

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71. *Id.* (The waiver request cited: Susan Decker & Christopher Yasiejko, *World War II-Style Mobilization Order May Carry Risks*, BLOOMBERG (Mar. 21, 2020), https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-may-carry-legal-risks-for-patriots [https://perma.cc/E8Z9-PC9R]; Morgan Watkins, *Kentucky Gov. Andy Beshear Calls on 3M to Release Patent for N95 Respirator Amid Pandemic*, COURIER J. (Apr. 3, 2020)).

72. *See Waiver from Provisions, supra* note 65.

73. *See id.*

74. *See* Simone McCarthy, *China Backs IP Waiver for Coronavirus Vaccines*, S. CHINA MORNING POST (May 17, 2021), https://www.scmp.com/news/china/science/article/3133831/china-backs-ip-waiver-coronavirus-vaccines [https://perma.cc/6RGX-YQ9U].

75. *See* Andrea Shalal, Jeff Mason & David Lawder, *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, REUTERS (May 5, 2021, 3:10 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ [https://perma.cc/XZ58-SFM3].

76. *See* John Zarocostas, *What Next for a COVID-19 Intellectual Property Waiver?*, 397 THE LANCET 1871, 1871 (2021).

77. *See* Miriam Berger, *What it Means for the U.S. to Back Waivers on Coronavirus Vaccine Patents*, WASH. POST (May 6, 2021, 4:42 PM), https://www.washingtonpost.com/world/2021/05/06/coronavirus-vaccine-patent-waiver-biden-wto [https://perma.cc/T9BC-2S9Z].

78. *See id.*

79. *See Over 120 Countries back IP Rights Waiver on Covid-19 Vaccines*, PHARM. TECH. (May 7, 2021), https://www.pharmaceutical-technology.com/news/ip-waiver-covid-19-vaccines [https://perma.cc/3RWF-TXLR].

80. *See* 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* 3 (LSE Legal Studies Working Paper No. 06/2021), https://papers.ssrn.com/sol3/

the scale of the COVID-19 pandemic necessitates an immediate and substantial response in the form of a temporary intellectual property waiver,[81] particularly in light of prevailing vaccine inequality. While the U.S. and U.K. had already vaccinated around half of their population by early May 2021, vaccination rates in developing economies were significantly lower,[82] with India having vaccinated just 9.4% of its population, and Asia and Africa's overall vaccination levels at 4.4% and below 1%, respectively.[83]

Proponents of a waiver also argue that the specific circumstances of innovation during this pandemic mean that pharmaceutical companies stand to lose much less than they would otherwise lose from an intellectual property waiver.[84] Government-funded initiatives, such as, Operation Warp Speed in the U.S., have substantially subsidized drug development and reduced the usual risks of investing in medical innovation.[85] Moreover, the companies that have developed new vaccine technologies in response to the pandemic have been rewarded with multi-billion dollar procurement contracts in various jurisdictions.[86] The common argument that removing intellectual property protection discourages future innovation carries less weight under these circumstances, as there are plenty of enticements for companies to develop vaccines and cures for new viral strains.[87]

Another argument is that the intellectual property waiver would facilitate a scaling up of vaccine production.[88] Currently, just 43% of global

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papers.cfm?abstract_id=3851737 [https://perma.cc/R2ZG-J3MN] ("The TRIPS waiver is an essential legal instrument in this context for enabling a radical increase in manufacturing capacity, and hence supply, of COVID-19 vaccines, creating a pathway to achieve global equitable access.").

81. *See* Matthew Kavanagh & Madhavi Sunder, *Opinion: Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That.*, WASH. POST (Mar. 10, 2021, 5:01 PM), https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination [https://perma.cc/V2X6-QDVT].

82. *See* Farasat Bokhari, *US-Backed Vaccine Patent Waiver: Pros and Cons Explained*, THE CONVERSATION (May 6, 2021, 12:08 PM), https://theconversation.com/us-backed-vaccine-patent-waiver-pros-and-cons-explained-160480 [https://perma.cc/UFL7-YQBR].

83. *See id.*; *See also* Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, 396 THE LANCET 1790, 1790 (2020) ("The co-sponsors of the patent waiver proposal say COVAX, funded through donations from HICs, is insufficient for ensuring timely and equitable access to COVID-19 products.").

84. *See* Luke Hawksbee et al., *Don't Worry About the Drug Industry's Profits When Considering a Waiver on Covid-19 Intellectual Property Rights*, 376 BMJ 189, 194 (2022).

85. *See* Ruth L. Okediji, *With a Covid-19 Vaccine Patent Waiver Likely, Time to Rethink Global Intellectual Property Rules*, CNN (May 7, 2021), https://edition.cnn.com/2021/05/07/opinions/covid-vaccine-patent-waiver-as-equals-intl-cmd/index.html [https://perma.cc/63L7-W5L4].

86. *See* Jorge L. Contreras, *US Support for a WTO Waiver of COVID-19 Intellectual Property - What Does it Mean?*, BILL OF HEALTH (May 7, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid [https://perma.cc/Z4KX-PVQJ].

87. *See id.*

88. *See* Anthony D. So, *WTO TRIPS Waiver for COVID-19 Vaccines*, JOHN HOPKINS BLOOMBERG SCH. PUB. HEALTH (May 10, 2021), https://publichealth.jhu.edu/2021/wto-trips-waiver-for-covid-19-vaccines [https://perma.cc/SJ8K-AVJW].

production capacity is being used.[89] Under the current TRIPS compulsory licensing mechanism, countries are required to work around one relevant patent at a time, while the blunt nature of the intended waiver would mean that would-be manufacturers could begin production quickly.[90] Similarly, the broad reach of an intellectual property waiver would allow more producers to step in to produce the raw materials, industrial parts, and components necessary for vaccine production.[91] With current production capacity not meeting global demand, there are many vaccine manufacturers ready to step in.[92] For instance, Teva from Israel, Incepta Vaccine from Bangladesh, and Biolyse Pharma from Canada have all tried and failed to get voluntary licensing deals,[93] while the general director of Doctors Without Borders Switzerland claims that, if the waiver was introduced they would be ready to scale up production in a number of countries immediately.[94]

Increased vaccine production would increase access for developing countries who, to date, have received only around 0.3% of the global COVID-19 vaccine supply.[95] The U.S. has already secured enough doses to vaccinate its entire population.[96] There is some precedent to suggest that WTO action could help to resolve this inequality, as enactment of the Doha Declaration resulted in price drops for HIV/AIDS drugs during the African crisis in the early 2000s.[97] If a waiver was introduced, manufacturers worldwide would face only production costs, enabling the sale of cheaper vaccines to poorer countries while those located in the world's poorest regions would also be able to offer cheaper distribution costs.[98] This could provide immediate relief for developing countries, depending on how

89. *See* Marc Botenga, Katerina Konecna & Dimitrios Papadimoulis, *We Need a Vaccine-Patent Waiver. Why is the EU Blocking it?*, EU OBSERVER (Apr. 26, 2021, 7:02 AM), https://euobserver.com/opinion/151650 [https://perma.cc/RQ8K-59LA].

90. *See Why Some Say Waiving COVID-19 Vaccine Patents Could Help Fix Disparity Issues*, CBC (May 8, 2021, 5:32 PM), https://www.cbc.ca/news/world/covid19-vaccines-patents-waiver-disparity-1.6018851 [https://perma.cc/SH38-7ARW].

91. *See* Gregg Gonsalves, *The Covid-19 Vaccine Patent Waiver: A Crucial Step Towards a "People's Vaccine,"* 373 BMJ 274, 275 (2021).

92. *See* Mikel Berdud et al., *Would Waiving COVID-19 Vaccines Patents Save Lives?*, OHE (May 18, 2021), https://www.ohe.org/news/would-waiving-covid-19-vaccines-patents-save-lives [https://perma.cc/A6XD-VP3H].

93. *See id.*

94. *See* Denis Balibouse, *Waive COVID Vaccine Patents to Benefit Poor Nations, Activists Say*, REUTERS (Mar. 4, 2021, 11:10 AM), https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN2AW1VO [https://perma.cc/6M7B-QXBM].

95. *See* Press Release, U.N. Secretary-General, *Low-Income States Receive 0.3 Per Cent of COVID-19 Vaccines, Secretary-General Warns, Calling on 'G20' Nations to Ensure Equal Access, Win War against Virus*, U.N. Press Release SG/SM/20734 (May 21, 2021).

96. *See Covid: US Backs Waiver on Vaccine Patents to Boostt Supply*, BBC NEWS (May 6, 2021), https://www.bbc.com/news/world-us-canada-57004302 [https://perma.cc/TYD7-XTL6].

97. *See* Akane Okutsu & Kiran Sharma, *Vaccine Patent Waiver: COVID Stopper or Innovation Killer?*, NIKKEI ASIA (May 14, 2021, 4:05 PM), https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer [https://perma.cc/A8PP-ELHH].

98. *See* Berdud et al., *supra* note 92.

many manufacturers actually take up production and how effectively existing producers transfer relevant know-how.[99]

Despite strong optimism about the intellectual property waiver, it is very unlikely that this proposal alone can immediately ameliorate the COVID-19 pandemic. First, the proposal approval procedure through the WTO renders the intellectual property waiver unlikely to produce any major short-term impact. Lengthy WTO negotiations are likely to take place before any waiver is announced and technical challenges are likely once an agreement is reached, meaning it could be years before the benefits of a waiver are felt.[100] Proponents of the waiver face the difficult challenge of securing consent from all 164 WTO member countries, with any one member able to block its adoption.[101] Evidence from previous WTO negotiations suggests that securing consensus can be far from swift. For instance, WTO negotiations following the Doha Declaration in 2001 dragged on throughout 2002 and most of 2003, with the U.S. acting as a major obstacle.[102] U.S. resistance included the rejection of a near deal on paragraph 6 of the Declaration for fears that it would undermine WTO rules on patents, which, provide incentives for the manufacture of new pharmaceutical products.[103] By the time the U.S. lifted its veto in late August 2003, a further 2 million Africans had died as a result of the ongoing AIDS crisis.[104] Several countries that possess enormous sway in the WTO negotiations process, such as the UK, Norway, and E.U. members, have already openly opposed the waiver.[105] The Swiss government, for instance, has stated that the U.S. backing of the waiver leaves many questions unanswered.[106]

Second, major pharmaceutical companies vehemently oppose the intellectual property waiver, arguing that it is unnecessary because it will not address the problems with technology transfer, raw materials, and

99. *See* Bokhari, *supra* note 82.

100. *See* Saeed Shah, Drew Hinshaw & Gabriele Steinhauser, *Covid-19 Vaccine Patent Waivers Could Take Months to Benefit Developing Nations*, THE WALL STREET J. (May 6, 2021, 4:43 PM), https://www.wsj.com/articles/covid-19-vaccine-patent-waivers-could-take-months-to-benefit-developing-nations-11620332442 [https://perma.cc/P2Y5-ERDW].

101. *See* David Lawder, *WTO Vaccine Waiver Could Take Months to Negotiate, Faces Opposition Experts*, REUTERS (May 6, 2021), https://www.reuters.com/world/china/vaccine-ip-waiver-could-take-months-wto-negotiate-experts-2021-05-06 [https://perma.cc/C7F5-G9J7].

102. *See* Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT'L L. 123, 146 (2004).

103. *See id.*

104. *See id.*

105. *See EU, UK, Switzerland, Norway must stop blocking negotiations on landmark pandemic monopoly waiver*, RELIEFWEB (June 7, 2021), https://reliefweb.int/report/world/eu-uk-switzerland-norway-must-stop-blocking-negotiations-landmark-pandemic-monopoly [https://perma.cc/M79Y-TU3D].

106. *See Switzerland Says U.S. Stance on Vaccine Patent Waiver Leaves Questions*, REUTERS (May 6, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/switzerland-says-us-announcement-vaccine-patent-waiver-leaves-questions-2021-05-06 [https://perma.cc/7WR6-49U7].

facilities for manufacturing COVID-19 vaccines.[107] To ramp up global vaccine production, the cooperation of these companies is necessary for the transfer of know-how, provision of raw materials, and sharing of facilities. They also contest that the waiver is unfair given their enormous investment in research, and that it would discourage others from doing the same. The CEO of Pfizer recently claimed that while a big company like his would continue to invest in science, he was not sure "if the same is true for the thousands of small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected".[108] Some estimates have suggested that 3 billion vaccine courses have the potential to generate a global benefit of $17.4 trillion, and it has been argued that taking this value away from companies would be extremely unfair.[109] Even though COVID-19 is a unique global emergency, if companies are denied short-term monopoly benefits, it is questionable whether companies will be willing to invest should another pandemic arise in the future.[110]

Third, unless pharmaceutical companies become willing to cooperate, the intellectual property waiver is unlikely to promote technology transfer, provision of the relevant raw materials, and construction of facilities, three factors necessary to boost manufacture of COVID-19 vaccines in developing countries. Transfer of substantial know-how to developing countries is necessary because vaccines are complex biological products highly dependent on specific manufacturing processes and practices which are often not disclosed in a patent.[111] For instance, there are significant difficulties

107. For instance, Pfizer CEO Albert Bourla stated that the waiver would create more problems than it would solve. *See* Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (May 7, 2021, 4:58 PM), https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html [https://perma.cc/H6H9-KNW8]. *See also* Sarah Lazare, *Pfizer Helped Create the Global Patent Rules. Now it's Using Them to Undercut Access to the COVID Vaccine*, IN THE TIMES (Dec. 17, 2020), https://inthesetimes.com/article/pfizer-covid-vaccine-world-trade-oganization-intellectual-property-patent-access-medicines [https://perma.cc/4ERJ-GG2F] ("Pfizer is not alone in staking out its opposition to pausing intellectual property rules. Pharmaceutical industry trade groups and individual companies—including Moderna, which is behind another leading COVID-19 vaccine—have all come out in full force against the proposal for reprieve from stringent intellectual property rules."). In addition, World Bank President David Malpass said the World Bank did not support waiving intellectual property rights for COVID-19 vaccines at the WTO. *See World Bank Opposes Vaccine Intellectual Property Waiver as WTO Talks Resume*, REUTERS (June 8, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/world-bank-chief-says-does-not-support-vaccine-intellectual-property-waiver-wto-2021-06-08 [https://perma.cc/6CTC-24XS].

108. Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (May 7, 2021), https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html [https://perma.cc/496W-WT3E]/

109. *See* Juan Camilo Castillo et al., *Market Design to Accelerate COVID-19 Vaccine Supply: Build More Capacity, and Stretch What We Already Have*, 371 SCI. 1107, 1107 (2021).

110. *See* Bokhari, *supra* note 82.

111. *See* Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, BILL OF HEALTH (May 5, 2021), https://

in replicating biological processes involving recombinant proteins from the information contained in patents alone, as "the high degree of process dependence in the cell-mediated synthesis of biologics" can make it "quite possible that an attempt to make the patented protein by a different method will yield a product that lacks the asserted utility of the claimed invention."[112] The cost and effort of reverse engineering originator firm manufacturing processes has contributed to a history of delays in the entry of biosimilars to the market and, in one recent case, Inovio even claimed in a court filing that its own experimental COVID-19 vaccine was being held hostage by a contract manufacturer's refusal to share its manufacturing details.[113]

A further obstacle to increased global vaccine production capacity is a shortage of necessary raw materials and technological facilities. Materials critical to the production of mRNA vaccines include polymerases, which are enzymes used to convert DNA to mRNA, as well as the ingredients needed to make lipid nanoparticles, which protect and stabilize mRNA while also facilitating uptake by human cells.[114] There is also the basic challenge of ensuring sufficient amounts of certain chemicals and hardware, including, glass vials and syringes.[115] Many commentators argue that a waiver would either fail to solve this problem or create further bottlenecks. For instance, the president of the Japan Pharmaceutical Manufacturers Association has warned that the introduction of more manufacturers may exacerbate the current shortage of raw materials or other necessary equipment.[116] The CEO of Pfizer has also cautioned that a vaccine waiver could initiate a scramble for raw materials and create a disruption of supply that could put "the safety and security of all at risk."[117]

Therefore, the intellectual property waiver must be supported by a sharing of know-how and improvement of technical facilities or be used in combination with another solution. The waiver alone will not be enough to deal with the current crisis. The Director-General of the WTO has already cautioned that the solution to the problem of vaccine inequality must be

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blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver [https://perma.cc/T296-JC3X].

112. Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 135–36 (2011).

113. *See* W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 SCI. 912, 912 (2020).

114. *See* Charles Schmidt, *New COVID Vaccines Need Absurd Amounts of Material and Labor*, SC. AM. (Jan. 4, 2021), https://www.scientificamerican.com/article/new-covid-vaccines-need-absurd-amounts-of-material-and-labor1 [https://perma.cc/CH43-HXNB].

115. *See id.*

116. *See* Press Release, Japan Pharm. Mfrs Ass'n, *JPMA Statement on WTO TRIPS Intellectual Property Waiver* (May 7, 2021), https://www.jpma.or.jp/english/reports/jpma_statement_on_wto_trips/eki4g60000004ubm-att/JPMA_press_release_template_EN_Final_3.pdf [https://perma.cc/P4JN-EKFR].

117. Nikou Asgari, *Pfizer Chief Warns of 'Scramble' for Raw Materials if Vaccine Patents Waived*, FIN. TIMES (May 8, 2021), https://www.ft.com/content/2f99beeb-e887-4c1e-977b-e5d334f7fd6a [https://perma.cc/MGR9-YS96].

holistic and that a waiver should not preclude further action.[118]

C. Summary

Both the compulsory licensing and intellectual property waiver proposals demonstrate that patents are a barrier to equal global access to COVID-19 vaccines. As this part shows, these proposals suffer from procedural problems that either prevent their expeditious adoption or delay their implementation for an undesirably long period. Even if such procedural problems were overcome, both proposals would still face a host of practical problems caused by the inadequate local manufacturing capacities in most developing countries. Absent adequate transfer of know-how and availability of the relevant raw materials and manufacturing facilities, it would be exceedingly difficult to implement either of the proposals to scale up global supply of COVID-19 vaccines. As the Director-General of the WTO has already cautioned, the solution to the problem of vaccine inequality must be holistic, and a waiver, for example, should not preclude further action.[119]

II. The Creation of the PPI

In the author's opinion, both proposals must be augmented by a new global mechanism. Pharmaceutical companies' vehement objections to the intellectual property waiver proposal indicate that any such mechanism must require these companies to take more responsibility for public health promotion through actions such as the transfer of medicine and vaccine production know-how. The mechanism must also improve developing countries' pharmaceutical research and manufacturing capacity.

Article 66 of the TRIPS Agreement states that "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[120] However, the WTO has yet to establish a mechanism for monitoring and assessing whether and how developed countries have fulfilled this treaty obligation.[121] The global

118. Philp Blenkinsop, *Vaccine Patent Waiver Will Not Be Enough - WTO chief*, REUTERS (May 20, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/vaccine-patent-waiver-will-not-be-enough-wto-chief-2021-05-20/ [https://perma.cc/K9QS-YZVG].

119. *Id.*

120. TRIPS Agreement, *supra* note 18, art. 66.2.

121. *See* Carlos Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?* in INT'L PUB. GOODS AND TRANSFER OF TECH. UNDER A GLOBALIZED INTELL. PROP. REGIME 253 (K. E. Maskus & J. H. Reichman eds., 2005) (arguing that Article 66.2 establishes a positive legal obligation, and it does not merely make a suggestion).

See Carlos Correa, *Intellectual Property in the LDCs: Strategies for Enhancing Technology Transfer and Dissemination*, BACKGROUND PAPER NO.4: UNCTAD: THE LEAST DEVELOPED COUNTRIES REPORT, 2007 (arguing that developed countries have generally failed to meet their obligations under Article 66.2). Suerie Moon, *Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council*

mechanism, therefore, is still absent due to lack of developed countries' efforts as encouraged by Article 66.[122]

In this Part, this article puts forward the Patent Philanthropy Initiative (PPI) as a global mechanism for bringing the goals of Article 66 to fruition and argues that the U.S. should take the lead in its implementation.

A. Structure of the PPI

In essence, the PPI is intended to require pharmaceutical companies to devote resources to sharing the benefits of their patented medical inventions for charitable purposes. For each patent acquired from the United States Patent and Trademark Office (USPTO), the PPI would require a pharmaceutical company to make a corresponding contribution to a domestic or global social welfare program. The USPTO can be the designated administrator of a pilot PPI program requiring each pharmaceutical company to contribute as PPI funds 1% of its annual post-tax profits from sales of patented products. Such financial contributions would apply to medical patents registered with the USPTO and within protection terms, as well as any future medical patents the USPTO grants. Pharmaceutical companies would be able to take a range of actions to fulfill this responsibility, provided that they spend approximately 50% of PPI funds domestically and 50% internationally.

1. Actions

To enforce their PPI responsibilities, this Article suggests that pharmaceutical companies carry out, in good faith, at least three categories of capacity-building actions as follows.

a. Technology Transfer

Despite longstanding arguments that local firms should be empowered to produce the medicines their residents need, most medicines and vaccines consumed in developing countries are imported.[123] Developing countries remain "systematically excluded from accessing the ability to produce highly complex drugs"[124] and thus lack self-sufficiency in addressing medical challenges. As of 1986, it was estimated that only 11% of global pharmaceutical production occurred in developing countries and over 80% in six industrialized countries.[125] The COVID-19 pandemic has demonstrated the urgency of capacity building in developing countries. Despite

(1999-2007), Policy Brief Number 2, December 2008, UNCTAD - ICTSD PROJECT ON IPRS AND SUSTAINABLE DEV., https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf [https://perma.cc/Z5QT-MEQ5] ("The evidence arising from this review of country reports to the TRIPS Council does not paint a rosy picture of compliance with article 66.2.").

122. *See* Correa, *supra* note 121; Moon, *supra* note 121.

123. Fisher et al., *supra* note 11, at 2.

124. Jeff Neal, *Waiving COVID Vaccine Patent Rights? It's Complicated*, HARV. L. TODAY (May 4, 2021), https://today.law.harvard.edu/waiving-covid-vaccine-patent-rights-its-complicated/ [https://perma.cc/8MU5-GCXM].

125. *See* Fisher et al., *supra* note 11, at 15.

global calls for the waiver of COVID-19 vaccine patent rights to increase availability in developing countries, capitalizing on the direct transfer of vaccine-production knowledge is more effective.[126]

Therefore, pharmaceutical companies may fulfill their responsibilities under the PPI by engaging in efforts to transfer the following four kinds of technologies to a company located in a developing country:

First, pharmaceutical companies may transfer essential medicine production know-how. According to the WHO, essential medicines "satisfy the priority health care needs of the population."[127] People should have access to these medicines at all times and in sufficient amounts, and their prices should be set at generally affordable levels. Transferring know-how to essential medicine producers in developing countries would greatly enhance efforts to promote public health.

Second is know-how about the production of essential vaccines. Vaccination is one of the best ways to protect people, including, infants, children, and teens, in particular, from diseases that can cause serious or deadly harm to health.[128] It plays a critical role in preventing and containing outbreaks of diseases that "[are] difficult to control and have consumed public health resources in affected areas."[129] Amid the COVID-19 pandemic, essential vaccines have been recommended or required for people in different age groups.[130] The transfer of know-how to vaccine producers in developing countries would enable public health interventions that improve lives and prevent deaths.

Third, pharmaceutical companies may transfer know-how to produce medicines and vaccines for neglected diseases. Every year, neglected diseases such as Chagas disease, sleeping sickness, and visceral leishmaniasis cause hundreds of thousands of deaths among the poor and marginalized

126. *See* Matthew Kavanagh & Madhavi Sunder, Opinion, *Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That*, WASH. POST (Mar. 10, 2021), https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/ [https://perma.cc/2UDN-BSEK] (arguing that "the covid-19 pandemic necessitates both a temporary intellectual property waiver from the WTO and a bold effort to share [technology to make COVID-19 vaccines]"). Ruth L. Okediji, *With a Covid-19 Vaccine Patent Waiver Likely, Time to Rethink Global Intellectual Property Rules Opinion*, CNN (May 7, 2021), https://edition.cnn.com/2021/05/07/opinions/covid-vaccine-patent-waiver-as-equals-intl-cmd/index.html [https://perma.cc/2PQ6-PK2U] ("[A]ccess to patents alone does not translate into optimal short or long-term ease of access to medicines . . . . There is a need for technology transfer related to the vaccine patents.").

127. *Essential Medicines*, WORLD HEALTH ORG., www.emro.who.int/health-topics/essential-medicines/index.html [https://perma.cc/LN75-3TDT] (last visited Apr. 17, 2023).

128. *See Recommended Vaccines by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/vpd/vaccines-age.html [https://perma.cc/GTG2-XC5G].

129. *See* Michaela Fleming, *Essential Vaccines by Age Group*, CONTAGION LIVE (Aug. 16, 2019), https://www.contagionlive.com/view/essential-vaccines-by-age-group [https://perma.cc/K8WV-N5FF].

130. *See Essential Programme on Immunization*, WORLD HEALTH ORG., https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization [https://perma.cc/N4AK-MDJE] (last visited July 23, 2022).

in developing countries.[131] There are few resources available in developing countries to address these diseases overlooked by policymakers.[132] Therefore, pharmaceutical companies could fulfill their responsibilities under the PPI by transferring neglected disease research know-how to a company located in a developing country.

Fourth, pharmaceutical companies may transfer to developing countries physical objects or equipment for production of pharmaceuticals at reduced prices compared to their prices in developed countries. Sufficient availability of such objects and equipment is vital if developing countries are to boost research and production capacities in protecting public health.[133]

b. Donation

To meet their PPI obligations, pharmaceutical companies may donate medical products and equipment to a not-for-profit organization or developing country. Such products and equipment include essential medicines and vaccines (whether produced or purchased by the company), testing toolkits, disease diagnostic equipment, medical research equipment, and manufacturing facilities.

Donation of raw materials also falls within this category of action. Pharmaceutical manufacturers require a complex range of raw materials, including, "starting compounds, intermediates, solvents, cell lines, yeast, bacteria, cell-culture media and feeds, excipients, production materials such as tubing, single-use manufacturing equipment, and packaging materials."[134] Raw material deficiencies can directly result in drug shortages. For instance, in 2012, the Food and Drug Administration (FDA) reported 117 drug shortages in the U.S., of which 27% resulted from raw material

131. *See Overcoming Neglect: Finding Ways to Manage and Control Neglected Tropical Diseases*, MEDECINS SANS FRONTIERES (Jan. 2021), https://reliefweb.int/report/world/overcoming-neglect-finding-ways-manage-and-control-neglected-tropical-diseases [https://perma.cc/M5N5-EAV7]; PANEL ON ACCESS, *supra* note 32.

132. Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1222 (2018) ("Even today, during the inter-outbreak period following the largest and most lethal Ebola pandemic in recorded history, it is not clear that the vaccines currently in advanced clinical development will have a 'clear commercial market.'") (quoting CTR. FOR INFECTIOUS DISEASE RSCH & POLICY, COMPLETING THE DEV. OF EBOLA VACCINES 25 (2017), https://www.cidrap.umn.edu/sites/default/files/public/downloads/ebola_team_b_report_3-011717-final_0.pdf [https://perma.cc/7SZ4-MZD7].

133. Jayashree Watal & Leticia Caminero, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, WORLD TRADE ORG. (Feb. 22, 2018), https://www.wto.org/english/res_e/reser_e/ersd201801_e.pdf [https://perma.cc/7FR7-QG2F] ("[T]here were different elements present in a technological base, including scientific knowledge, *physical objects*, actual production and know-how, along with different channels for transferring technology.") (emphasis added).

134. Govindra Singh, *Raw Material Suppy: Many Issues to Manage, Pharmaceutical Outsourcing*, PHARMA OUTSOURCING (Sept. 30, 2016), https://www.pharmoutsourcing.com/Featured-Articles/192371-Raw-Material-Supply-Many-Issues-to-Manage/ [https://perma.cc/8DWW-VV9G].

issues.[135] Amid the COVID-19 crisis, raw material shortages have been frequently cited as a major obstacle to universal vaccine access.[136]

c. Facility Building

As proved by the production of COVID-19 vaccines, manufacturing lines are of critical importance. The manufacture of mRNA vaccines, for instance, requires equipment to produce lipid nanoparticles.[137] Pfizer's car garage-sized lipid production suite at its Michigan plant "is crisscrossed by pumps and pipes, and crowded with tanks, filtration units and half-dollar size jet mixers," with about 100 of these mixers being used simultaneously for lipid formulation.[138] Although "several commercial kits are available to produce mRNA for preclinical studies at laboratory scale, their costs are high."[139] Experts have pointed out that there are currently few existing factories capable of producing mRNA vaccines and that retrofitting of existing sites would potentially cost billions of dollars.[140] For mRNA vaccine production to occur across the globe, the need for sustainable and cost-effective manufacturing must first be addressed.[141] c This could be achieved through donation by pharmaceutical companies of both basic and special equipment and facilities for the construction of medicine and vaccine manufacture lines.

Pharmaceutical companies may also assist in building and improving distribution channels for medicines and vaccines. Pfizer/BioNTech's COVID-19 vaccines, for example, must be stored in ultra-cold temperatures and should be distributed using thermal shipping containers, freezers, temperature monitoring devices, and ancillary supply kits for diluting, mixing, and disposing vaccines.[142] Donation of such facilities by pharmaceutical companies would represent an important contribution to the safe and sufficient distribution of medicines and vaccines both in the U.S. and developing countries.

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135. Patricia Van Arnum, *Industry Weighs In on Mfg Issues to Mitigate Drug Shortages*, DCAT VALUE CHAIN INSIGHTS (Feb. 13, 2019), https://www.dcatvci.org/features/industry-weighs-in-on-mfg-issues-to-mitigate-drug-shortages [https://perma.cc/G9N9-THY2].

136. Rowland et al., *Drug companies defend vaccine monopolies in face of global outcry*, WASH. POST (Mar. 20, 2021), https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/ [https://perma.cc/C77A-D8C8].

137. Jared S. Hopkins, Joel Eastwood & Dylan Moriarty, *mRNA Covid-19 Vaccines Are Fast to Make, but Hard to Scale*, THE WALL STREET J. (Mar. 3, 2021), https://www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401 [https://perma.cc/6EU7-ED82].

138. *Id.*

139. Sara Sousa Rosa et al., *mRNA Vaccines Manufacturing: Challenges and Bottlenecks*, 39 VACCINE 2190, 2195 (2021).

140. Katie Jennings & Aayushi Pratap, *Waiving Patents on Covid-19 Vaccines Isn't Enough To Speed Up Production*, FORBES (May 4, 2021), https://www.forbes.com/sites/aayushipratap/2021/05/04/waiving-patents-on-covid-19-vaccines-isnt-enough-to-speed-up-production/ [https://perma.cc/56CE-DZH6].

141. *See* Rosa et al., *supra* note 139, at 2197.

142. *Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf [https://perma.cc/8W8R-8UZB].

d. Professional Training

Pharmaceutical companies may also deploy staff to train and boost the knowledge and skills of medical professionals and pharmaceutical researchers in low-income regions in the U.S. and developing countries. Local production of pharmaceuticals in developing countries offers general benefits, including the creation of high-paying skilled jobs, which would support sustainable long-term economic development and allow local firms to respond more quickly and flexibly to future crises.[143] Effective local production could be encouraged by collaboration between developing governments, local firms and developed-country pharmaceutical companies, international internship initiatives to facilitate the acquisition of technological know-how, and strengthening legal and administrative apparatuses to prevent dissemination of substandard or falsified drugs.[144]

Under the PPI, major pharmaceutical companies could contribute to this process through schemes to increase the number of pharmaceutical scientists and researchers in developing countries. Such schemes could take the form of apprenticeship programs for scientists from existing or prospective local firms to "absorb crucial technical knowledge and then return to their own countries of residence to set up and run similar production facilities."[145] For such a system to work, developing country governments would need to be responsible for selecting and supporting apprentices, while local firms would need to commit to not exporting the drugs they create to developed countries.[146]

e. Public Knowledge Sharing

Pharmaceutical companies should develop educational programs to better disseminate health care knowledge to the U.S. public and in developing countries. They could deploy their own professionals, hire similar professionals, or commission a medical care organization for online and face-to-face activities such as open lectures and talks, distribution of health care brochures, and meetings with doctors and nurses. Such programs would reflect the ethos of preventive medical care, whereby the spread of basic knowledge on topics ranging from blood pressure to cancer to mental health screenings prompts people to take precautionary measures to maintain personal health and prevent infection.[147] The programs would also promote a communal sense of health care, where "nobody is fully protected

143. *See* Fisher et al., *supra* note 11, at 2.

144. *Id.* at 44–45.

145. *Id.* at 32–33.

146. *Id.* at 34.

147. Anjali Stenquist, *Types of Preventive Care: 8 Proactive Ways to Ward Off Health Problems*, RASMUSSEN UNIV. (Jan. 20, 2020), https://www.rasmussen.edu/degrees/health-sciences/blog/types-of-preventive-care/ [https://perma.cc/ZHM7-93TA] ("Preventive care is any medical service that reduces the risk of later negative health outcomes such as medical emergencies, disability or chronic disease. Preventive care often involves regular screening for diseases before they become serious enough to exhibit symptoms.").

until everyone is protected."[148]

The COVID-19 pandemic has proven the special importance of sharing public health knowledge. Despite sufficient availability of COVID-19 vaccines, vaccination rates are still relatively low in many parts of the U.S., making the country very vulnerable to new coronavirus variant outbreaks.[149] Vaccine hesitancy has been identified as the leading cause of low vaccination rates,[150] with some declining vaccinations based on mis/disinformation obtained from social media.[151] Many young people are hesitant because they feel that COVID-19 is not something that will impact their health.[152] Vaccine producers are well-positioned to share information about COVID-19 vaccines and reduce vaccine hesitancy. Also, vaccination rates have remained lower in Black and Latino communities in the U.S. due to public health inequalities and the relative lack of health knowledge.[153] Pharmaceutical companies may fill such public health "blind spots" left by the government, delivering information about vaccine efficacy and vaccination locations to communities in need.

2. 1%

With regard to the 1% of pharmaceutical companies' annual post-tax profits from patented medical product sales that would fund PPI actions, a few questions arise. How should such annual profits be calculated? Some patented medical products contain one patent, while others consist of multiple patents. Should these patents be treated as equal? Further, a pharmaceutical company may manufacture many kinds of medical products, not all of which utilize medical patents. As of July 2021, Pfizer has 189 approved drugs and 29 medical patents registered in the U.S.[154] Some of those drugs use Pfizer's existing patents, some use Pfizer's expired patents,

148. *No-One Is Safe Until Everyone Is Safe - Why We Need A Global Response To COVID-19,* UNICEF (May, 24 2021), https://www.unicef.org/press-releases/no-one-safe-until-everyone-safe-why-we-need-global-response-covid-19 [https://perma.cc/R2KY-MKMU].

149. Maria Clark, Melissa Brown & Sarah Haselhorst, *Low Vaccination Rates, Delta Variant Fuel Surge in New COVID-19 Cases Across the South*, THE AM. S. (July 20, 2021), https://www.tennessean.com/story/news/american-south/2021/07/20/covid-19-vaccinations-delta-variant-fuel-surge-cases-across-south/7967943002/ [https://perma.cc/BJC5-SQ9B].

150. Elliott Davis, *As COVID-19 Cases Increase, Vaccine Hesitancy Still High in Some States*, US NEWS (July 15, 2021), https://www.usnews.com/news/best-states/articles/2021-07-15/covid-19-vaccine-hesitancy-rates-still-high-in-some-states [https://perma.cc/LUG2-L784].

151. Aallyah Wright, *Lowest Rates, Highest Hurdles: Southern States Tackle Vaccine Gap*, PEW (June 17, 2021), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/06/17/lowest-rates-highest-hurdles-southern-states-tackle-vaccine-gap [https://perma.cc/XE3Q-NUAG].

152. *Id.*

153. Misha Ketchell, *US Black and Latino Communities Often Have Low Vaccination Rates - But Blaming Vaccine Hesitancy Misses the Mark,* THE CONVERSATION (July 7, 2021), https://theconversation.com/us-black-and-latino-communities-often-have-low-vaccination-rates-but-blaming-vaccine-hesitancy-misses-the-mark-163169 [https://perma.cc/R77B-YGEU].

154. *Pfizer Company Profile*, DRUG PAT. WATCH, https://www.drugpatentwatch.com/p/applicant/Pfizer, [https://perma.cc/SV6G-EVAZ] (last visited Aug. 8, 2022).

and some do not use any patents at all. Should Pfizer's annual profits be calculated on sales of all Pfizer drugs in the marketplace in a given year or only those that use its medical patents? Pfizer may also license its patents to another company to make and sell medical products. For PPI purposes, should Pfizer's patent royalties be included in its profits?

This Article suggests that annual profits for PPI purposes should be determined as follows. First, such annual profits should be calculated based on sales of medical products using a company's patents. The number of patents used in a medical product should be considered, and medical products that do not use a company's patents should be excluded from the calculation of annual profits. However, a company's royalties from licensing its medical patents should be included. Second, such annual profits should deduct the relevant taxes pharmaceutical companies pay.

Pharmaceutical companies should bear the burden of calculating their annual profits derived from sales of their patented medical products, and each should then submit an end-of-financial-year profit report to the USPTO. It would be relatively easy for these companies to calculate such profits. Many are publicly listed companies that utilize accounting firms to prepare documents about quarterly and annual profits for public release, and they also need to make annual tax filings. Therefore, as long as they identify the medical products that use their patents, they can figure out the post-tax profits accrued from sales of these products and contribute 1% to the PPI.

Meanwhile, the USPTO should provide channels for the public to make financial donations to the PPI. If the donor designates a specific company that is willing to accept the donation, the USPTO may allocate the donation accordingly. If a donor does not designate a company, the USPTO may allocate the donation to a company willing to use it for PPI actions.

While 1% may sound like a small contribution, Johnson & Johnson earned post-tax profits of approximately USD $15 billion each year from 2018 to 2020,[155] and Pfizer earned around $11, $12, and $9 billion in 2018, 2019, and 2020, respectively.[156] Based on these earnings, their respective contributions to a PPI fund would be approximately USD $150 million and $110 million each year.[157] Adding other pharmaceutical companies and potential donations, the PPI could contribute enormous amounts of funds to the promotion of public health in the U.S. and developing countries.

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155. *2020 Annual Report* at 56, JOHNSON & JOHNSON, https://www.investor.jnj.com/annual-meeting-materials/2020-annual-report [https://perma.cc/9EBD-NWNJ] (last visited Apr. 17, 2023).

156. *Annual Report Pursuant to Section 13 Or 15(D) of The Securities Exchange Act of 1934*, at 47–48 and 58, PFIZER, https://s21.q4cdn.com/317678438/files/doc_financials/2020/ar/PFE-2020-Form-10K-FINAL.pdf [https://perma.cc/9ZVV-DPDD] (last visited Apr. 17, 2023).

157. These amounts are subject to deductions of profits from sales of medical products that do not use patents.

3. Review

The USPTO should require each participating pharmaceutical company to submit an annual report detailing the nature, scope, and effects of its actions taken in fulfillment of the responsibility attached to each of its medical inventions. In particular, the report should explain how a company's expenditures on PPI actions have amounted to the requisite 1% of post-tax profits from sales of its medical products. The USPTO could review those reports every five years with a panel consisting of its own administrators, independent patent experts, auditing professionals, and public interest activists. The panel would decide whether a relevant pharmaceutical company has met its responsibility and, if not, make recommendations to the USPTO on mitigating actions the company should take.

Every 10 years, the USPTO should conduct a comprehensive review of the PPI, studying its efficacy and how it should be improved with new measures to boost social welfare and safeguards to protect pharmaceutical companies' interests. For example, the USPTO may review whether any of the five categories of PPI actions should be removed, or any new category added. It may also review other issues such as whether 1% is a proper rate for financial contributions and how to improve the calculation of annual profits accrued from sales of patented medical products. Therefore, the PPI would continue to create dynamic schemes reflective of social and technological developments. To better implement the PPI, the USPTO should consider how it could collaborate with other governmental agencies, such as, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the United States Trade Representative, as well as international organizations such as the World Health Organization (WHO). The USPTO may invite them to share their expert opinions about how to improve the PPI and how to work together on specific programs to enhance the efficacy of pharmaceutical companies' PPI actions.

Meanwhile, all USPTO decisions (including those by the panel it designates to review the PPI) could be announced subject to judicial review, allowing pharmaceutical companies to utilize judicial proceedings to settle their disputes with the USPTO should negotiations fail. The availability of this dispute resolution mechanism would prevent improper decisions that are unfair to pharmaceutical companies.

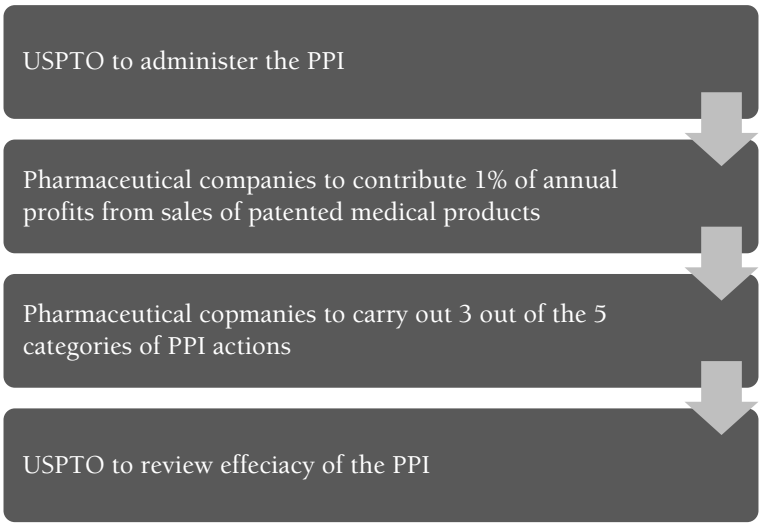
Non-profit organizations may contribute to the PPI through actions such as creating a ranking of best-performing pharmaceutical companies entitled, for example, The World's Most Responsible Pharma.[158] Every year, this program would access and rank the performance of pharmaceutical companies' PPI actions, thereby encouraging pharmaceutical companies to design and carry out PPI actions diligently. It would also create an

158. Access to Medicine Index provides a similar annual ranking. *See* Access to Medicine Index, *About the Index*, https://accesstomedicinefoundation.org/access-to-medicine-index/about-the-index [https://perma.cc/6MBJ-LDTA] (last visited Apr. 17, 2023) ("The 2021 Index analyses how 20 of the world's largest pharmaceutical companies are addressing access to medicine in 106 low- and middle-income countries for 82 diseases, conditions and pathogens.").

additional oversight system to monitor any problems with PPI actions and generate public discussion about subsequent solutions.

The figure below shows the holistic operation of the PPI:

Patent Philanthropy Initiative (PPI)



The PPI's Effects on Improving Public Health

How would the PPI promote public health in the U.S. and developing countries? The COVID-19 pandemic provides a vantage point for a thought experiment about the PPI's efficacy. If we assume the PPI were implemented five or ten years ago, the U.S. and the rest of the world would be better prepared to cope with the COVID-19 pandemic.

First, the PPI would provide a feasible framework for large pharmaceutical companies' sharing of technologies and know-how in developing countries. Deficiencies in the current global approach to technology transfer are evident in the current struggle to provide universal access to COVID-19 vaccines. Vaccine production has been largely limited to wealthy and highly industrialized countries and regions, including the U.S., the U.K., and the EU.[159] Vaccine acquisition has similarly favored such countries, with nearly 85% of all COVID-19 vaccines administered by May 26, 2021 going to people in high-income and upper-middle-income countries.[160] Patent monopolies and the reluctance of firms to share technology through

159. *Covid Vaccines: Where are Oxford/AstraZeneca, Pfizer and Moderna Jabs Made?*, ITV NEWS (Mar. 24, 2021), https://www.itv.com/news/2021-03-24/covid-vaccines-where-are-oxfordastrazeneca-pfizer-and-moderna-jabs-made [https://perma.cc/7YSV-MWSU].

160. Jon Cohen & Kai Kupferschmidt, *Rich Countries Cornered COVID-19 Vaccine Doses. Four Strategies to Right a 'Scandalous Inequity'*, SCI. MAG. (May 26, 2021), https://www.sciencemag.org/news/2021/05/rich-countries-cornered-covid-19-vaccine-doses-four-strategies-right-scandalous [https://perma.cc/KQ8G-W372].

licenses have prevented pharmaceutical manufacturers in under-represented regions from taking matters into their own hands, leaving only 43% of the estimated global vaccine manufacturing capacity being used as of February 2021.[161]

Moreover, even if all COVID-19 vaccine patents were to be waived, a lot of essential information is still not included in the patents, preventing manufacturers from immediately beginning production.[162]As complex biological inventions, COVID-19 vaccines are "highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent."[163] The challenge of reverse engineering such processes is one reason behind the expense and delay historically associated with the entry of biosimilars into the market.[164]

The PPI responds to the much-needed transfer of technologies and know-how. In public health crises, the PPI would encourage pharmaceutical companies to increase technology transfer and donate manufacturing ingredients and equipment to boost the production and distribution of vaccines, as well as medicines. After containment, the initiative would promote the medical capacities of low-income regions in the U.S. and developing countries in the long term. Efforts from developing countries alone have been insufficient to address deficiencies in local production of pharmaceuticals. For instance, through tax and import duty exemptions and import bans on 44 locally-made medicines, the government of Ghana sought to promote local pharmaceutical production and has reportedly established a 30% market share for local producers.[165] However, the success of these measures is tempered by "limited product choice amongst local companies, low capacity utilization, and a lack of ability to manufacture APIs or expand production into new therapeutic categories."[166] Greater efforts by major pharmaceutical companies to transfer technology and know-how could be instrumental in overcoming such deficiencies.

By facilitating technology transfer measures towards developing regions, the PPI could promote greater global access to COVID-19 medicines and vaccines. Pharmaceutical companies would be more willing to transfer COVID-19 vaccine production know-how because their efforts could count towards fulfilling their PPI obligations. Such efforts are critical for enabling vaccine manufacturers in developing countries to ramp up production. As scholars have found, "[to] get off the ground, [firms in developing countries] typically need assistance from the enterprises already engaged in that process. The same is true for vaccines, where the production of bulk antigens remains the most daunting step to be mastered

161. *Monopolies Causing "Artificial Rationing" in COVID-19 Crisis as 3 Biggest Global Vaccine Giants Sit on Sidelines*, OXFAM (Feb. 5, 2021), https://www.oxfam.org/en/press-releases/monopolies-causing-artificial-rationing-covid-19-crisis-3-biggest-global-vaccine [https://perma.cc/DBN6-2H5W].

162. *See* Price, Rai & Minssen, *supra* note 26.

163. Rutschman & Barnes-Weise, *supra* note 111.

164. *See* Price, Rai & Minssen, *supra* note 26.

165. Fisher et al., *supra* note 11, at 18.

166. *Id.* at 18, 12.

by developing country manufacturers."[167] Pharmaceutical companies could also take the PPI action of entering into collaborative licenses with vaccine manufacturers in developing countries, which would also promote COVID-19 vaccine production in these countries.[168]

Second, the PPI would promote greater self-sufficiency in developing countries, countering the nationalism that has occurred at the expense of much of the world's population during the current pandemic. One means of pursuing this goal is through training healthcare workers in developing countries. The WHO has declared the scaling up and strengthening of health workforce training and education a priority in both its 2019 Sustainable Development Goals global action plan and 13th General Programme of Work. This plan is intended "to address the global gap of 18 million health workers, and to support, strengthen and empower the existing health workforce."[169] Similarly, Global Health Progress has operated the Healthworker Programme since 2009 to address "the estimated shortfall of at least 7.2 million health workers."[170]

Third, the PPI could help pursue the more general goal of ensuring universal access to affordable medicines. Drugs fall under two major categories: global drugs created for rich markets but also of benefit to developing countries[171] (a prime example of which are drugs developed to treat cancer[172]), and drugs specific to developing countries, such as those designed to treat malaria or tuberculosis.[173] Historically, pharmaceutical investment has overwhelmingly favored research into global drugs. For instance, in 2001, the Harvard School of Public Health surveyed of 20 major firms. It found that only eight respondents had conducted no research over the previous year into tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease, while seven others had spent less than 1% of their research and development budgets on any of these disorders.[174] Currently, funds for research into developing country-specific drugs often come from public or philanthropic sources or public-private partnerships.[175]

Pharmaceutical companies under the PPI could, therefore, commit to investing more in addressing developing country-specific diseases to produce more effective drugs and increase competition to drive down prices. This would be instrumental in addressing diseases which have been largely

167. *Id.* at 11.
168. *See* Okediji, *supra* note 85.
169. Health Workforce Education and Training, WORLD HEALTH ORG., https://www.who.int/activities/health-workforce-education-and-training [https://perma.cc/9J92-CPLD] (last visited July 9, 2021).
170. *Healthworker Programme*, GLOB. HEALTH PROGRESS, https://globalhealthprogress.org/collaboration/healthworker-programme/ [https://perma.cc/XU4N-5FCS] (last visited July 9, 2021).
171. Coleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation*, 18 BERKELEY TECH. L.J. 853, 892 (2003).
172. *Id.*
173. *Id.*
174. *Id.*
175. *Id.*

eradicated in rich countries but remain a problem in the developing world. For instance, whereas the WHO recently declared that China was now malaria-free after reporting 30 million annual cases of the disease in the 1940s, malaria continues to kill hundreds of thousands annually, especially in sub-Saharan Africa.[176] In parts of Kenya specifically, cases are reported to be as high as 725 per 1,000 people.[177] Moreover, the challenge of COVID-19 has undermined existing efforts to combat malaria. For instance, malaria cases have spiked in some parts of Zimbabwe since the beginning of the pandemic.[178] There is also the possibility that this problem could continue to develop as the anti-malaria drug chloroquine has shown potential as a treatment for COVID-19, which could make the drug less accessible for malaria patients in developing countries.[179]

B. Summary: The U.S.'s Leadership in Protecting Public Health Globally

The COVID-19 pandemic has exposed deep-seated problems in the U.S. public health care system[180] and an imperative for its reform. The COVID-19 pandemic is also a global public health crisis necessitating a global response.[181] When developing countries face severe lack of patented vaccines, this raises the question as to how to adjust the patent protection system that has been heavily influenced by developed countries with the greatest access to vaccines.[182] Moreover, given the comparative fragility of developing economies, such nations have been hit hardest by lockdowns and curtailment of trade, and are also predicted to recover much more slowly than richer countries.[183] A global recovery from the pandemic benefits the U.S. in terms of decreasing domestic transmission of infection from abroad. However, global recovery will also drive quicker national economic recovery from normalization of global trade and invest-

176. *See, e.g. From 30 Million Cases to Zero: China is Certified Malaria-Free by WHO*, WORLD HEALTH ORG. (June 30, 2021), https://www.who.int/news/item/30-06-2021-from-30-million-cases-to-zero-china-is-certified-malaria-free-by-who [https://perma.cc/8CML-RHSR].

177. Lillian Mageto, *Malaria is Still a Public Health Crisis in Kenya - Here's How Data Can Help*, PALLADIUM (Feb. 12, 2021), https://thepalladiumgroup.com/news/Malaria-is-Still-a-Public-Health-Crisis-in-Kenya-Here's-How-Data-Can-Help [https://perma.cc/A6EK-7BXV].

178. Ayat Zawawi et al., *The Impact of COVID-19 Pandemic on Malaria Elimination*, 11 PARASITE EPIDEMIOLOGY & CONTROL 1, 2 (2020).

179. *Id.* at 3–4.

180. UNICEF, *supra* note 148.

181. *See* Mikel Berdud et al., *Would Waiving COVID-19 Vaccines Patents Save Lives?*, OHE (May 18, 2021), https://www.ohe.org/news/would-waiving-covid-19-vaccines-patents-save-lives [https://perma.cc/95Q4-GQU8].

182. Neal, *supra* note 124 ("The developers of several of the vaccines have obtained intellectual property protection of one sort or another, either on the compounds themselves or on the technologies necessary to produce them. Most of the holders of those intellectual property rights have used them to prevent the manufacture and distribution of competitive products, and have not licensed the production of generic versions by other companies.").

183. Fisher et al., *supra* note 11, at 5.

ments.[184] As demonstrated in this Part, the PPI would greatly promote public health in the U.S. and abroad, and would not disrupt pharmaceutical innovation in the U.S. Therefore, the U.S. government should take the lead in protecting public health globally and implement the PPI under the auspices of the USPTO.

III. The Legitimacy of the PPI

In Part II, I examined the case for establishing the PPI and its economic and social functions in promoting public health, both in the U.S. and abroad. In Part III, I seek to respond to potential concerns that the PPI would run afoul of U.S. obligations under the TRIPS Agreement as well as the Takings Clause of the U.S. Constitution. I also consider whether the PPI would disincentivize pharmaceutical companies from investing in research and development and thereby severely disrupt innovation in the medical sector.

A. International Law Obligations and Constitutional Protection

1. TRIPS Agreement

Would the PPI violate the TRIPS Agreement? This agreement sets out minimum standards for intellectual property protection in WTO member states, including the U.S.[185] In my opinion, the U.S. would remain in full compliance with the TRIPS Agreement notwithstanding USPTO implementation of the PPI.

First, the PPI does not alter patentability standards. Pursuant to the TRIPS Agreement, member states must make patent protection available for inventions that have novelty, inventiveness and industrial applicability.[186] It is obvious that the PPI would leave those standards intact as it only imposes the relevant responsibilities after a medical patent is granted.

Second, the PPI does not affect the exercise of patent rights. The TRIPS Agreement confers upon a patent owner rights to make, use, offer for sale, sell, and import the patented product and process.[187] Under the PPI, pharmaceutical companies fully enjoy this bundle of exclusive rights with no effect on their ability to merchandize their products in the marketplace.

Third, the PPI stays within the scope of patent limitations that WTO member states can carve out in their domestic patent laws. The TRIPS Agreement allows member states to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do

184. *Id.* at 3.

185. *See* J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L L. 345, 347 (1995) (observing that "the TRIPS Agreement significantly elevates the level of protection beyond that found in existing conventions").

186. TRIPS Agreement, *supra* note 18, art. 27.1.

187. *Id.* art. 28.1.

not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[188] A "limited" exception to patent rights, according to the WTO dispute resolution panel, "makes only a small diminution of the rights in question."[189] The PPI only requires pharmaceutical companies to contribute 1% of their annual post-tax profits; absolutely "a small diminution" compared with the 99% of total profits that would go into their pockets. In this sense, the PPI is a limited exception.

With respect to the second condition, the PPI would not unreasonably conflict with a normal exploitation of a patent. As shown above, the PPI does not disrupt the exercise of patent rights by a pharmaceutical company when it seeks to merchandize its products on the market. Only after the company's annual exploitation of its patent rights is completed should it contribute 1% of post-tax profits to the PPI.

Nor would the PPI run counter to the third condition. As the following section shows, a pharmaceutical company's charitable actions would not unreasonably prejudice their economic investment in medical patents.[190] As interpreted by the WTO panel, the second prong of the third condition, "taking account of the legitimate interests of third parties," permits a member state to impose and enforce a legitimate patent limitation, provided that it is "supported by relevant public policies or other social norms."[191] The PPI satisfies this second prong given its ostensible support from policies promoting public health.

2. U.S. Constitution

Pharmaceutical companies may allege that the PPI violates the Takings Clause of the Fifth Amendment to the U.S. Constitution, which stipulates that just compensation must be provided for any private taken for public use.[192] The Supreme Court has ruled that deprivation of patent rights is subject to this clause.[193] The PPI triggers two kinds of allegations of taking of patent rights: the prospective application of the PPI to new patents to be granted by the USPTO, and the retroactive application of the PPI to existing patents that have already been granted by the USPTO and still remain within their protection terms.

With respect to the former, the prospective PPI application would not constitute a taking of a patent under the Fifth Amendment. This is because the PPI is an additional legal requirement for the grant of a new medical

188. *Id.* art. 30.

189. *TRIPS Provisions as Interpreted by the WTO Dispute Settlement Organs*, L. EXPLORER, https://lawexplores.com/trips-provisions-as-interpreted-by-the-wto-dispute-settlement-organs/ [https://perma.cc/UE2S-RWCV] (last visited Apr. 17, 2023).

190. *Id.*

191. *Id.*

192. U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation.").

193. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002) (invoking standard from the regulatory takings doctrine that patent rights constitute "the legitimate expectations of inventors in their property").

patent. It becomes a *quid pro quo* for the USPTO to approve a new patent application. Once a medical patent is granted, its owner has a responsibility to participate in the PPI.

However, the retroactive application of the PPI to existing patents may give rise to property taking concerns, given that it requires pharmaceutical companies to financially contribute to the PPI for public use without just compensation. Both the direct taking away of 1% of their post-tax profits[194] and the potential diminution in the value of their patent(s)[195] may constitute compensable takings under the Fifth Amendment. However, the USPTO may maintain that the PPI requirements are by nature equivalent to the patent maintenance fees that it charges patentees.[196] As the USPTO has the power to increase patent maintenances fees,[197] it can duly include the PPI requirements as additional maintenance fees for pharmaceutical patents it grants. As judicial rulings have demonstrated,[198] courts will not invoke the Takings Clause to rule against such decisions as they are within the ambit of the USPTO's legal powers.

Were all these constitutional concerns about the PPI not to be addressed, the USPTO may petition Congress. Since Congress has the power to "prescribe conditions" on which patents rights are granted and exercised,[199] it could pass an amendment to the Patent Act authorizing it to establish the PPI and apply it to all pharmaceutical patents, both prospectively and retroactively.

B. Pharmaceutical Companies

The third concern about the PPI's legitimacy relates to whether it would disincentivize pharmaceutical companies from investing in and developing new medicines and vaccines. There is virtually unanimous

194. *Id.*

195. *See* Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978) (ruling that regulatory takings may result in harm to the value of property); Lucas v. South Carolina Coastal Council, 112 S. Ct. 2886, 2895 (1992) (ruling that courts should consider "the economic impact of the regulation on the claimant and . . . the extent to which the regulation has interfered with distinct investment-backed expectations").

196. USPTO, *Summary of FY 2020 Final Patent Fee Rule*, https://www.uspto.gov/about-us/performance-and-planning/summary-fy-2020-final-patent-fee-rule [https://perma.cc/6K2J-F79T] (last visited Apr. 17, 2023) (Maintenance fees are due 3.5, 7.5, and 11.5 years after the date of issue and can be paid during the six months before the due date).

197. USPTO, *Fee Setting and Adjusting*, https://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting [https://perma.cc/DF7L-2BN8] (last visited Apr. 17, 2023) (Section 10 of the AIA authorizes the Director of the USPTO to set or adjust by rule all patent and trademark fees established, authorized, or charged under Title 35 of the U.S. Code and the Trademark Act of 1946 [15 U.S.C. § 1051 et seq.], respectively).

198. Oil States Energy Services, LLC v. Greene's Energy Group, LLC., 138 S. Ct. 1365 (2007) (rejecting a constitutional challenge to the Patent Trial & Appeal Board's authority to invalidate patents in post-grant reviews); Christy, Inc. v. United States, No. 19-1738 (Fed. Cir. 2020) (The cancellation of patent claims in an IPR does not amount to a compensable taking).

199. Wheaton v. Peters, 8 Pet. 591, 663–664, 8 L.Ed. 1055 (1834) (noting that Congress has "the power to prescribe the conditions on which such right shall be enjoyed").

agreement that the patent system is designed to promote innovation, as well as the societal benefits innovation provides, by rewarding investment with the opportunity to charge monopoly prices in exchange for the benefits of the innovation.[200] It is therefore necessary to explore whether, in practice, the 1% of post-tax profits from patented inventions required by the PPI would harm medical innovation by discouraging investment in research.

Studies have frequently supported the notion that the pharmaceutical industry is especially reliant on the patent system. For instance, one study of U.S. firms found that between 1981 and 1983, around 65% of pharmaceutical products would have not been introduced in the absence of patent protection.[201] The study also found that 60% of products would not have been developed in the first place, a much higher percentage than in other industries studied.[202] Similarly, a survey of U.K. research and development managers led economists to estimate that research and development expenditure would be reduced by 64% in the absence of patent protection, in contrast to an estimated 8% reduction across all other industries.[203] These findings accurately reflect the reality of modern day research and development in medicine, which typically requires years of work by large teams of scientists and can cost hundreds of millions of dollars.[204] The development of new drugs often takes more than a decade to complete and only around one in eight survive clinical testing and go on to reimburse firms for their efforts.[205] Once a formula is found, products can be reversed engineered or imitated at very low costs, making it easy for competitors with free access to the market to price out the creators and make it difficult for them to recoup their costs.[206] However, research in the 1980s found that the cost of imitating drugs was made 30% more expensive thanks to patent protection.[207]

There are multiple reasons to suggest that the PPI is unlikely to have an impact sufficient to undermine patent law's function in promoting med-

200. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003) ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge.").

201. *See* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174–175 (1986).

202. *Id.* ("An estimated 38% of chemicals, 25% of machinery, 12% of fabricated metal products, 1% of primary metals and 0% of motor vehicles would not have been developed without patent protection.").

203. *See* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 851 (2002).

204. *Id.* at 1581.

205. *See* Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302, 303 (2015).

206. *See id.*; Jeffrey Miron & Pedro Braga Soares, *Opinion: Waiving COVID-19 Vaccine Patents Would Be Disastrous*, MARKET WATCH (May 19, 2021), https://www.marketwatch.com/story/waiving-covid-19-vaccine-patents-would-be-disastrous-11621430167 [https://perma.cc/48PV-TSWE].

207. Edwin Mansfield, Mark Schwartz & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J. 907, 913 (1981) (This median price increase was "in contrast to about 10% in chemicals and about 7% in electronics and machinery").

ical innovation. First, pharmaceutical investment in innovation is also based upon demand, and so long as diseases continue to be a problem pharmaceutical companies will continue to attempt to meet demand. To maximize profits, the pharmaceutical industry tends to focus on drugs to treat chronic conditions that affect a large number of people, and endeavors to stimulate this market demand by spending much more on marketing than on research and development.[208]

Moreover, as described above, pharmaceutical companies have traditionally focused their research on "global drugs" which are in the widest demand and offer the largest market.[209] Studies have shown that the pull of market demand has been sufficient to encourage investment in innovation, even following the introduction of limitations on patent rights. For instance, one study of six antitrust consent decrees found that only one resulted in a reduction in investment.[210] The study concluded that only the highly predictable imposition of a compulsory license on a highly significant market would be likely to discourage innovation.[211] As the PPI offers a choice of voluntary measures and will not force pharmaceutical companies to sacrifice their markets for global drugs in large wealthy nations such as the U.S., the outcome is unlikely to be any different.

Throughout history, medical innovations have occurred regardless of the level of patent protection available. Commentators offer Switzerland as an example of an environment in which pharmaceutical innovation flourished even in the absence of patent protection.[212] In the early 1900s, Swiss pharmaceutical companies began to produce drugs protected in other countries and quickly developed one of the most innovative and successful pharmaceutical industries in the world, resisting international pressure to introduce patent protection for pharmaceutical inventions until 1977.[213]

Second, an examination of how pharmaceutical companies currently use their funds suggests that the 1% of post-tax profits from patented products required by the PPI should not force firms to reduce research expenditure. Currently, the pharmaceutical industry only spends around 1–2% of gross revenues on basic research to discover new molecular entities, with most basic knowledge now coming from publicly funded laboratories and institutions.[214] Although private pharmaceutical companies continue to be the primary contributor to overall research investment,[215] their focus

208. Peter C. Gøtzsche, *Patients Not Patents: Drug Research and its Development as a Public Enterprise*, 48 EUR. J. CLINICAL INV. 1 (2018).

209. Bing Chen, Franck Le Deu, & Jin Wang, *Rethinking the Big Pharma Sales Model: Thoughts from China*, *in* UNLOCKING PHARMA GROWTH 5 (2020).

210. *See* Chien, *supra* note 171, at 891.

211. *Id.*

212. *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?*, THE WALL STREET J. (Jan. 23, 2012), https://www.wsj.com/articles/SB10001424052970204542404577156993191655000 [https://perma.cc/VA3A-U937].

213. *Id.*

214. *See* Gøtzsche, *supra* note 208.

215. *See, e.g.* E. Ray Dorsey et al., *Funding of US Biomedical Research, 2003-2008*, 303 J. AM. MED. ASS'N 137, 140 (2010) ("As in the previous study, industry remained the largest contributor to biomedical research, accounting for 58% of all expenditures in

has been increasingly on late-stage clinical development and distribution of products, while academic researchers are increasingly responsible for the discovery and pre-clinical and early-stage evaluation of potential new pharmaceutical products.[216]

In fact, more pharmaceutical industry funds are directed towards efforts to maximize shareholder value than research and development. For instance, one study of how the 18 largest U.S. pharmaceutical companies use their profits found that, from 2006 to 2015, 99% of profits were distributed to shareholders, with 50% as stock buybacks and 49% as dividends.[217] The total USD $261 billion spent on buybacks amounted to 56% of their combined total of research and development expenditure.[218] This data suggests that there would be profits available to redirect toward innovation after 1% of profits from patented products have been donated through the PPI.

Last, but not least, in addition to assuming more responsibility for early research, the public sector offers many incentives to innovate in the form of funding, subsidies and other benefits. For instance, though the majority of the National Institutes of Health's (NIH) 2020 budget went toward funding research in universities, private pharmaceuticals were also beneficiaries, with the three top recipients receiving USD $31,493,555, $11,323,283 and $8,428,162, respectively.[219] The pharmaceutical industry also benefits from a research and development tax break, introduced in 1981, to encourage private sector investment in pioneering research.[220] Moreover, in cases of sufficient demand, advance purchase orders from national governments can reduce the risks traditionally associated with pharmaceutical research. For instance, while in the process of developing COVID-19 vaccines, Johnson & Johnson, Moderna and Pfizer all sold millions of doses to the U.S. government.[221] The combination of these *ex-ante* and *ex-post* rewards suggests that innovation would be encouraged "even in

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2007"); *U.S. Investments in Medical and Health Research and Development, 2013 - 2015*, RSCH. AM. 1, 3 (2016), https://www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf [https://perma.cc/YE2T-GNUV] (noting the pharmaceutical industry's contribution to total research and development expenditure rose to 64.7% in 2015).

216. Remco L. A. de Vrueh & Daan J. A. Crommelin, *Reflections on the Future of Pharmaceutical Public-Private Partnerships: From Input to Impact*, 34 PHARM. RES. 1985, 1986 (2017).

217. William Lazonick et al., *US Parama's Financialized Business Model*, 60 INST. NEW ECON. THINKING WORKING PAPER SERIES 1, 3 (2017).

218. *Id.* at 4.

219. Alex Keown, *Top 10 Pharm Country Companies to Receive NIH Funding in 2020*, BIOSPACE (Mar. 3, 2021), https://www.biospace.com/article/top-10-pharm-country-companies-to-receive-nih-funding-in-2020/ [https://perma.cc/T82T-L24E].

220. Abbey Meller & Hauwa Ahmed, *How Big Pharma Reaps Profits While Hurting Everyday Americans*, CTR. FOR AM. PROGRESS (Aug. 30, 2019), https://www.americanprogress.org/issues/democracy/reports/2019/08/30/473911/big-pharma-reaps-profits-hurting-everyday-americans/ [https://perma.cc/FEW3-GYUK].

221. Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, HEALTH AFF. (May 14, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210512.191448/full/ [https://perma.cc/P84N-VR7U].

the absence of patent protection."[222]

IV. The Ethical Functions of the PPI

In Part III, I discussed reasons why the PPI would not violate the TRIPS Agreement and the U.S. Constitution's Takings Clause, and that it would not harm pharmaceutical innovation. In Part IV, I explore the PPI's ethical function in inducing the USPTO and pharmaceutical companies to fulfill their responsibilities to guarantee patent protection that promotes public health.

A. Responsibilities of the USPTO

1. The Conventional Role of the USPTO

The USPTO is the federal agency responsible for granting patents and registering trademarks in the U.S., with the former aimed at fulfilling the mandate of the intellectual property clause of the U.S. Constitution.[223] The clause holds that, in order to "promote the progress of science and useful arts," Congress should have the power to provide inventors limited periods of exclusive rights over their discoveries.[224] In pursuit of this goal, the USPTO is responsible for examining patent applications to determine whether an applicant is entitled to a patent under the law.[225] While the USPTO lacks substantive rulemaking authority,[226] it provides advice to the U.S. president and government agencies to further "effective IP protection for U.S. innovators and entrepreneurs."[227]

Once a patent application is submitted to the USPTO, patent examiners review its conformance with formal requirements of patent law, investigate any relevant prior art and negotiate with the applicant as to the proper scope of the claims.[228] The work of patent examiners is divided among a number of technology centers, with each center having jurisdiction over certain areas of technology.[229] If patent grants are refused by examiners,

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222. *See* Burk & Lemley, *supra* note 200, 1586; *See also*, Brink Lindsey, *Why Intellectual Property and Pandemics Don't Mix*, BROOKING INST. (June 3, 2021), https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/ [https://perma.cc/X4RD-787J] ("Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support.").

223. *About Us*, U.S. PAT. TRADEMARK OFF., https://www.uspto.gov/about-us [https://perma.cc/CCW8-LXHG] (last visited July 21, 2021).

224. U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power . . . 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 . . .").

225. *Functions of the USPTO*, SCHWARTZ, https://www.schwartz-iplaw.com/functions-of-the-united-states-patent-and-trademark-office/ [https://perma.cc/QP5K-26DD] (last visited July 21, 2021).

226. John R. Thomas, *The Responsibility of the RuleMaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 741–742 (2002).

227. *See* Meller & Ahmed, *supra* note 220.

228. THOMAS N. DUENING, ROBERT D. HISRICH & MICHAEL A. LECHTER, TECHNOLOGY ENTREPRENEURSHIP – TAKING INNOVATION TO THE MARKETPLACE 103 (2021).

229. *See* Burk & Lemley, *supra* note 200.

appeals can be made to the Patent Trial and Appeal Board (PTAB).[230] The USPTO publishes granted patents, and most patent applications, 18 months from the earliest effective application filing date, records assignments of granted patents, and maintains a search room for the public to examine granted patents and records.[231]

Why should the USPTO expand its conventional role to administer the PPI? In the following two sub-sections, I argue that oversight of the PPI would enhance the USPTO's capacities in fulfilling its responsibilities to promote innovation and protect patents as public franchises, both of which will ultimately promote public health.

2. Responsibility for Promoting Innovation

As outlined above, the USPTO examines and grants patents for the purpose of promoting innovation. However, several USPTO practices arguably work against this purpose. By assuming responsibility for oversight of the PPI, the USPTO could counteract some of these practices.

The primary way in which the USPTO can be considered as failing to promote innovation is in the granting of poor-quality patents, which have a range of negative effects on entrepreneurship and innovation. For example, the grant of poor-quality patents facilitates holdup licensing and patent thickets, creates deal-killing transaction costs by forcing contracting parties to reexamine the validity of USPTO-granted patents, and encourages rent-seekers to form "speculative patent acquisition and enforcement ventures."[232] There have been persistent accounts of diminished patent quality at the USPTO, and it has been cautioned that its patents risk becoming no more than "R&D Completion Certificates."[233]

As evidenced by the practice of evergreening, low quality patents are certainly a problem in the pharmaceutical industry. Evergreening involves the artificial extension of patent terms through secondary patent applications for minor changes to drugs that are often neither novel, non-obvious nor useful.[234] For instance, before GlaxoSmithKline's patent for the heavily prescribed antibiotic Augmentin was due to expire in 2002, the company was able to secure a secondary patent and prevent generic competition from entering the market to reduce costs for patients.[235] Augmentin's original patent was for a combination of amoxicillin and a salt of clavulanic acid, and the secondary based on the same priority document used in 1975, for the single claim of a "solid pharmaceutically acceptable salt of clavulanic acid."[236] Although the patent was invalidated by a U.S.

230. *Id.*
231. *Id.*
232. *See* Thomas, *supra* note 226, at 731.
233. *Id.*
234. *See* Tahir Amin, *The Problem With High Drug Prices isn't 'Foreign Freeloading,' it's the Patent System*, CNBC (June 27, 2018), https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html [https://perma.cc/QB3G-2KCA].
235. *See* Thomas, *supra* note 226, at 735–36.
236. *Id.*; U.S. Patent No. 6,031,093 (issued Feb. 29, 2000).

court in 2002,[237] the fact such a poor-quality patent was granted sounds alarm bells for the USPTO.

The practice of evergreening pervades the pharmaceutical industry. A study of every drug on the market between 2005 and 2015 found that 80% of best-selling drugs had extended their exclusivity at least once and 50% had done so more than once.[238] By granting such patents, the USPTO must assume some responsibility for the role evergreening plays in inhibiting the progress of science. Most significantly, in a "blithe disregard" for the exchange of secrets justification for patent law, instead of allowing a pharmaceutical invention to fall into the public domain after the expiry of a patent term, evergreening denies the public the benefit offered by the intended diffusion of inventive knowledge.[239]

USPTO efforts to improve patent quality have encountered numerous practical and legislative challenges. For instance, Professor Mark Lemley has argued that investment in efforts to curb poor USPTO patents would be wasteful.[240] Primarily he claims that the costs of having examiners spend more time examining patents and searching prior art would not be justified as 95% of patents are either never used or are used in contexts which do not rely on the determination of validity.[241] Moreover, he contends that the assumption that more examination time would weed out more bad patents without weeding out good ones is unrealistic. Such false negatives risk reducing innovation incentives.[242] Placing too much emphasis on the denial of patents, therefore, counterintuitively risks further limiting the progress of science.

Similar problems can be found in efforts and proposals to curb the practice of evergreening. For instance, the USPTO attempted to introduce a limitation to the availability of continuation applications, with only two such applications being available per application family.[243] The limitation was controversial as it risked blocking legitimate patent extensions, and in any case, was ultimately invalidated in court for exceeding the USPTO's authority to regulate.[244] Despite the grant of a rehearing, the USPTO ultimately decided to voluntarily withdraw its proposed limitation.[245] Other

237. *GlaxoSmithKline Hit by US Patent Ruling on Augmentin Antibiotic*, THE PHARMA LETTER (Mar. 25, 2002), https://www.thepharmaletter.com/article/glaxosmithkline-hit-by-us-patent-ruling-on-augmentin-antibiotic [https://perma.cc/YNZ6-TG5Z].

238. *See* Robin Feldman, *May Your Drug Price be Evergreen*, OXFORD J.L. & BIOSCIENCES 1, 13 (2018).

239. *See* Muhammad Z Abbas, *Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System*, 15 J. GENERIC MEDICINES 53, 57 (2019).

240. *See* Lemley, *supra* note 29, at 752.

241. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1, 13-15 (2001).

242. *Id.* at 24-25.

243. *See* John R. Thomas, *Patent "Evergreening": Issues in Innovation and Competition*, CONG. RSCH. SERV. 1, 10-11 (2009); Christopher M. Holman, *Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection*, 51 U. PAC. L. REV. 493, 505 (2020).

244. *See* Thomas, *supra* note 243, at 11.

245. *See* Holman, *supra* note 243.

proposed legislation presents similar challenges. For instance, a 2019 bill called the "No Combination Drug Patents Act" would create a presumption that follow-on pharmaceutical patents were obvious.[246] Critics have also questioned the impact of this presumption on legitimate conduct. They pointed out that secondary patents could be essential in bringing certain necessary treatments to the market, as in the case of the failed cancer drug AZT being granted a secondary method patent for use to treat AIDS.[247]

Oversight of the PPI provides the USPTO with a golden opportunity to drive innovation in public health through the patents it grants. Rather than turning away from incentivizing disclosure through the grant of patents and focusing on increasing examination scrutiny and the denial of patent grants, the USPTO could counteract the negative effects of poor-quality patents by ensuring pharmaceutical companies appropriately give back to the public as a means of promoting innovation.

Under the PPI, efforts to promote voluntary technology transfer could help overcome evergreening's attempts to delay the introduction of inventions to the public domain. For instance, the ongoing COVID-19 crisis has highlighted the need for greater sharing of essential information not contained in patent documents. As complex biological inventions, COVID-19 vaccines are "highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent".[248] Collaborative licenses between patent-owning firms and individual manufacturers have, therefore, been proposed as the most efficient way to advance vaccine production.[249] By ensuring that companies engage in such measures to fulfil their duties under the PPI, the USPTO would be able to promote innovation more proactively than through focusing on the denial of patents.

3. Responsibility to Protecting Patents as Public Franchises

A second reason that the USPTO should assume responsibility for oversight of the PPI is that patents granted by the USPTO are by nature public franchises. This should confer some responsibility on the USPTO to ensure that the patents are used in the public interest, and the PPI can provide a vehicle for ensuring this.

The designation of patents as public franchises came in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*.[250] The case concerned a patent for technology to protect wellhead equipment used in hydraulic fracturing, allegedly infringed by Greene's Energy Group.[251]

246. *Id.* at 513.
247. *See* Holman, *supra* note 243, at 513.
248. W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge transfer for large-scale vaccine manufacturing*, 369 SCI. MAG. 912 (2020).
249. Ruth L. Okediji, *With a Covid-19 Vaccine Patent Waiver Likely, Time to Rethink Global Intellectual Property Rules Opinion*, CNN (May 7, 2021), https://edition.cnn.com/2021/05/07/opinions/covid-vaccine-patent-waiver-as-equals-intl-cmd/index.html [https://perma.cc/5X2T-GZ2V].
250. Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365 (2018).
251. *Id.* at 1368.

Greene's initiated validity proceedings at the District Court and petitioned the USPTO to conduct *inter partes* review.[252] The Patent Trial and Appeal Board (PTAB) of the USPTO issued a decision concluding that all of Oil States' claims were unpatentable.[253] Oil States then appealed on the grounds that *inter partes* review was unconstitutional.[254]

When considering Oil States' arguments, the Supreme Court began by noting that the grant of a patent involves the USPTO taking from the public rights of substantial value and offering them to the patentee.[255] The court likened this to the granting of public franchises and noted that such franchises can be qualified by the authority of the grantor to reexamine and perhaps cancel the grant.[256] Oil States argued that patents conferred private property rights to a patentee, but this claim was held not to contradict the Court's decision as the specific property right granted by a patent was a public franchise.[257] As public franchises can only confer the rights that a statute provides, patents rights are limited by the provisions of the Patent Act, which include *inter partes* review.[258]

The primary objective of all franchise grants is to benefit the public at large. The interests of grantors and grantees are secondary to such grants.[259] Generally, the public benefit sought is market regulation, for example by ensuring low prices or subsidizing costs.[260] Grantees' agreement to pay certain fees, shoulder some responsibility or perform a public duty is the *quid pro quo* to receive a franchise from the government. It is the responsibility of the state or a duly authorized body to oversee the agreement.[261] In the case of patents, it can be argued that, as the granting government agency, the USPTO should assume responsibility for ensuring patents are used as public franchises in the public interest.

In the pharmaceutical industry, there are notable examples of patents being used against the public interest and failing to serve their role as public franchises. For example, as outlined above, evergreening artificially extends patent monopolies and delays the entrance of medicines into the public domain.[262] The practice of price gouging is another example. Taking advantage of the substantial freedom to set prices that a patent monopoly offers,[263] patent owners frequently engage in abusive practices. In the

252. *Id.*
253. *Id.*
254. *Id.*
255. *Id.* at 1373–74.
256. *Id.* at 1374–75.
257. *Id.* at 1375.
258. *Id.*
259. *Franchise: Government Franchises*, L. LIBR., https://law.jrank.org/pages/6995/Franchise-Government-Franchises.html [https://perma.cc/Y2WT-TNEK] (last visited July 24, 2021).
260. Owen Rogers, *What Is a Public Franchise?*, BIZFLUENT (Sept. 26, 2017), https://bizfluent.com/facts-7212317-public-franchise-.html [https://perma.cc/AED3-MLHA].
261. *See* Holman, *supra* note 243.
262. *See supra* notes 234, 238–237 and accompanying text.
263. Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices - Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 310 (2020).

first half of 2019, more than 3400 drugs saw their prices raised by an average of 10.5%, with about 41 these experiencing price increases greater than 100% and one experiencing an increase of 879%.[264] Generally, the most dramatic price rises occur in the category of "specialty drugs" which may be used to treat rare conditions, require special handling such as ongoing clinical assessment, or simply fall into the category for costing in excess of $10,000 a year.[265] From 2010 to 2015, specialty drugs accounted for more than two thirds of growth in drug spending and in 2016 it was projected that specialty drug prices would mean that 1% of all drugs would account for 50% of all drug spending in the U.S. by 2018.[266]

In cases of abusive price gouging that relies upon medical patents, it could be argued that the USPTO should be empowered to intervene. However, determining the nature of this intervention is a challenge. In cases of patents with questionable validity, it might be suggested that *inter partes* or post-grant review could be used as a means for the USPTO to revoke monopoly rights. *Inter partes* review can be initiated by petitioners either nine months after the grant of a patent or following the termination of post-grant review.[267] In contrast, post-grant review must be initiated within the nine months following the grant of a patent.[268] While *inter partes* review focuses only on non-obviousness and considers only patents and printed publications as prior art, the post-grant review covers all grounds for invalidity and considers a broader range of evidence.[269] Currently, *inter partes* review is more common as the window to institute it is wider.[270]

The first problem with this approach is that it would only be available to the USPTO in the case of weak patents. However, the strategy of pursuing revocation of weak patents being used against the public interest is also not without its flaws. For instance, while it is cheaper for prospective generic manufacturers to pursue *inter partes* review than court litigation, "*inter partes* review filing fees of $23,000 and attorney costs of around $400,000 or more are still substantial".[271] Furthermore, drugs are often covered by multiple patents and "30-month stays will remain available so long as at least one Orange Book-listed patent remains".[272] Even if all relevant patents were invalidated, generic-free periods provided for new drugs (five years), drugs for rare diseases (seven years), and biologics (12 years)

264. Aimee Picchi, *Drug Prices in 2019 are Surging, With Hikes at 5 Times Inflation*, CBS NEWS (July 1, 2019), https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/ [https://perma.cc/2T3R-3KDA].

265. *See* Feldman, *supra* note 263, at 315.

266. *Id.*

267. Dorian Ojemen, *The Ethics of Inter Partes Review before the USPTO*, 47 ST. MARY'S L.J. 645, 657 (2016).

268. *Id.* at 661.

269. *Id.*

270. *Id.*

271. Jonathan J Darrow, Reed F Beall & Aaron S Kesselheim, *Will Inter Partes Review Speed US Drug Entry?*, 35 NATURE BIOTECHNOLOGY – PATENTS 1139, 1140 (2017).

272. *Id.*

are not affected by patent invalidation.[273]

Commentators have argued that promoting post-grant opposition mechanisms such as *inter partes* review risks providing challengers with too many bites of the apple, "allowing them to inundate patentees with an endless set of challenges".[274] Other statements cautioning this approach have been made. For instance, it is claimed that the decision to label patents as public franchises is unfounded.[275] This is because as a category of legal rights, patents have historically been understood to impart private interests.[276] However, commentators also claim that allowing the revocation of patents to become too commonplace risks "effectively stating that a public franchise remains a public right, even after the public right has been conferred upon the individual".[277]

Rather than focusing on the invalidation of patents, the USPTO could ensure patents are being used in the public interest through oversight of the PPI. Practices like price gouging could be counteracted by ensuring that pharmaceutical firms commit a fraction of profits from patented products to efforts aimed at improving public health. Aside from engaging in voluntary technology transfer, as described above, pharmaceutical companies could be encouraged to participate in schemes aimed at promoting universal access to affordable medicines. Such efforts would ensure that the public franchises offered to pharmaceutical companies are not abused while also not undermining the private interests that a public franchise confers. It would also avoid some of the limitations of *inter partes* review, especially problems unique to the pharmaceutical industry, such as generic-free periods. Furthermore, as the PPI would require 1% of profits from pharmaceutical products with both strong and weak patents, it would allow the USPTO to ensure that even the former category is used in the public interest.

B. Responsibilities of Pharmaceutical Companies

This section suggests that pharmaceutical companies' participation in the PPI should be understood as a responsibility attached to the patents they obtain from the USPTO. I argue that they have responsibilities to sufficiently disclose patent information and to reciprocate for others' prior research and public funding on which their innovations are built. These responsibilities, as I show, translate into a responsibility to participate in the PPI that should be fulfilled by pharmaceutical companies in good faith.

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273. *Id.*

274. Mark A. Lemley, *Fixing the Patent Office*, 13 INNOVATION POL'Y & ECON. 83, 95 (2013).

275. Evan Jones, *Reckoning Patents as Public Franchises*, Bos. Pat. L. Ass'n (2021), https://newsletter.bpla.org/reckoning-patents-as-public-franchises [https://perma.cc/7XY7-3PPQ].

276. *Id.*

277. *Id.*

1. Respecting Patent Law's Disclosure Goal

The award of a twenty-year patent monopoly entails social costs, including "deadweight loss, allocative inefficiency, and wealth transfer from consumers to the patentee".[278] Patent law is intended to ensure that society gets something in return, with most observers contending that public disclosure is what is exchanged in the bargain.[279]

The disclosure requirement is enshrined in 35 U.S.C. § 112(a) which holds that patents must contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same."[280] This provision contains two legal requirements intended to promote disclosure.[281] The requirement of a full, clear and concise written description aims to ensure that inventions are sufficiently disclosed, while enablement aims to ensure that others can use disclosures to replicate inventions.[282] The relevant standard of enablement is that patent disclosures allow others to make and use inventions without undue experimentation, ensuring that inventors do not fail to hold up their end of the patent law bargain by patenting unreproducible inventions.[283]

However, certain characteristics of pharmaceutical or biotechnological inventions make it more difficult for the pharmaceutical industry to hold up its end of the patent law bargain. For instance, it is extremely challenging to draft enabling disclosures for inventions involving recombinant protein synthesis.[284] Recombinant proteins are engineered through the introduction of recombinant DNA into a cell but, as every cell line is unique, structure and behavior of a final protein is highly dependent on the cell line used to synthesize it and the production of truly identical cop-

278. Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 407 (2010).

279. *See* Brenner v. Manson, 383 U.S. 519, 534 n.21 (1966) ("As a reward for inventions and to encourage their disclose, the United States offers a . . . monopoly to an inventor who refrains from keeping his invention a trade secret.") (quoting Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944)); Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 331 (1945) ("[The patent law's] inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure."); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) ("'In consideration of [the fulfillment of] disclosure and the consequent benefit to the community, the patent is granted.'") (quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933)); *see also,* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 542 (2009); Lisa L. Ouellette, *Do Patents Disclose Useful Information?*, 12 HARV. J.L. & TECH. 545, 571 (2012).

280. Patentability of Inventions and Grant of Patents, 35 U.S.C. § 112(a) (2022).

281. Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 525 (2018).

282. *Id.*

283. Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 112 (2011).

284. *Id.* at 141.

ies of proteins using different production cell lines is nearly impossible.[285] Moreover, it also means that attempts to reproduce a protein using different methods could yield products that lack the utility of the claimed invention.[286]

It is also hard to establish rules that ensure enabling disclosures in the pharmaceutical industry. For instance, while patents are static documents, scientific understanding is constantly developing such that a disclosure initially appearing to be enabling may later turn out not to be.[287] According to USPTO guidelines, descriptions including single working examples, animal studies or in vitro analyses may be sufficient.[288] However, in the case of Eli Lilly & Co's drug Xigris, after patent protection was obtained following a single pre-clinical trial carried out on only ten baboons, subsequent research made it clear that the results could not be reproduced and it was ultimately discovered Xigris simply did not work as intended.[289]

Many pharmaceutical companies have intentionally engaged in efforts to undermine patent law's disclosure function.[290] As acknowledged by the Supreme Court in *Brenner v. Manson*,[291] patent law has resulted in the art of drafting claims that disclose very little useful information while also broadening the scope of protection as widely as possible.[292] This practice is common in the pharmaceutical industry. For instance, many pharmaceutical patents now contain claims describing hundreds of theoretical ways a product can be used before it has even entered the clinical trial phase.[293]

For the benefit of a patent's early disclosure, society pays the high price of a twenty-year monopoly granted to an inventor, after which others will be free to use the information disclosed to their benefit.[294] However, in blithe disregard of this notion, many pharmaceutical companies have engaged in significant efforts to extend patent monopolies through the practice of evergreening.[295] As discussed above, this is a practice particular to the pharmaceutical industry.[296] It involves a patent owner filing for a new patent based on minor modifications to their existing product in

285. *Id.* at 135.
286. *Id.* at 136.
287. Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 904 (2017).
288. *Id.*
289. *Id.* at 962, 974.
290. *Id.* at 267–68.
291. Brenner v. Manson, 383 U.S. 519 (1966).
292. *Id.* at 534.
293. Aaron S. Kesselheim, *Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System*, 9 AM. ASS'N PHARM. SCIENTISTS J. 306, 308 (2007).
294. Abbas, *supra* note 239, at 57.
295. *Id.*
296. Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, 11 GLOBAL POL'Y 46, 50 (2020).

order to begin the twenty-year term anew.[297] Evergreening can consist of filing a patent for a new formulation or composition of an existing drug, combining two existing drugs, patents for new uses of a known drug, or new dosage forms.[298] The triviality of modifications usually involved has led to evergreening generally being regarded as patent abuse.[299]

Evergreening has had a significant impact on global access to drugs. For instance, the practice has been employed in relation to HIV and AIDS treatments, despite the challenges these diseases have presented in developing countries.[300] The antiretroviral drug Zidovudine was originally discovered as a cancer medication in 1964, but it was patented again in 1985 when it was discovered that it could be used to treat HIV/AIDS.[301] GlaxoSmithKline subsequently filed for patent protection on combinations of Zidovudine with other antiretroviral drugs in 1992, 1996 and 1997. Thus, the drug's final patent did not expire until 2017.[302] Within this protection period, the general absence of generic competition for Zidovudine and other antiretroviral drugs meant that HIV medicine costs as much as $10,000 per person per year, whereas now the same medicines can be purchased for $150 or less.[303]

2. Reciprocating for Another's Prior Research

Innovation does not occur in a vacuum, and the notion of "the lone genius inventor" is untenable.[304] Professor Mark Lemley has shown that, in the case of hundreds of significant new technologies, almost all were invented simultaneously by two or more teams working independently from one another.[305] While innovation can take different forms, these forms tend to reflect the notion that innovation relies on what came before it.

Innovation can be defined as sequential as inventions tend not to be independent ideas formed in isolation, but rather part of an incremental process in which one inventor looks at the ideas of others and attempts to build on them to produce something new.[306] Most inventions are generally characterized as incremental inventions, in contrast to radical inven-

297. Yahong Li, *Intellectual Property and Public Health: Two Side of the Same Coin*, 6 ASIAN J. WTO & INT'L HEALTH 389, 397 (2011).
298. *See* Abbas, *supra* note 239, at 54.
299. *See* Li, *supra* note 297, at 397.
300. *Id.*
301. *Id.* at 396–97.
302. *See* Abbas, *supra* note 239, at 54.
303. *Id.*
304. *See* Lemley, *supra* note 29, at 711 (2011) ("Invention appears in significant part to be a social, not an individual, phenomenon."); Laura Pedraza-Fariña, *Patent Law and the Sociology of Innovation*, 2013 WIS. L. REV. 813, 838–39 (concluding that discovery is "inherently relational, emerging from a complex, interactive back-and-forth among researchers, often in different communities of practice or social worlds"); Haochen Sun, *Patent Responsibility*, 16 Stan. J. C.R. & C.L. 347–56 (2021) (discussing the social conditions of inventions).
305. *See* Lemley, *supra* note *29, at 711.*
306. *See id.* at 713–14.

tions which are considered to constitute a risky departure from existing practice.[307] However, a study of 157 radical invention patents found that, contrary to conventional wisdom, they were more dependent on existing knowledge and emergent technology than non-radical inventions.[308] For instance, radical patents cite more existing patents which are, on average, younger than those cited by non-radical patents.[309]

Sequential innovation is certainly evident in the pharmaceutical industry. For example, revolutionary scientific discoveries in the 1970s, such as gene splicing and the ability to create monoclonal antibodies, opened up significant areas of research and dramatically accelerated the pace of discovery in biomedical science in subsequent decades.[310] This dramatically affected the organization and management of drug discovery, with drug companies beginning to behave more like universities by placing an increased emphasis on "collaboration, publication, and exchange of (precompetitive) information" and becoming increasingly willing to exploit external sources of technology through licensing agreements.[311]

The pharmaceutical industry now exhibits a great dependency on the use of gene sequences which, aside from being discrete molecules themselves, also provide a foundation for other areas of innovation ranging from diagnosis to targeted treatments.[312] Big pharma now increasingly relies on research tools and product leads provided by biotechnological research, with a reported 25–40% of its sales now coming from drugs that originated in the biotechnology sector.[313] Furthermore, breakthrough products, which inevitably display some deficiencies, are being widely distributed and built upon by other pharmaceutical companies which use the deficiencies as opportunities to develop more effective competing products.[314]

Evidence of sequential innovation can also be found in products identified as potential treatments for COVID-19. For instance, in the early stages of the pandemic, Gilead's antiviral drug, remdesivir, was touted as a potential coronavirus treatment after leaked University of Chicago trials of 113 patients found that most were discharged within a week after being treated with daily infusions of the drug.[315] While research now suggests it is not a very effective treatment, studies have still shown that it can block

307. *See* Wilfred Schoenmakers & Geert Duysters, *The Technological Origins of Radical Inventions*, 39 RES. POL'Y 1051 (2010).

308. *Id.* at 1057.

309. *Id.* at 1056–57.

310. *See* Iain M. Cockburn, *The Changing Structure of The Pharmaceutical Industry*, 23 HEALTH AFF. 10, 15 (2004).

311. *Id.* at 15–16.

312. *See* Kyle A. Marchini, *Patents and Innovation in the Pharmaceutical Industry*, 4 GROVE CITY C. J. L. PUB. POL'Y 47, 49 (2013).

313. *See* Cockburn, *supra* note 310, at 16.

314. Fredric J. Cohen, *Macro Trends in Pharmaceutical Innovation*, 4 NATURE REV. DRUG DISCOVERY 78, 79 (2005).

315. Bret Stephens, *The Story of Remdesivir*, N.Y. TIMES (Apr. 17, 2020), https://www.nytimes.com/2020/04/17/opinion/remdesivir-coronavirus.html [https://perma.cc/Z554-YFRV].

coronavirus activity.[316] Gilead initially developed remdesivir as a potential treatment for hepatitis C in 2009, before seeing it employed as a treatment for Ebola during an outbreak in the Congo.[317] However, the origins of the drug cannot be solely attributed to Gilead. For instance, while Gilead may have discovered the initial compound, federal scientists were responsible for identifying the compound as a potential treatment for Ebola and coronaviruses.[318] After screening a thousand compounds from Gilead's library, federal researchers identified remdesivir as a precursor and proceeded to refine, develop and evaluate the compound.[319]

Similarly, sequential innovation can be found in the vaccines now being employed as the primary tool to end the COVID-19 pandemic. For instance, the Pfizer and Moderna vaccines both rely on synthetic messenger RNA (mRNA) which scientists have been attempting to apply medically for decades.[320] Researchers have long understood mRNA's potential as a recipe book for the body's trillions of cells but faced government grant and corporate funding rejections.[321] However, after a hybrid mRNA that could be injected into cells without altering the immune system was discovered, new researchers, including founders of Pfizer's partner BioNTech, became interested in the technology.[322] Subsequent researchers, including the scientist whose team was responsible for the specifically designed spike protein employed by the Pfizer/BioNTech and Moderna vaccines, identified the potential application of mRNA as a coronavirus treatment.[323]

Innovation can also be characterized as combinatorial. This term refers to the creative integration of multiple pre-existing technologies to provide new technological functions.[324] The most prominent example is the smartphone which employs previously invented technological components including "central processors, memory, communications, navigation, messaging, applications, transistors, the Internet technologies and so on."[325] The technical classification of patents can be used to illustrate how

316. JV Chamary, *The Strange Story of Remdesivir, A Covid Drug That Doesn't Work*, FORBES (Jan. 31, 2021), https://www.forbes.com/sites/jvchamary/2021/01/31/remdesivir-covid-coronavirus/?sh=DC92f6766c27 [https://perma.cc/7W69-4HM5].

317. *See* Stephens, *supra* note 315.

318. *The Real Story of Remdesivir*, PUB. CITIZEN (May 7, 2020), https://www.citizen.org/article/the-real-story-of-remdesivir [https://perma.cc/W8TN-3XCP].

319. *Id.*

320. Damian Garde, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race*, STAT NEWS (Nov. 10, 2020), https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race [https://perma.cc/754N-GCEM].

321. *Id.*

322. *Id.*

323. Carolyn Y. Johnson, *A Gamble Pays off in 'Spectacular Success': How the Leading Coronavirus Vaccines Made it to the Finish Line*, THE WASH. POST (Dec. 6, 2020), https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/ [https://perma.cc/LY69-LUJK].

324. Mehmet Yildiz, *Combinatorial Innovation*, MEDIUM (Mar. 14, 2020), https://medium.com/illumination-blog/combinatorial-innovation-16e6cefd6163 [https://perma.cc/JZM6-45L8].

325. *Id.*

important technological combination has been in the inventive process, as 77% of all U.S. patents granted between 1790 and 2010 contain a combination of at least two technology codes.[326]

Combination is an important form of innovation in the pharmaceutical industry. In recent decades a process called "combinatorial chemistry" has increasingly been used in pursuit of the discovery of new drugs.[327] The practice involves, for example, selecting two sets of 30 existing compounds and then mixing and matching "every amine with every carboxylic acid to form new molecules called amides," with the reactions collectively generating 900 different combinations which can then be screened for potential medicinal value.[328] Innovation in the pharmaceutical industry can also involve the combination of distinct areas of technology. For example, artificial intelligence models have been applied to predict "how combinations of different cancer drugs kill various types of cancer cells."[329] Moreover, rapidly developing nanotechnology is being investigated for its potential use in drug delivery, with the potential to increase the permeability of biofilm, change distribution in vivo and improve bioavailability.[330]

3. Reciprocating for Public Funding

Public funding is an important aspect of pharmaceutical research. For instance, the National Institutes of Health (NIH), the largest federal contributor to biomedical research funding in the U.S., accounted for 27% of total research expenditure in 2007.[331] In 2015, federal agencies invested USD $35.9 billion in pharmaceutical research, with USD $29.6 billion of this coming from the NIH.[332] While still significant, this meant that the NIH's total contribution to pharmaceutical research expenditure fell to 18.7%.[333] However, by 2020, the NIH investment budget had risen to USD $41.9 billion, enabling "almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state."[334]

Pharmaceutical companies benefit substantially from government support, meaning taxpayers have already contributed to private pharma-

326. Hyejin Youn et al., *Invention as a Combinatorial Process: Evidence from US Patents*, 12 J. ROYAL SOC. INTERFACE 1, 3 (2014).

327. Matthew J. Plunkett & Jonathan A. Ellman, *Combinatorial Chemistry and New Drugs*, 276 SCI. AM. 68, 69 (1997).

328. *Id.*

329. *AI Predicts Which Drug Combinations Kill Cancer Cells*, TECHNOLOGY.ORG (Dec. 2, 2020), https://www.technology.org/2020/12/02/ai-predicts-which-drug-combinations-kill-cancer-cells/ [https://perma.cc/3F9Y-MTLT].

330. Ying Du & Baoan Chen, *Combinations of Drugs and Carriers in Drug Delivery Technology and Its Development*, 13 DRUG DESIGN, DEV. THERAPY 1401, 1402 (2019).

331. E. Ray Dorsey et al., *Funding of US Biomedical Research, 2003-2008*, 303 J. AM. MED. ASS'N 137, 140 (2010).

332. *U.S. Investments in Medical and Health Research and Development, 2013 - 2015*, RSCH. AM. 1, 4 (2016), https://www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf [https://perma.cc/M9Q7-3LBZ].

333. *Id.*

334. *What We Do: Budget*, NAT'L INST. HEALTH, https://www.nih.gov/about-nih/what-we-do/budget [https://perma.cc/2LDV-ZWYV] (last visited June 27, 2021).

ceutical research before paying for the products of this research at the pharmacy.[335] Contributions can take indirect forms, such as subsidies or public university research funding that many pharmaceutical companies rely on.[336] A federal research and development tax break, for instance, was introduced in 1981 to encourage private sector investment in pioneering research.[337] Pharmaceutical companies also receive tax deductions for marketing and advertising expenses.[338] After the Trump administration introduced a 14% corporate tax reduction, the pharmaceutical industry was able to save a total of USD $76 billion, with Eli Lilly alone receiving a tax cut of nearly USD $4.5 billion on offshore profits.[339]

Despite a long tradition of pharmaceutical companies' reliance on publicly funded research, research and development partnerships have changed in recent decades.[340] Alongside traditional bilateral interactions between academic and industrial scientists, there are now multiple stakeholder public-private partnerships that may also involve charities, patient organizations and even regulators.[341] In these partnerships, pharmaceutical companies increasingly focus on late-stage clinical development and distribution of products, meaning, academic researchers are increasingly responsible for discovery and pre-clinical and early-stage evaluation of potential new pharmaceutical products.[342]

Gleevec, Novartis' cancer drug, provides an example of how this new research and development model can impact the funding that precedes the introduction of a new drug. Much of the early work on Gleevec was carried out by an Oregon Health & Science University researcher whose funding came primarily from the National Cancer Institute, the Leukemia and Lymphoma Society, and the university itself, with only 10% coming from Novartis.[343] Following this early research, Novartis was convinced to invest in further testing by conducting three Phase II clinical trials.[344]

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335. Jason Cone, *Pharmaceutical Corporations Need to Stop Free-Riding on Publicly-Funded Research*, THE HILL (Mar. 3, 2018), https://thehill.com/opinion/healthcare/376574-pharmaceutical-corporations-need-to-stop-free-riding-on-publicly-funded [https://perma.cc/A7AJ-YLWB].

336. *Id.*

337. Abbey Meller & Hauwa Ahmed, *How Big Pharma Reaps Profits While Hurting Everyday Americans*, CTR. AM. PROGRESS (Aug. 30, 2019), https://www.americanprogress.org/issues/democracy/reports/2019/08/30/473911/big-pharma-reaps-profits-hurting-everyday-americans [https://perma.cc/39DJ-48H9].

338. *Id.*

339. *Id.*

340. Remco L. A. de Vrueh & Daan J. A. Crommelin, *Reflections on the Future of Pharmaceutical Public-Private Partnerships: From Input to Impact*, 34 PHARM. RES. 1985 1988 (2017).

341. *Id.* at 1989.

342. *Id.* at 1986.

343. James Love, *R&D Costs for Gleevec*, KNOWLEDGE ECOLOGY INT'L (Apr. 3, 2013), https://www.keionline.org/22170 [https://perma.cc/SR9M-7C72] ("his laboratory's funding sources were: 50% National Cancer Institute; 30% Leukemia and Lymphoma Society; 10% Novartis; 10% Oregon Health and Science University").

344. *Id.*

Public funding can also take more direct forms. For instance, some NIH funding goes directly toward agreements with private parties that lead to the development and patenting of drugs.[345] While universities received the majority of NIH funding in 2020, many private pharmaceutical companies also received substantial sums of money.[346] The greatest beneficiary was Cognition Therapeutics, which received USD $31,493,555, followed by Venatorx Pharmaceuticals and PsychoGenics Inc., which received USD $11,323,283 and USD $8,428,162, respectively.[347]

The NIH's overall impact on pharmaceutical research, through both direct and indirect contributions, has been massive. One study into public contribution to new drug discovery found that NIH-funded publications and projects were directly related to all 210 new molecular entities approved by the FDA from 2010 to 2016.[348] Moreover, this impact has been accompanied by a reduction in pharmaceutical products discovered within private pharmaceutical companies. For instance, a study of Pfizer's and Johnson & Johnson's 2017 annual reports found that discovery and early development only occurred in-house for 10 of Pfizer's 44 products and two of Johnson & Johnson's 18 leading products.[349]

Given the substantial direct and indirect public funding channeled toward the pharmaceutical industry, the government could, to an extent, be regarded as a co-inventor or co-patent owner. However, there is little evidence of such recognition from pharmaceutical companies. Despite NIH investment in early research and development, for example, the public receives no direct return on investment when resulting drugs become profitable.[350] Furthermore, as described above, no federal researchers were acknowledged as inventors in the remdesivir patent despite their crucial involvement.[351]

Prior to the Bayh-Doyle Act of 1980, government agencies obtained patents for the inventions that they funded based on the rationale that ownership of publicly funded inventions should be retained by the public.[352] Since the introduction of the Act, entities that received public funding in

345. Natalie Goldberg, *The Bayh-Dole Act: Is It the Proper Treatment for the Big Pharma Price-Gouging Epidemic?*, 29 FED. CIR. B.J. 387, 394 (2020).

346. Alex Keown, *Top 10 Pharm Country Companies to Receive NIH Funding in 2020*, BIOSPACE (Mar. 3, 2021), https://www.biospace.com/article/top-10-pharm-country-companies-to-receive-nih-funding-in-2020 [https://perma.cc/4864-L3K3].

347. *Id.*

348. Ekaterina Galkina Cleary et al., *Contribution of NIH Funding to New Drug Approvals 2010-2016*, 115 PROC. NAT'L ACAD. SCI. 2329, 2332 (2018).

349. Emily H. Jung, Alfred Engelberg & Aaron S. Kesselheim, *Do Large Pharma Companies Provide Drug Development Innovation? Our Analysis Says No*, STAT NEWS (Dec. 10, 2019), https://www.statnews.com/2019/12/10/large-pharma-companies-provide-little-new-drug-development-innovation [https://perma.cc/6GRP-82SK].

350. John LaMattina, *Does The NIH Deserve A Piece Of Biopharma's Profits?*, FORBES (Feb. 8, 2019), https://www.forbes.com/sites/johnlamattina/2019/02/08/does-the-nih-deserve-a-piece-of-biopharmas-profits/?sh=48e1be3f4a74 [https://perma.cc/HAN8-MXRD].

351. *See supra* notes 318 and accompanying text.

352. *See* Goldberg, *supra* note 345, at 395.

the process of innovation have been allowed to patent their inventions.[353] The public interest is, instead, to be protected through limitations on the private ownership of such patents. Limitation mechanisms include: "(1) exceptional circumstances; (2) forfeiture for failure to follow disclosure provisions; (3) march-in rights; and (4) licensing the subject invention."[354]

March-in rights allow a federal agency to retrieve a patent following ineffective use of an invention, a health or safety concern, or when goods are substantially manufactured outside the United States.[355] In practice, the government has been notably reluctant to exercise march-in rights. Despite NIH involvement in drug development and many petitions for their exercise following significant pharmaceutical price spikes, "march-in rights have never been utilized by any federal agency."[356]

Notwithstanding legislation permitting private ownership of publicly funded patents and the U.S. government's unwillingness to utilize the limitations available to it, there has been insufficient reciprocation from pharmaceutical companies. This is most evident in the long-running practice of price gouging. In the first half of 2019, more than 3,400 drugs saw their prices raised by an average of 10.5%, with 41 of these experiencing price increases greater than 100% and one an increase of 879%.[357] While companies are quick to claim that price gouging is necessary to fund innovation, one study has suggested that the 18 largest pharmaceutical companies in the United States spent a total of USD $261 billion on buybacks of their own corporate stock for the purposes of increasing their stock prices.[358]

4. Responsibility to Participate in the PPI

How should we deal with pharmaceutical companies' failure to meet their responsibilities for sufficient disclosure and reciprocation for another's prior research and public funding? As demonstrated above, current patent law is silent on these issues, and no relevant patent reforms have been proposed. Therefore, there is systemic asymmetry of pharmaceutical patent owners' rights and responsibilities.[359] Without radical reform, this asymmetry may even perpetuate the increasing difficulty to drive pharmaceutical companies to behave socially responsibly[360] given

353. Jennifer Penman & Fran Quigley, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-in Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171, 174 (2017).

354. *See* Goldberg, *supra* note 345, at 398.

355. *Id.* at 400.

356. *Id.* at 402–03.

357. Aimee Picchi, *Drug Prices in 2019 are Surging, With Hikes at 5 Times Inflation*, CBS NEWS (July 1, 2019), https://www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation [https://perma.cc/FRV7-S6UY].

358. Lazonick et al., *supra* note 217, at 2–4.

359. *See* Sun, *supra* note 304 ("U.S. patent law encourages the irresponsible exercise of patent rights through its asymmetric allocation of rights and responsibilities.").

360. *See* Fisher et al., *supra* note 11, at 34–35 ("The third task is likely to be the hardest. There is little chance that the major pharmaceutical firms would participate in this system voluntarily").

that they are institutions whose priority is to maximize profits for their shareholders.[361] As shown in Part III, 18 of the largest U.S. pharmaceutical companies allocate 99% of their profits to shareholders.[362]

The creation of the PPI can help correct this asymmetry of patent protection by establishing a mechanism that imposes more legal responsibilities upon pharmaceutical companies in relation to their patents. Instead of relying upon the "benevolence" of pharmaceutical companies, this mechanism requires them take proactive actions to fulfill their responsibilities. It is intended to bring about an ethical awakening through which pharmaceutical companies' patent responsibilities would gradually be taken as seriously as their exclusive rights.

First, this mechanism legalizes and enforces pharmaceutical companies' responsibilities for sufficient disclosure and reciprocation for another's prior research and public funding. Pharmaceutical companies currently rely on the patent protection system to keep drug prices high. While the PPI could not overcome such practices alone, asking companies to donate a small share of profits toward efforts to provide the public with better access to affordable medicines could help offset some of the harms. To reciprocate for substantial opportunities, companies are given to profit from their medical patents, pharmaceutical companies should be encouraged to contribute to global efforts to promote access to life-saving medicines. The 1% of post-tax profits required by the PPI is not too much to ask for.

Second, the mechanism that the PPI creates serves as a forum through which stakeholders and the public would discuss openly the nature and scope of pharmaceutical companies' responsibilities and how they should meet such responsibilities in a good faith manner.[363] The PPI mechanism would foster discourse about ways in which pharmaceutical companies' responsibilities should be adjusted in times of public health crisis. The discourse may be centered on how pharmaceutical companies should voluntarily take action or follow legal mandates to transform their responsibilities for sufficient disclosure and reciprocation for prior research by others and receipt of public funding.

With respect to pandemics like COVID-19, the PPI mechanism would perform these two functions by encouraging pharmaceutical companies to take more responsibility through their pandemic relief efforts. It could contribute to alleviating insufficient disclosure problems. While contain-

361. *See* Sun, *supra* note 33, at 913 ("The upshot of the minimization of technology companies' responsibilities is that the whole world cares too much about the economic value of these companies."); MILTON FRIEDMAN, CAPITALISM AND FREEDOM 133 (1962) ("[T]here is one and only one social responsibility of business—to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition, without deception or fraud.").

362. Lazonick et al., *supra* note 217, at 3.

363. This function is quite akin to compulsory licensing. *See* SUNDER, *supra* note 1, at 187 (arguing that compulsory licensing is designed to "correct a moral failure, not a market failure").

ing broad claims, pharmaceutical patents often exclude information essential for the reproduction of an invention, and efforts required to reverse-engineer inventor firms' manufacturing processes have resulted in expense and delay in introducing biosimilars into the market.[364] This concern has been raised in response to recent calls for an intellectual property waiver. As vaccines are complicated biological products highly dependent on undisclosed manufacturing process and practices, it has been argued that waiving patent rights alone will not be sufficient to increase production by pharmaceutical companies.[365] While manufacturing secrecy, which improperly overlaps with patent protection, is not unique to the pharmaceutical industry, the ongoing pandemic has highlighted the potential consequences of the practice.[366] For some firms, COVID-19 appears to have provided insufficient motivation to share. For instance, in June 2020, Inovio claimed in a court filing that its experimental vaccine was being held hostage by its contracted manufacturer's refusal to share manufacturing details.[367]

The PPI also requires pharmaceutical companies to reciprocate for prior research done by others. Dependence on public funding has also been evident throughout the COVID-19 pandemic. For instance, the NIH quickly launched partnerships between federal researchers and 16 major pharmaceutical companies with the aim of standardizing research and prioritizing research into drugs and vaccines with high near-term potential.[368] Moreover, the U.S. Operation Warp Speed has directed substantial funds towards the pharmaceutical industry, with the program having allocated more than USD $12 billion to vaccine makers alone by December 2020.[369] Despite offering such significant funds to pharmaceutical companies, the U.S. government did so without securing guarantees that vaccines and treatments would be made affordable to those who needed them.[370]

The U.S. government should therefore be considered a major contributor to the successful production of COVID-19 vaccines. Therefore, pharmaceutical companies should take responsibility to transfer know-how through their participation in the PPI. Some commentators have suggested

364. Price, Rai & Minssen, *supra* note 26, at 912.

365. Rutschman & Barnes-Weise, *supra* note 111.

366. *See* Price, Rai & Minssen, *supra* note 26, at 913.

367. *Id.* at 912.

368. Lev Facher, *NIH Partners With 16 Drug Companies in Hopes of Accelerating Covid-19 Treatments and Vaccines*, STAT NEWS (Apr. 17, 2020), https://www.statnews.com/2020/04/17/nih-partners-with-16-drug-companies-in-hopes-of-accelerating-covid-19-treatments-and-vaccines [https://perma.cc/DUA8-5PL6].

369. Emily Barone, *The Trump Administration's 'Operation Warp Speed' Has Spent $12.4 Billion on Vaccines. How Much Is That, Really?*, TIME (Dec. 14, 2020), https://time.com/5921360/operation-warp-speed-vaccine-spending [https://perma.cc/BR8A-A74W].

370. Margarida Jorge, *Big Pharma is Taking Big Money from U.S. Taxpayers to Find a Coronavirus Vaccine - and Charge Whatever They Want for It*, MKT. WATCH (June 24, 2020), https://www.marketwatch.com/story/big-pharma-is-taking-big-money-from-us-taxpayers-to-find-a-coronavirus-vaccine-and-charge-whatever-they-want-for-it-2020-06-24 [https://perma.cc/5CEC-RTKM].

that the Moderna vaccine be called the "People's Vaccine" because of the public funding that enabled its development and NIH involvement in the discovery of the stabilized spike protein it relies on.[371] While Pfizer did not receive any money from Operation Warp Speed, it was granted USD $445 million from the German government to help accelerate manufacture of its vaccine.[372] Both companies received advance purchase contracts from the U.S. government, which reduced market risks and justified the devotion of firm resources to the vaccine efforts.[373]

The PPI could encourage pharmaceutical companies to take action so as to reciprocate for the public funding they acquire. Price gouging remains a concern even in the current pandemic. For instance, after House Democrats announced a plan to ensure that COVID-19 treatments were made affordable and available to all, a coalition of groups published a letter that "called on Congress to reject the drug pricing guidelines and defended patents and the exclusive right to profit from drugs."[374] Furthermore, though vaccine manufacturers have committed to low pricing models during the pandemic, companies have indicated that they will begin to increase prices once the pandemic is over, despite many scientists predicting that booster shots are going to form a large part of the ongoing fight against COVID-19.[375] In response, as donation is one category of PPI action, the PPI may require pharmaceutical companies to donate COVID-19 vaccines to COVAX or directly to a region in the United States or developing country in dire need.

Conclusion

"No one is safe until everyone is safe" has become a mantra in this time of pandemic.[376] The actions of pharmaceutical companies, however, have demonstrated that everyone's safety is not their top concern. It is the profits they can make from their patents, not the health of billions of people, that motivates these companies.

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371. Judy Stone, *The People's Vaccine—Moderna's Coronavirus Vaccine Was Largely Funded by Taxpayer Dollars*, FORBES (Dec. 3, 2020), https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=193970346303 [https://perma.cc/A3AB-EHVP].

372. Riley Griffin & Drew Armstrong, *Pfizer Vaccine's Funding Came from Berlin, Not Washington*, BLOOMBERG (Nov. 10, 2020), https://www.bloomberg.com/news/articles/2020-11-09/pfizer-vaccine-s-funding-came-from-berlin-not-washington [https://perma.cc/JLU9-BZ5U].

373. Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, HEALTH AFF. (May 14, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210512.191448/full [https://perma.cc/2DZ7-M8PQ].

374. Sharon Lerner, *Big Pharma Attacks Efforts to Guard Against Coronavirus Price Gouging*, THE INTERCEPT (June 30, 2020), https://theintercept.com/2020/06/02/big-pharma-coronavirus-treatment-price-gouging [https://perma.cc/NCB9-3JAD].

375. David E. Mitchell, *Taxpayers Fund Research and Drug Companies Make a Fortune*, N.Y. TIMES (Mar. 24, 2021), https://www.nytimes.com/2021/03/24/opinion/coronavirus-vaccine-cost-pfizer-moderna.html [https://perma.cc/A8ZG-DJHW].

376. *See, e.g.*, UNICEF, *supra* note 148.

When the TRIPS Agreement was passed to strengthen global protection of patents, Nobel Prize in Economics winner, Joseph Stiglitz, cautioned that the world had signed a "death warrant" for thousands of those in developing countries who would be deprived of life-saving drugs.[377] Pharmaceutical companies have now executed this warrant through their insistence on the sanctity of their patents while COVID-19 claims hundreds of thousands of lives across the globe.

The PPI, as I propose in this Article, seeks to nullify this warrant. It requires the United States, despite being devastated by COVID-19, to take leadership and transform the PPI from thought experiment into effective patent reform, driving pharmaceutical companies to develop a new sense of responsibility for the promotion of public health in the United States and developing countries. The PPI would position the USPTO to proactively tackle the public health problems that arise from the medical patents it grants. If the USPTO can lead by example, other patent offices throughout the global community will also be prompted to implement a PPI.

Crisis brings opportunity for change. We cannot afford to waste it.[378] The COVID-19 pandemic has revealed the asymmetry of patent owners' rights and responsibilities and, along with this disturbing clarity, an opportunity for reform. The PPI has the potential to be an institutional "vaccine," offering global immunity against the devastating effects of the prevailing patent system.

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377. *See* JOSEPH E. STIGLITZ, MAKING GLOBALIZATION WORK 105 (2007) ("Unfortunately, those prices made medicines unaffordable to all but the wealthiest individuals. As they signed TRIPs, the trade ministers were so pleased they had finally reached an agreement chat they didn't notice they were signing a death warrant for thousands of people in the poorest countries of the world.").

378. Jeroen Kraaijenbrink, *3 Reasons Why You Should Use This Crisis to Make A Change*, FORBES (May 13, 2020), https://www.forbes.com/sites/jeroenkraaijenbrink/2020/05/13/3-reasons-why-you-should-use-this-crisis-to-make-a-change/?sh=6e365b4656f5 [https://perma.cc/7SBY-KHQZ] ("Every crisis the words 'never waste a good crisis' pop up. The COVID-19 crisis is no exception to this. And along with these words, there is action too.").