6

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 the supply of medicines and vaccines amid the devastating COVID-19 pandemic. Compulsory licensing and an intellectual property (IP) waiver have been put forward as solutions. However, as other chapters of this volume 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. As the Director General of the WTO has already cautioned, the solution to the problem of vaccine inequality must be holistic, and the IP waiver, for example, should not preclude further action.[1]

In this chapter, I propose the establishment of a Patent Philanthropy Initiative (PPI) as an alternative approach to equipping 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 percent 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.

Section 1 of the chapter presents the PPI as an alternative, or complement, to the existing proposals on patent law and public health, detailing the structure of a potential USPTO-administered pilot program. Section 2 examines how the PPI could improve public health globally and also considers why the USPTO should

[†] I am grateful to Rochelle Dreyfuss, Jeanne Fromer, Calvin Ho, Peter Lee, Madhavi Sunder, and participants at Georgetown-HKU joint conference on Intellectual Property, COVID-19, and the Next Pandemic for comments.

[1] Philp Blenkinsop, *Vaccine Patent Waiver Will Not Be Enough – WTO chief*, Reuters (May 20, 2021), www.reuters.com/business/healthcare-pharmaceuticals/vaccine-patent-waiver-will-not-be-enough-wto-chief-2021-05-20/ (last visited Jul. 23, 2022)..

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take responsibility for overseeing the PPI. Section 3 responds to concerns that the PPI may violate the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the US Constitution and disincentivize investment in medical innovation.

1 THE CREATION OF THE PPI

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 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 percent of its annual post-tax profits from sales of patented medical products. Such financial contributions would apply to medical patents registered with the USPTO and already under patent protection, 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 percent of PPI funds domestically and 50 percent internationally.

Actions

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

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.[2] Developing countries remain "systematically excluded from accessing the ability to produce highly complex drugs"[3] and thus lack self-sufficiency in addressing medical challenges. As of 1986, it was estimated that only 11 percent of global pharmaceutical production occurred in developing countries and over 80 percent in six industrialized countries.[4] The COVID-19 pandemic has demonstrated the urgency of capacity building in developing countries. Despite global calls for the waiver of COVID-19 vaccine

[2] William Fisher, Ruth L. Okediji & Padmashree G. Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 MICH. J. INT'L L. 1 (2022).

[3] 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/ (last visited Jul. 23, 2022).

[4] *See* Fisher et al., *supra* note 2, at 17.

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patent rights to increase availability in developing countries, capitalizing on the direct transfer of vaccine production knowledge is more effective.[5]

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."[6] 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 – infants, children, and teens in particular – from diseases that can cause serious or deadly harm to health.[7] 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."[8] Amid the COVID-19 pandemic, essential vaccines were recommended or required for people in different age groups.[9] 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 in developing countries.[10] There are few resources available in developing countries to address these diseases overlooked by

[5] *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), www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/ (last visited Jul. 23, 2022) (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 (last visited Jul. 23, 2022). ("access 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").

[6] WHO, *Essential Medicines*, www.emro.who.int/health-topics/essential-medicines/index.html (last visited Jul. 23, 2022).

[7] *See* CDC, *Recommended Vaccines by Age*, www.cdc.gov/vaccines/vpd/vaccines-age.html (last visited Jul. 23, 2022).

[8] *See* Michaela Fleming, *Essential Vaccines by Age Group*, Contagion Live (Aug. 16, 2019), www.contagionlive.com/view/essential-vaccines-by-age-group (last visited Jul. 23, 2022).

[9] *See* WHO, *Essential Programme on Immunization*, www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization (last visited Jul. 23, 2022).

[10] *See* Medécins Sans Frontières, *Overcoming Neglect: Finding Ways to Manage and Control Neglected Tropical Diseases* (Jan. 2021), https://reliefweb.int/report/world/overcoming-neglect-finding-ways-manage-and-control-neglected-tropical-diseases (last visited Jul. 23, 2022).

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policymakers.[11] 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.[12]

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."[13] 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 United States, of which 27 percent resulted from raw material issues.[14] Amid the COVID-19 crisis, raw material shortages have been frequently cited as a major obstacle to universal vaccine access.[15]

[11] 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 CENTER FOR INFECTIOUS DISEASE RESEARCH & POLICY, COMPLETING THE DEVELOPMENT OF EBOLA VACCINES 25 (2017), www.cidrap.umn.edu/sites/default/files/downloads/ebola_team_b_report_3-011717-final_0.pdf (last visited Jul. 23, 2022).

[12] Jayashree Watal & Leticia Caminero, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, WTO (Feb. 22, 2018), www.wto.org/english/res_e/reser_e/ersd201801_e.pdf (last visited Jul. 23, 2022) ("[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).

[13] Govindra Singh, *Raw Material Supply: Many Issues to Manage*, *Pharmaceutical Outsourcing*, PHARMA OUTSOURCING (Sep. 30, 2016), www.pharmoutsourcing.com/Featured-Articles/192371-Raw-Material-Supply-Many-Issues-to-Manage/ (last visited Jul. 23, 2022).

[14] Patricia Van Arnum, *Industry Weighs In on Mfg Issues to Mitigate Drug Shortages*, DCAT VALUE CHAIN INSIGHTS (Feb. 13, 2019), www.dcatvci.org/features/industry-weighs-in-on-mfg-issues-to-mitigate-drug-shortages (last visited Jul. 23, 2022).

[15] Rowland et al., *Drug Companies Defend Vaccine Monopolies in Face of Global Outcry*, WASH. POST (Mar. 20, 2021), www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/ (last visited Jul. 23, 2022).

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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.[16] 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.[17] Although "several commercial kits are available to produce mRNA for preclinical studies at laboratory scale, their costs are high."[18] 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.[19] For mRNA vaccine production to occur across the globe, the need for sustainable and cost-effective manufacturing must first be addressed.[20] 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 dispensing vaccines.[21] Donation of such facilities by pharmaceutical companies would represent an important contribution to the safe and sufficient distribution of medicines and vaccines in both the United States and developing countries.

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 United States 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.[22] Effective local production could be encouraged by

[16] Jared S. Hopkins, Joel Eastwood & Dylan Moriarty, *mRNA Covid-19 Vaccines Are Fast to Make, but Hard to Scale*, WALL STREET J. (Mar. 3, 2021), www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401 (last visited Jul. 23, 2022).

[17] *Id*.

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

[19] Katie Jennings & Aayushi Pratap, *Waiving Patents on Covid-19 Vaccines Isn't Enough to Speed Up Production*, FORBES (May 4, 2021), www.forbes.com/sites/aayushipratap/2021/05/04/waiving-patents-on-covid-19-vaccines-isnt-enough-to-speed-up-production/ (last visited Jul. 23, 2022).

[20] *See* Rosa et al., *supra* note 18, at 2197.

[21] CDC, *Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary*, www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf (last visited Jul. 23, 2022).

[22] *See* Fisher et al., *supra* note 2, at 2.

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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.[23]

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."[24] 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.[25]

PUBLIC KNOWLEDGE SHARING Pharmaceutical companies should develop educational programs to better disseminate health-care knowledge to the US 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 screening prompts people to take precautionary measures to maintain personal health and prevent infection.[26] The programs would also promote a communal sense of health care, where "nobody is fully protected until everyone is protected."[27]

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 United States, making the country very vulnerable to new coronavirus variant outbreaks.[28] Vaccine hesitancy has been

[23] *Id.*, at 44–45.
[24] *Id.*, at 32–33.
[25] *Id.*, at 34.
[26] Anjali Stenquist, *Types of Preventive Care: 8 Proactive Ways to Ward Off Health Problems*, Rasmussen University (Jan. 20, 2020), www.rasmussen.edu/degrees/health-sciences/blog/types-of-preventive-care/ (last visited Jul. 23, 2022) ("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").
[27] UNICEF, *No-One Is Safe until Everyone Is Safe – Why We Need a Global Response to COVID-19* (May, 24 2021), www.unicef.org/press-releases/no-one-safe-until-everyone-safe-why-we-need-global-response-covid-19 (last visited Jul. 23, 2022).
[28] Maria Clark, Melissa Brown & Sarah Haselhorst, *Low Vaccination Rates, Delta Variant Fuel Surge in New COVID-19 Cases across the South*, THE AM. S. (Jul. 20, 2021), www.tennessean

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identified as the leading cause of low vaccination rates,[29] with some declining vaccinations based on mis/disinformation obtained from social media.[30] Many young people are hesitant because they feel that COVID-19 is not something that will impact their health.[31] 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 United States due to public health inequalities and the relative lack of health knowledge.[32] 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.

B *1 percent*

With regard to the 1 percent 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 United States.[33] Some of those drugs use Pfizer's existing patents, some use Pfizer's expired patents, 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 chapter 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

.com/story/news/american-south/2021/07/20/covid-19-vaccinations-delta-variant-fuel-surge-cases-across-south/7967943002/ (last visited Jul. 23, 2022).

[29] Elliott Davis, *As COVID-19 Cases Increase, Vaccine Hesitancy Still High in Some States*, US News (Jul. 15, 2021), www.usnews.com/news/best-states/articles/2021-07-15/covid-19-vaccine-hesitancy-rates-still-high-in-some-states (last visited Jul. 23, 2022).

[30] Aallyah Wright, *Lowest Rates, Highest Hurdles: Southern States Tackle Vaccine Gap*, PEW (Jun. 17, 2021), www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/06/17/lowest-rates-highest-hurdles-southern-states-tackle-vaccine-gap (last visited Jul. 23, 2022).

[31] *Id.*

[32] Misha Ketchell, *US Black and Latino Communities Often Have Low Vaccination Rates – But Blaming Vaccine Hesitancy Misses the Mark*, The Conversation (Jul. 7, 2021), https://theconversation.com/us-black-and-latino-communities-often-have-low-vaccination-rates-but-blaming-vaccine-hesitancy-misses-the-mark-163169 (last visited Aug. 8, 2022).

[33] Drug Patent Watch, *Pfizer Company Profile*, www.drugpatentwatch.com/p/applicant/Pfizer (last visited Aug. 8, 2022).

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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 percent 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 percent may sound like a small contribution, Johnson & Johnson earned post-tax profits of approximately $15 billion each year from 2018 to 2020,[34] and Pfizer earned around $11, $12, and $9 billion in 2018, 2019, and 2020, respectively.[35] Based on these earnings, their respective contributions to a PPI fund would be approximately $150 million and $110 million each year.[36] Adding other pharmaceutical companies and potential donations, the PPI could contribute enormous amounts of funds to the promotion of public health in the United States and developing countries.

C *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 percent 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

[34] Johnson & Johnson, 2020 *Annual Report*, at 56, www.investor.jnj.com/files/doc_financials/2020/ar/2020-annual-report.pdf (last visited Aug. 8, 2022).

[35] Pfizer, *Annual Report Pursuant to Section 13 Or 15(D) of The Securities Exchange Act of 1934*, at 47–48 and 58, https://s21.q4cdn.com/317678438/files/doc_financials/2020/ar/PFE-2020-Form-10K-FINAL.pdf (last visited Aug. 8, 2022).

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

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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 ten 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 percent 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 FDA, 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.

Nonprofit 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.[37] Every year, this program would access and rank the performance of pharmaceutical companies' PPI actions, thereby encouraging companies to design and carry out PPI actions diligently. It would also create an additional oversight system to monitor any problems with PPI actions and generate public discussion about subsequent solutions. Figure 6.1 shows the holistic operation of the PPI:

2 THE INSTITUTIONAL NEED OF THE PPI

A *The PPI's Potential Effects on Improving Public Health*

How would the PPI promote public health in the United States and developing countries? COVID-19 provides a vantage point for a thought experiment about the

[37] Access to Medicine Index provides a similar annual ranking. *See* Access to Medicine Index, *About the Index*, https://accesstomedicinefoundation.org/resource/2022-access-to-medicine-index (last visited Aug. 8, 2022) ("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").

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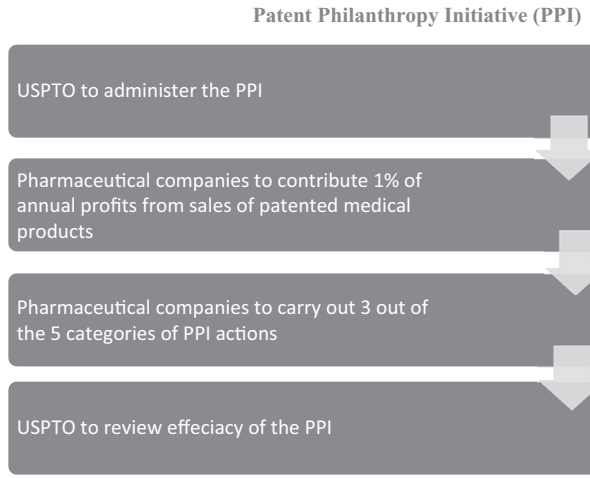


FIGURE 6.1 Patent Philanthropy Initiative (PPI)

PPI's efficacy. If the PPI had been implemented five or ten years ago, the United States and the rest of the world would have been 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 United States, the United Kingdom, and the European Union.[38] Vaccine acquisition has similarly favored such countries, with nearly 85 percent of all COVID-19 vaccines administered by May 26, 2021 going to people in high-income and upper-middle-income countries.[39] Patent monopolies and the reluctance of firms to share technology through licenses have prevented pharmaceutical manufacturers in underrepresented regions from taking matters into their own hands, leaving only 43 percent of the estimated global vaccine manufacturing capacity being used as of February 2021.[40]

[38] *Covid Vaccines: Where Are Oxford/AstraZeneca, Pfizer and Moderna Jabs Made?*, ITV NEWS (Mar. 24, 2021), www.itv.com/news/2021-03-24/covid-vaccines-where-are-oxfordastrazeneca-pfizer-and-moderna-jabs-made (last visited Aug. 8, 2022).

[39] Jon Cohen & Kai Kupferschmidt, *Rich Countries Cornered COVID-19 Vaccine Doses. Four Strategies to Right a "Scandalous Inequity,"* SCI. (May 26, 2021), www.sciencemag.org/news/2021/05/rich-countries-cornered-covid-19-vaccine-doses-four-strategies-right-scandalous (last visited Aug. 8, 2022).

[40] Oxfam, *Monopolies Causing "Artificial Rationing" in COVID-19 Crisis as 3 Biggest Global Vaccine Giants Sit on Sidelines* (Feb. 5, 2021), www.oxfam.org/en/press-releases/monopolies-causing-artificial-rationing-covid-19-crisis-3-biggest-global-vaccine (last visited Aug. 8, 2022).

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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.[41] 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."[42] 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.[43]

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 United States 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 forty-four locally made medicines, the government of Ghana sought to promote local pharmaceutical production and has reportedly established a 30 percent market share for local producers.[44] 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."[45] Greater efforts by major pharmaceutical companies to transfer technology and know-how could be instrumental in overcoming such deficiencies.

By facilitating technology transfer measures toward 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 toward 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 by developing country manufacturers."[46] Pharmaceutical companies could also take the PPI action of entering into collaborative licenses with vaccine manufacturers in

[41] *See* W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 Sci. Mag. 912 (2020).

[42] 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://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver (last visited Aug. 8, 2022).

[43] *See* Price, Rai & Minssen, *supra* note 41.

[44] Fisher et al., *supra* note 2, at 18.

[45] *Id.*, at 18, 12.

[46] Fisher et al., *supra* note 2, at 11.

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developing countries, which would also promote COVID-19 vaccine production in these countries.[47]

Second, the PPI would promote greater self-sufficiency in developing countries, countering the nationalism that occurred at the expense of much of the world's population during the COVID-19 pandemic. One means of pursuing this goal is through training health-care 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."[48] Similarly, Global Health Progress has operated the Healthworker Programme since 2009 to address "the estimated shortfall of at least 7.2 million health workers."[49]

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[50] (a prime example of which are drugs developed to treat cancer[51]), and drugs specific to developing countries, such as those designed to treat malaria or tuberculosis.[52] Historically, pharmaceutical investment has overwhelmingly favored research into global drugs. For instance, in 2001, the Harvard School of Public Health surveyed twenty major firms. It found that only eight respondents had conducted research over the previous year into tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease, while seven others had spent less than 1 percent of their research and development budgets on any of these.[53] Currently, funds for research into developing country-specific drugs often come from public or philanthropic sources or public–private partnerships.[54]

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 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

[47] *See* Okediji, *supra* note 5.
[48] WHO, Health Workforce Education and Training, www.who.int/activities/health-workforce-education-and-training (last visited Jul. 9, 2021).
[49] Global Health Progress, *Healthworker Programme*, https://globalhealthprogress.org/collaboration/healthworker-programme/ (last visited Jul. 9, 2021).
[50] 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).
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*

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of the disease in the 1940s, malaria continues to kill hundreds of thousands annually, especially in Sub-Saharan Africa.[55] In parts of Kenya specifically, cases are reported to be as high as 725 per 1,000 people.[56] Moreover, the challenge of COVID-19 has undermined existing efforts to combat malaria. For instance, malaria cases spiked in some parts of Zimbabwe after the beginning of the pandemic.[57] This problem could have continued to develop as the antimalaria drug chloroquine did show potential as a treatment for COVID-19, which could have made the drug less accessible for malaria patients in developing countries.[58]

B *Responsibilities of the USPTO*

The Conventional Role of the USPTO

The COVID-19 pandemic has exposed deep-seated problems in the US public health-care system[59] and reform is imperative. The COVID-19 pandemic was also a global public health crisis necessitating a global response.[60] 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.[61] 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.[62] A global recovery from the pandemic benefits the United States in terms of decreasing domestic transmission of infection from abroad. Global recovery will also drive quicker national economic recovery through normalization of global trade and investments.[63] As demonstrated in this section, the PPI would greatly promote public health in the United States and abroad, and would not

[55] *See, e.g.*, WHO, *From 30 Million Cases to Zero: China Is Certified Malaria-Free by WHO* (Jun. 30, 2021), www.who.int/news/item/30-06-2021-from-30-million-cases-to-zero-china-is-certified-malaria-free-by-who (last visited Aug. 8, 2022).

[56] 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%27s-How-Data-Can-Help (last visited Aug. 8, 2022).

[57] Ayat Zawawi et al., *The Impact of COVID-19 Pandemic on Malaria Elimination*, 11 Parasite Epidemiology & Control 1, 2 (2020).

[58] *Id.*, at 3–4.

[59] UNICEF, *supra* note 27.

[60] *See* Mikel Berdud et al., *Would Waiving COVID-19 Vaccines Patents Save Lives?*, OHE (May 18, 2021), www.ohe.org/news/would-waiving-covid-19-vaccines-patents-save-lives (last visited Aug. 8, 2022).

[61] Neal, *supra* note 3 ("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").

[62] Fisher et al., *supra* note 11, at 5.

[63] *Id.*, at 3.

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disrupt pharmaceutical innovation in the United States. Therefore, the US government should take the lead in protecting public health globally and implement the PPI under the auspices of the USPTO.

The USPTO is the federal agency responsible for granting patents and registering trademarks in the United States, with the former aimed at fulfilling the mandate of the IP clause of the US Constitution.[64] 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.[65] 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.[66] While the USPTO lacks substantive rulemaking authority,[67] it provides advice to the US president and government agencies to further "effective IP protection for U.S. innovators and entrepreneurs."[68]

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.[69] The work of patent examiners is divided among a number of technology centers, with each center having jurisdiction over certain areas of technology.[70] If patent grants are refused by examiners, appeals can be made to the Patent Trial and Appeal Board (PTAB).[71] The USPTO publishes granted patents, and most patent applications, eighteen 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.[72]

Why should the USPTO expand its conventional role to administer the PPI? In the following two subsections, 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.

[64] US Patent and Trademark Office, *About Us*, www.uspto.gov/about-us (last visited Jul. 21, 2021).

[65] US Constitution 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").

[66] Schwartz, *Functions of the USPTO*, www.schwartz-iplaw.com/functions-of-the-united-states-patent-and-trademark-office/ (last visited Jul. 21, 2021).

[67] John R. Thomas, *The Responsibility of the RuleMaker: Comparative Approaches to Patent Administration Reform*, 17 Berkeley Tech. L.J. 727, 741–742 (2002).

[68] *See* Abbey Meller & Hauwa Ahmed, *How Big Pharma Reaps Profits While Hurting Everyday Americans*, Center for American Progress (Aug. 30, 2019), www.americanprogress.org/issues/democracy/reports/2019/08/30/473911/big-pharma-reaps-profits-hurting-everyday-americans/ (last visited Aug. 8, 2022).

[69] Thomas N. Duening, Robert D. Hisrich & Michael A. Lechter, Technology Entrepreneurship – Taking Innovation to the Marketplace 103 (2021).

[70] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003).

[71] *Id.*

[72] *Id.*

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Responsibility for Promoting Innovation

As outlined, 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."[73] 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."[74]

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 not novel, nonobvious, or useful.[75] 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.[76] Augmentin's original patent was for a combination of amoxicillin and a salt of clavulanic acid, and the secondary was based on the same priority document used in 1975, for the single claim of a "solid pharmaceutically acceptable salt of clavulanic acid."[77] Although the patent was invalidated by a US court in 2002,[78] 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 percent of best-selling drugs had extended their exclusivity at least once and 50 percent had done so more than once.[79] By granting such patents, the USPTO must assume some responsibility for the role evergreening plays in inhibiting the progress of science.

[73] *See* Thomas, *supra* note 226, at 731.

[74] *Id.*

[75] *See* Tahir Amin, *The Problem With High Drug Prices Isn't "Foreign Freeloading," It's the Patent System*, CNBC (Jun. 27, 2018), www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html (last visited Aug. 8, 2022).

[76] *See* Thomas, *supra* note 67, at 735–736.

[77] *Id.*; U.S. Patent No. 6,031,093 (issued Feb. 29, 2000).

[78] *GlaxoSmithKline Hit by US Patent Ruling on Augmentin Antibiotic*, The Pharma Letter (Mar. 25, 2002), www.thepharmaletter.com/article/glaxosmithkline-hit-by-us-patent-ruling-on-augmentin-antibiotic (last visited Aug. 8, 2022).

[79] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, Oxford J.L. & Biosciences 1, 13 (2018).

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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.[80]

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.[81] Primarily he claims that the costs of having examiners spend more time examining patents and searching prior art would not be justified as 95 percent of patents are either never used or are used in contexts which do not rely on the determination of validity.[82] 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.[83] 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.[84] 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.[85] Despite the grant of a rehearing, the USPTO ultimately decided to voluntarily withdraw its proposed limitation.[86] Other 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.[87] 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.[88]

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

[80] *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).
[81] *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 Mich. L. Rev. 709, 752 (2011).
[82] *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1, 13–15 (2001).
[83] *Id.*, at 24–25.
[84] *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).
[85] *See* Thomas, *supra* note 84, at 11.
[86] *See* Holman *supra* note 84.
[87] *Id.*, at 513.
[88] *See* Holman *supra* note 84, at 513.

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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."[89] Collaborative licenses between patent-owning firms and individual manufacturers have, therefore, been proposed as the most efficient way to advance vaccine production.[90] By ensuring that companies engage in such measures to fulfill their duties under the PPI, the USPTO would be able to promote innovation more proactively than through focusing on the denial of patents.

Responsibility to Protect 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.[91] The case concerned a patent for technology to protect wellhead equipment used in hydraulic fracturing, allegedly infringed by Greene's Energy Group.[92] Greene's initiated validity proceedings at the District Court and petitioned the USPTO to conduct *inter partes* review.[93] The PTAB of the USPTO issued a decision concluding that all of Oil States' claims were unpatentable.[94] Oil States then appealed on the grounds that *inter partes* review was unconstitutional.[95]

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.[96] The court likened this to the granting of public franchises and noted that such franchises can be qualified by the

[89] Price, Rai & Minssen, *supra* note 41.
[90] Okediji, *supra* note 5.
[91] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365 (2018).
[92] *Id.*, at 1368.
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*, at 1373–1374.

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authority of the grantor to reexamine and perhaps cancel the grant.[97] 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.[98] As public franchises can only confer the rights that a statute provides, patent rights are limited by the provisions of the Patent Act, which include *inter partes* review.[99]

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.[100] Generally, the public benefit sought is market regulation, for example by ensuring low prices or subsidizing costs.[101] 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.[102] 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.[103] The practice of price gouging is another example. Taking advantage of the substantial freedom to set prices that a patent monopoly offers,[104] patent owners frequently engage in abusive practices. In the first half of 2019, more than 3,400 drugs saw their prices raised by an average of 10.5 percent, with about 41 of these experiencing price increases greater than 100 percent and one increased by 879 percent.[105] 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.[106] 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 percent of all

[97] *Id.*, at 1374–1375.
[98] *Id.*, at 1375.
[99] *Id.*
[100] *Franchise: Government Franchises*, L. Libr., https://law.jrank.org/pages/6995/Franchise-Government-Franchises.html (last visited Jul. 24, 2021).
[101] Owen Rogers, *What Is a Public Franchise?*, BizFluent (Sep. 26, 2017), https://bizfluent.com/facts-7212317-public-franchise-.html (last visited Aug. 8, 2022).
[102] *See* Holman, *supra* note 84.
[103] *See supra* note 84 and accompanying text.
[104] 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).
[105] Aimee Picchi, *Drug Prices in 2019 are Surging, With Hikes at 5 Times Inflation*, CBS News (Jul. 1, 2019), www.cbsnews.com/news/drug-prices-in-2019-are-surging-with-hikes-at-5-times-inflation/ (last visited Aug. 8, 2022).
[106] *See* Feldman *supra* note 104, at 315.

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drugs would account for 50 percent of all drug spending in the United States by 2018.[107]

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.[108] In contrast, post-grant review must be initiated within the nine months following the grant of a patent.[109] While *inter partes* review focuses only on nonobviousness 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.[110] Currently, *inter partes* review is more common as the window to institute it is wider.[111]

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."[112] 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."[113] Even if all relevant patents were invalidated, generic-free periods provided for new drugs (five years), drugs for rare diseases (seven years), and biologics (twelve years) are not affected by patent invalidation.[114]

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."[115] Other statements cautioning against this approach have been made. For instance, it is claimed that the decision to label patents as public franchises is unfounded.[116] This is because as a category of legal rights, patents have historically been

[107] *Id.*
[108] Dorian Ojemen, *The Ethics of Inter Partes Review before the USPTO*, 47 St. Mary's L.J. 645, 657 (2016).
[109] *Id.*, at 661.
[110] *Id.*
[111] *Id.*
[112] Jonathan J. Darrow, Reed F. Beall & Aaron S. Kesselheim, *Will Inter Partes Review Speed US Drug Entry?*, 35 Nature Biotechnology – Patents 1139, 1140 (2017).
[113] *Id.*
[114] *Id.*
[115] Mark A. Lemley, *Fixing the Patent Office*, 13 Innovation Pol'y & Econ. 83, 95 (2013).
[116] Evan Jones, *Reckoning Patents as Public Franchises*, Boston Patent Law Association (2021), https://newsletter.bpla.org/reckoning-patents-as-public-franchises (last visited Aug. 8, 2022).

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understood to impart private interests.[117] 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."[118]

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 earlier, 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 percent 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.

3 THE LEGITIMACY OF THE PPI

In the preceding sections, I examined the case for establishing the PPI and its economic and social functions in promoting public health, both in the United States and abroad. In this section, I seek to respond to potential concerns that the PPI would run afoul of US obligations under the TRIPS Agreement as well as the Takings Clause of the US 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*

TRIPS Agreement

Would the PPI violate the TRIPS Agreement? This agreement sets out minimum standards for IP protection in WTO member states, including the United States.[119] In my opinion, the United States would remain in full compliance with the TRIPS Agreement notwithstanding USPTO implementation of the PPI.

[117] *Id.*
[118] *Id.*
[119] *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").

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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.[120] 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.[121] 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 not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[122] A "limited" exception to patent rights, according to the WTO dispute resolution panel, "makes only a small diminution of the rights in question."[123] The PPI only requires pharmaceutical companies to contribute 1 percent of their annual post-tax profits; absolutely "a small diminution" compared with the 99 percent 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 earlier, 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 percent 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 its economic investment in medical patents.[124] 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."[125] The PPI satisfies this second prong given its ostensible support from policies promoting public health.

[120] TRIPS Agreement, art. 27.1.
[121] *Id.*, art. 28.1.
[122] *Id.*, art. 30.
[123] *TRIPS Provisions as Interpreted by the WTO Dispute Settlement Organs*, Law Explorer (Nov. 4, 2015), https://lawexplores.com/trips-provisions-as-interpreted-by-the-wto-dispute-settlement-organs/ (last visited Aug. 8, 2022).
[124] *Id.*
[125] *Id.*

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US Constitution

Pharmaceutical companies may allege that the PPI violates the Takings Clause of the Fifth Amendment to the US Constitution, which stipulates that just compensation must be provided for any private property taken for public use.[126] The Supreme Court has ruled that deprivation of patent rights is subject to this clause.[127] 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 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 percent of their post-tax profits[128] and the potential diminution in the value of their patent(s)[129] may constitute compensatable 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.[130] As the USPTO has the power to increase patent maintenances fees,[131] it can duly include the PPI requirements as additional maintenance fees for pharmaceutical patents it grants. As judicial rulings have demonstrated,[132] courts

[126] US Constitution amendment V ("[N]or shall private property be taken for public use, without just compensation").

[127] 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").

[128] *Id.*

[129] *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").

[130] USPTO, *Summary of FY 2020 Final Patent Fee Rule*, www.uspto.gov/about-us/performance-and-planning/summary-fy-2020-final-patent-fee-rule (last visited Aug. 8, 2022) (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).

[131] USPTO, *Fee Setting and Adjusting*, www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting (last visited Aug. 8, 2022) (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 US Code and the Trademark Act of 1946 [15 U.S.C. § 1051 et seq.], respectively).

[132] 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

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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,[133] 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 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.[134] It is therefore necessary to explore whether, in practice, the 1 percent 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 US firms found that between 1981 and 1983, around 65 percent of pharmaceutical products would not have been introduced in the absence of patent protection.[135] The study also found that 60 percent of products would not have been developed in the first place, a much higher percentage than in other industries studied.[136] Similarly, a survey of UK research and development managers led economists to estimate that research and development expenditure would be reduced by 64 percent in the absence of patent protection, in contrast to an estimated 8 percent reduction across all other industries.[137] These findings accurately reflect the reality of modern-day research and development in medicine, which typically requires years of work by large teams

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).

[133] 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").

[134] *See*, *e.g.*, Burk & Lemley, *supra* note 70 ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge").

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

[136] *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").

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

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of scientists and can cost hundreds of millions of dollars.[138] The development of new drugs often takes more than a decade to complete and only around one in eight will survive clinical testing and go on to reimburse firms for their efforts.[139] Once a formula is found, products can be reverse engineered or imitated at very low cost, 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.[140] However, research in the 1980s found that the cost of imitating drugs was made 30 percent more expensive thanks to patent protection.[141]

There are multiple reasons to suggest that the PPI is unlikely to have an impact sufficient to undermine patent law's function in promoting medical 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.[142]

Moreover, as described, pharmaceutical companies have traditionally focused their research on "global drugs," which are in the widest demand and offer the largest market.[143] 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.[144] The study concluded that only the highly predictable imposition of a compulsory license on a very significant market would be likely to discourage innovation.[145] 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 United States, 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

[138] *Id.*, at 1581.

[139] *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).

[140] *See Id.*; Jeffrey Miron & Pedro Braga Soares, *Opinion: Waiving COVID-19 Vaccine Patents Would Be Disastrous*, MARKET WATCH (May 19, 2021), www.marketwatch.com/story/waiving-covid-19-vaccine-patents-would-be-disastrous-11621430167 (last visited Aug. 8, 2022).

[141] 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").

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

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

[144] *See* Chien, *supra* note 50, at 891.

[145] *Id.*

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environment in which pharmaceutical innovation flourished even in the absence of patent protection.[146] 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.[147]

Second, an examination of how pharmaceutical companies currently use their funds suggests that the 1 percent 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 percent of gross revenues on basic research to discover new molecular entities, with most basic knowledge now coming from publicly funded laboratories and institutions.[148] Although private pharmaceutical companies continue to be the primary contributor to overall research investment,[149] their focus 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.[150]

In fact, more pharmaceutical industry funds are directed toward efforts to maximize shareholder value than research and development. For instance, one study of how the eighteen largest US pharmaceutical companies use their profits found that, from 2006 to 2015, 99 percent of profits were distributed to shareholders, with 50 percent as stock buybacks and 49 percent as dividends.[151] The total $261 billion spent on buybacks amounted to 56 percent of the combined total of research and development expenditure.[152] This data suggests that there would be profits available to redirect toward innovation after 1 percent 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,

[146] *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?*, The Wall Street J. (Jan. 23, 2012), www.wsj.com/articles/SB10001424052970204542404577156993191655000 (last visited Aug. 8, 2022).

[147] *Id.*

[148] *See* Gøtzsche, *supra* note 142.

[149] *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 2007"); *U.S. Investments in Medical and Health Research and Development, 2013–2015*, Research Am. 1, 3 (2016), www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf (last visited Aug. 8, 2022) (noting the pharmaceutical industry's contribution to total research and development expenditure rose to 64.7 percent in 2015).

[150] 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).

[151] William Lazonick et al., *US Parama's Financialized Business Model*, 60 Inst. New Econ. Thinking Working Paper Series 1, 3 (2017)

[152] *Id.*, at 4.

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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 beneficiaries as well, with the three top recipients receiving $31,493,555, $11,323,283, and $8,428,162, respectively.[153] The pharmaceutical industry also benefits from a research and development tax break, introduced in 1981, to encourage private sector investment in pioneering research.[154] 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 US government.[155] The combination of these ex ante and ex post rewards suggests that innovation would be encouraged "even in the absence of patent protection."[156]

4 CONCLUSION

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.[157] Some pharmaceutical companies have now executed this warrant through their insistence on the sanctity of their patents while COVID-19 has claimed millions of lives across the globe. The actions of these companies, however, have demonstrated that equitable access is not their top concern. It is the profits they can make from their patents, not the health of billions of people, that motivates them.

The PPI requires the United States to take leadership toward 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.

[153] Alex Keown, *Top 10 Pharm Country Companies to Receive NIH Funding in 2020*, BioSpace (Mar. 3, 2021), www.biospace.com/article/top-10-pharm-country-companies-to-receive-nih-funding-in-2020/ (last visited Aug. 8, 2022).

[154] Meller & Ahmed, *supra* note 68.

[155] Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, Health Aff. (May 14, 2021), www.healthaffairs.org/do/10.1377/hblog20210512.191448/full/ (last visited Aug. 8, 2022).

[156] *See* Burk & Lemley, *supra* note 70, 1586; *see also* Brink Lindsey, *Why Intellectual Property and Pandemics Don't Mix*, Brookings Inst. (Jun. 3, 2021), www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/ (last visited Aug. 8, 2022) ("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").

[157] *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").

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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.[158] 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.

[158] Jeroen Kraaijenbrink, 3 *Reasons Why You Should Use This Crisis to Make a Change*, Forbes (May 13, 2020), www.forbes.com/sites/jeroenkraaijenbrink/2020/05/13/3-reasons-why-you-should-use-this-crisis-to-make-a-change/?sh=6e365b4656f5 (last visited Aug. 8, 2022) ("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").

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