Harvard Journal of Law & Technology
Volume 35, Number 2 Spring 2022

OVERCOMING PATENT BARRIERS TO INCREASE ACCESS TO MEDICINES: A NEW PATH FORWARD FOR COMPULSORY LICENSING

*Neil Davey**

TABLE OF CONTENTS

I. INTRODUCTION

The COVID-19 pandemic has made one thing clear: "Nobody on this planet is safe until everyone is safe."[1] Many nations recognize the need for solidarity in this crisis, and it is clear that the Global North simply cannot afford to ignore the Global South.[2] Of course, turning a blind eye to vaccine and drug access issues in the Global South would

* Harvard Law School, Candidate for J.D., 2023. I am very grateful to Professor Ruth Okediji for her helpful comments and suggestions. This Note benefitted greatly from discussions in her course entitled "Intellectual Property, Public Health, and Access to Medicines" at Harvard Law School in Fall 2021.

1. Ciarán Cannon, *Foreword* to COVID-19 IN THE GLOBAL SOUTH: IMPACTS AND RESPONSES, at xix (Pádraig Carmody et al. eds., 2020).

2. Ayoade Alakija, *Global North and South Must Work Hand in Glove to Stop COVID-19*, 6 NATURE HUM. BEHAV. 171 (2022).

unquestionably be a "catastrophic moral failure."[3] But as noted by World Health Organization ("WHO") Director-General Tedros Adhanom Ghebreyesus, since continued outbreaks in the Global South due to low vaccination rates would "keep 'the pandemic burning' and would result in a 'very slow' global economic recovery," developed countries should also act in their own self-interest by helping vaccinate the Global South.[4] The recent Omicron variant acutely demonstrates this dilemma. It was first identified in South Africa, where less than thirty percent of the population was fully vaccinated,[5] and its high infectivity caused fear and a surge in new cases worldwide.[6]

Unfortunately, patents on biopharmaceutical products are a serious barrier to access in the Global South, often precluding people in developing countries from accessing much-needed medicines.[7] Specifically, patents give their holders monopoly rights for a certain period of time,[8] during which the holders have nearly unrestricted power to set prices.[9] Importantly, these patent barriers present a problem for lower-income populations in the United States as well.[10] Though the pharmaceutical industry often cites a need to recoup high research and development ("R&D") costs,[11] critics have properly noted that the industry still enjoys substantial profit margins and often spends more on advertising and marketing than R&D.[12] Beyond concerns about price, another

3. Tommy Beer, *WHO: Vaccine Hoarding Would Be A "Catastrophic Failure" That Keeps "Pandemic Burning"*, FORBES (Jan. 29, 2021, 5:17 PM), https://www.forbes.com/sites/tommybeer/2021/01/29/who-vaccine-hoarding-would-be-a-catastrophic-moral-failure-that-keeps-pandemic-burning/?sh=2d1f017215ac [https://perma.cc/3EEJ-9QPT] (quoting WHO Director-General Tedros Adhanom Ghebreyesus).

4. *Id.*

5. Edouard Matthieu et al., *Coronavirus (COVID-19) Vaccinations*, OUR WORLD IN DATA (Feb. 17, 2022), https://ourworldindata.org/covid-vaccinations [https://perma.cc/2L64-NXDW].

6. *See* Carl Zimmer & Andrew Jacobs, *Omicron: What We Know About the New Coronavirus Variant*, N.Y. TIMES (Jan. 3, 2022), https://www.nytimes.com/article/omicron-coronavirus-variant.html [https://perma.cc/GKH5-Q8JD].

7. Richard T. De George, *Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis*, 15 BUS. ETHICS Q. 549, 549 (2005).

8. 35 U.S.C. § 154(a)(1) (2013) ("Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.").

9. Dean Baker, *End Patent Monopolies on Drugs,* N.Y. TIMES (Jan. 10, 2016, 2:07 PM), https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs [https://perma.cc/G2FX-R5XG].

10. Michelle Chen, *Patents Against People: How Drug Companies Price Patients Out of Survival*, DISSENT MAG. (Fall 2013), http://www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival [https://perma.cc/6VWC-HN39].

11. S. Vincent Rajkumar, *The High Cost of Prescription Drugs: Causes and Solutions*, 10 BLOOD CANCER J. 1, 2 (2020).

12. De George, *supra* note 7.

prevalent issue with pharmaceutical patents is the creation of copy-cat "me-too" drugs, which reward large pharmaceutical companies with new patents for "trivial and minor inventions" over their competitors' existing products for lifestyle-related conditions.[13] This phenomenon ultimately crowds out the development of more "socially-useful radical" therapies.[14] A similar patent abuse is "evergreening," which involves minor tweaks to small molecules by branded manufacturers to increase patent life.[15] Further, the industry has frequently employed "pay-for-delay" tactics to keep cheaper, generic products off the market.[16] While patents have been shown to be critical in spurring biomedical innovation,[17] ongoing abuse of the patent system has had a substantial adverse impact on access to medicines, both in the United States and abroad.[18] One tool that could be promising in overcoming such patent abuse is compulsory licensing.

II. COMPULSORY LICENSING

Compulsory licensing describes "when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[19] Such circumventing of patents by governments to produce essential technologies during national emergencies has been touted as a tool that could overcome many patent-related access concerns.[20] For example, permitting local manufacturers to produce patented technologies and distribute them at a lower price could greatly increase access to care in developing markets. Further, compulsory licensing would allow a country to build up both local production capacity and its own

13. GRAHAM DUTFIELD, THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY 1880–2020 449 (World Sci. ed., 2020).

14. *Id.*

15. Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 322 (2015).

16. *See* Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive [https://perma.cc/Z6BF-4KD4].

17. *See generally* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009).

18. *See* De George, *supra* note 7; Chen, *supra* note 10.

19. *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/UF2F-WC57]. The concept of compulsory licensing has been around for more than a century, since the Paris Convention of 1883. *See also* Paris Convention for the Protection of Intellectual Property art. 5(A)(2), Mar. 20, 1883 ("Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent . . . .") (as amended on Sept. 28, 1979) (official translation).

20. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 255 (2009).

industry, from which it could then export drugs to other nations.[21] Common concerns about reduced foreign investment and innovation from the reliance on compulsory licensing in these countries seem to be overstated based on the evidence, as nations like China still present irresistible market opportunities for the pharmaceutical industry.[22] Regarding innovation incentives in the branded pharmaceutical sector, since drugs for most noncommunicable diseases are geared for developed-country markets (with negligible revenues in poorer countries), compulsory licenses on these products would have little impact on innovation.[23] Namely, the economic losses to the pharmaceutical industry from compulsory licensing of these products by lower-income countries would be minimal relative to the profits achieved in higher-income countries, having little deterrence effect on innovation. And R&D to develop medicines for tropical diseases that *are* prevalent in low-income countries is limited anyway.[24] Thus, compulsory licensing presents a favorable path forward to increase global access to medicines.

A. Compulsory Licensing Abroad

Unfortunately, most of the patenting in the pharmaceutical sector occurs in the Global North, which has often left countries in the Global South helpless during crises.[25] For example, during the HIV/AIDS epidemic, pharmaceutical players with patents on lifesaving antiretroviral drugs did not budge to decrease prices for low-and-middle-income countries ("LMICs").[26] Some countries, however, have successfully employed compulsory licenses to overcome these hurdles. Larger LMICs like Brazil and Thailand — which had greater leverage and lesser fear of backlash — enacted such licenses on antiretrovirals between 2006 and 2007.[27] Importantly, political economy plays a huge role in dictating whether countries can successfully employ compulsory licensing. A developing country's ability to legally prevail against the

---

21. *See id.* at 257.

22. *See* Peter Yu, *Intellectual Property, Economic Development, and the China Puzzle*, *in* INTELL. PROP. TRADE & DEV. 173, 176–83 (Daniel J. Gervais ed., 2007).

23. *See* Reichman, *supra* note 20, at 257 ("In short, and under present-day conditions, the issuance of compulsory licenses on [noncommunicable disease] medications in poor countries would have virtually no impact on incentives to innovate in rich countries.").

24. *See* Robert Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 37 J.L. MED. & ETHICS 209, 215–16 (2009).

25. *See* Jorge A. Huete-Pérez et al., *Biotech Gap Between North and South*, 294 SCIENCE 2289, 2290 (2001).

26. *See* Donald G. McNeil, Jr., *Drug Companies Are Focusing on the Poor After Decades of Ignoring Them*, N.Y. TIMES (June 24, 2019), https://www.nytimes.com/2019/06/24/health/drugs-poor-countries-africa.html [https://perma.cc/5NXQ-FAM7].

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

United States "would likely depend heavily on the political context and on the way in which its initiative were [sic] depicted in the media."[28] This puts nations like Brazil, Thailand, India, and South Africa at an advantage over many African countries, which lack both political leverage and manufacturing capacity. However, even these larger countries cannot act without consequence. After Thailand invoked a series of compulsory licenses in 2006–2007, the United States Trade Representative "exerted extraordinary pressure on Thailand by placing it on the Priority Watch List (PWL) under Section 301 of the Omnibus Trade and Competitiveness Act of 1988" and "threatened to revoke [Thailand's] trade privileges."[29]

In the international context, Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") permits nations to employ compulsory licenses in times of crisis.[30] However, while Article 31(b) permits compulsory licensing "[i]n situations of national emergency or other circumstances of extreme urgency," the text of Article 31(f) is stringent in that it limits compulsory licensing "predominantly for the supply of the domestic market of the Member authorizing such use."[31] Many experts have aptly noted how "notoriously vague" this language is — for example, there are no definitions for "national emergency" or "extreme urgency."[32] This vagueness has led to serious disputes between countries in the Global South and pharmaceutical companies.[33]

Beyond the lack of textual clarity, Article 31(f) has presented a significant barrier for the Least Developed Countries ("LDCs"), which lack the manufacturing capacity to produce drugs protected by patents and therefore cannot benefit from domestic compulsory licenses.[34] Consequently, in November 2001, the Doha Declaration to TRIPS reaffirmed the ability of member states to utilize compulsory licenses,[35] and in Paragraph 6 noted: "We recognize that [World Trade Organization ("WTO")] Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making

28. William Fisher & Talha Syed, *Chapter 3: Intellectual Property*, *in* A WAR NOT EASILY WON: CURBING INFECTIOUS DISEASES IN DEVELOPING COUNTRIES 1, 15 (2021).

29. Jakkrit Kuanpoth, *Compulsory Licenses: Law and Practice and Thailand*, *in* COMPULSORY LICENSING 61, 67 (R.M. Hilty & K.C. Liu eds., 2015).

30. Maria Jurua, *Access to Drugs at Risk: Securing Access to Medicines for Least Developed Countries*, 42 AFR. DEV. 101, 107 (2017).

31. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31(f), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 313, 313 I.L.M. 1197, 1210 [hereinafter TRIPS Agreement].

32. Fisher & Syed, *supra* note 28, at 9.

33. *Id.* (describing the WTO dispute between Brazil and the United States in 1996).

34. Reichman, *supra* note 20, at 248. Even in cases where an international patent has *not* been filed in a developing country, that country often cannot take advantage of this fact given it lacks sufficient manufacturing capacity.

35. *Id.*

effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."[36] This provision effectively initiated a process through which countries without manufacturing capacity could finally benefit from these licenses. Eventually, legal machinery was set in place for a country "to issue a compulsory license for a medicine it could not produce and then to seek help from any other country having that capacity that was willing to assist it."[37] This back-to-back licensing scheme was laid out in a waiver and is now embodied in Article 31*bis*. It took more than twelve years before the Amendment that enacted Article 31*bis* was finally ratified in January 2017.[38]

Unfortunately, the procedures set out in 31*bis* are very cumbersome, and "any license issued under the TRIPS Agreement requires a determination on a country-by-country, product-by-product and case-by-case basis."[39] More specifically, only one Article 31*bis*-like proceeding has taken place, to import HIV/AIDS drugs from Canada to Rwanda in 2007, and it took more than two years for Rwanda to finally receive the necessary drugs.[40] Critics have noted that "[t]he time lost in waiting for the deliveries of drugs could almost certainly wipe out the possibility of using this in particular circumstances of national emergencies."[41] Thus, there is not yet a clear way for low-income countries without manufacturing capacity to compulsorily license pharmaceutical products. Importantly, Thailand and Brazil issued licenses between 2006 and 2007 under the standard Article 31(f) pathway, not 31*bis*, which was only possible because they had sufficient capacity to manufacture the drugs themselves.[42]

Thus, despite the recent push to employ compulsory licensing given the dire nature of the COVID-19 pandemic, some scholars have argued that compulsory licensing may not be the appropriate path for COVID-19 given the manufacturing complexities of mRNA vaccines.[43] Others contend that the annual number of TRIPS-related

---

36. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755, para. 6 (2002) [hereinafter Doha Declaration].

37. Reichman, *supra* note 20, at 249.

38. Peter K. Yu, *A Critical Appraisal of the COVID-19 TRIPS Waiver*, *in* INTELLECTUAL PROPERTY RIGHTS IN THE POST PANDEMIC WORLD: AN INTEGRATED FRAMEWORK OF SUSTAINABILITY, INNOVATION AND GLOBAL JUSTICE (forthcoming 2022) (manuscript at 9) (available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3945304 [https://perma.cc/N8PX-Z7UV]).

39. *Id.* at 4.

40. Nicholas G. Vincent, *TRIP-ing Up: The Failure of TRIPS Article 31bis*, 24 GONZ. J. INT'L L. 1, 19–20 (2020).

41. *Id.* at 20.

42. Reichman, *supra* note 20, at 250.

43. Nicholson Price, Rachel Sachs, Jacob S. Sherkow & Lisa Larrimore Ouellette, *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism,*

compulsory licenses has possibly decreased since 2004, not due to inflexibility of TRIPS,[44] but because "firms may have taken [the] willingness" of developing countries to invoke compulsory licenses "into account when negotiating the prices they charge."[45] In essence, the threat of compulsory licenses would be sufficient to ensure lower prices. But, as the world has seen from the COVID-19 pandemic, companies like Pfizer and Moderna have not so far been supportive of external efforts to increase access to their products in the Global South.[46] Thus, further consideration should be given to overcoming the issues presented by the complex TRIPS agreement.

1. Assessing the Potential of a TRIPS Waiver

The aforementioned inadequacies with Articles 31(f) and 31*bis* have led to discussions about enacting a TRIPS waiver for the COVID-19 pandemic. Specifically, in October 2020, South Africa and India proposed a waiver to the WTO that would suspend certain intellectual property ("IP") rights recognized by TRIPS for COVID-19 technologies.[47] The proposed waiver presents significant benefits: For example, it would eliminate the complexities of Articles 31(f) and 31*bis*, which are amplified in the COVID-19 context because novel products like Moderna's vaccine implicate patent rights of myriad stakeholders.[48] The waiver's collective sidestepping of the TRIPS inflexibilities also reduces stigma associated with compulsory licensing, which is currently a serious obstacle for countries with limited political power. Furthermore, the waiver proposal is narrow, specifically tailored to "prevention, containment and treatment of COVID-19," and not other diseases.[49] Additionally, the original October 2020 waiver was revised in May 2021 to set the duration to "at least 3 years," rather than leaving the time frame open-ended, and to limit the range of products

---

an Effective Spur to Innovation, or Something in Between?, WRITTEN DESCRIPTION (Aug. 5, 2020), https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html [https://perma.cc/Y4FG-MECK].

44. *See* Ellen F.M. 't Hoen et al., *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, 96 BULL. WORLD HEALTH ORG. 185 (2018).

45. Fisher & Syed, *supra* note 28, at 22.

46. *See, e.g.*, Amy Maxmen, *South African Scientists Copy Moderna's COVID Vaccine*, NATURE (Feb. 3, 2022), https://www.nature.com/articles/d41586-022-00293-2 [https://perma.cc/EB98-8X3E] (explaining how the South African mRNA tech-transfer hub reverse-engineered Moderna's vaccine alone, without any help from the company).

47. Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patent Ban*, 396 LANCET WORLD REP. 1790 (2020).

48. *See* Yu, *supra* note 38, at 4–5.

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

covered.[50] Thus, while the waiver seems like a categorical approach that eliminates IP rights altogether, it applies only to COVID-19 technologies and for a limited timeframe. Therefore, concerns that this one-size-fits-all approach is "broader than the remedy needed to combat the global pandemic"[51] are likely overstated. Fears about the erosion of broader IP rights represent a general reluctance for change even amidst a once-in-a-lifetime pandemic.

Some experts contend that this "consensus-based" approach may take a long time (like the ratification of Article 31*bis*) and may not prove particularly effective given the supposed lack of manufacturing capacity and local implementation capabilities (e.g., approval by domestic legislatures and interference with other treaty obligations) in developing countries.[52] On the one hand, such critics could be underestimating the capacity of many developing nations, like India and China, which already manufacture and export the lion's share of the world's generic products to developed markets like the United States and Europe.[53] Regardless, taking measures with even a small positive impact and minimal downside would help prepare the globe for the *next* pandemic, if not improve the state of the current one. Specifically, unblocking IP barriers by easing current restrictions around compulsory licensing could be a first step to addressing the local manufacturing and know-how problems in developing countries.[54] For example, without having to deal with the procedural hurdles of Article 31*bis*, countries can independently agree to back-to-back licensing schemes under the waiver more quickly, which could eventually help spur domestic manufacturing in a cyclical manner.

2. Solving the Know-How Problem

For access-to-medicines activists, the TRIPS waiver does not do enough. James Love, Director of Knowledge Ecology International, has said that the waiver is, to some extent, a "distraction."[55] Beyond worries

50. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID*-19, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

51. Yu, *supra* note 38, at 11.

52. *Id.* at 7–10 (discussing some of the arguments against the TRIPS waiver).

53. *See* Rory Horner, *The World Needs Pharmaceuticals from China and India to Beat Coronavirus*, THE CONVERSATION (May 25, 2020, 3:00 AM), https://theconversation.com/the-world-needs-pharmaceuticals-from-china-and-india-to-beat-coronavirus-138388 [https://perma.cc/JM86-NEUK].

54. *See generally* William Fisher, Ruth L. Okediji & Padmashree Gehl Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 MICH. J. INT'L L. 1 (2022) (describing the need to develop strategies to spur local pharmaceutical production and know-how in developing countries).

55. James Love (@Jamie_Love), TWITTER (May 11, 2021, 9:01 AM), https://twitter.com/jamie_love/status/1392102515395727361 [https://perma.cc/HJG8-EQ5T].

about how long the process will take, Love is concerned about whether overcoming the IP barriers alone will alleviate the COVID-19 crisis. The fundamental problem, in his view, is sharing "manufacturing know-how" for privatized pharmaceutical products.[56] Much of this know-how is covered not by the underlying patents but by experience and trade secrets.[57]

There is undoubtedly a tremendous gap in vaccine production capacity between the Global North and the Global South.[58] Gehl Sampath and Pearman appropriately take a long-term view in proposing *sustainable* solutions to this problem.[59] Relying on bespoke acts of charity from developed countries is not advisable for LDCs, which would be given suitable access to medicines only after the developed world has had its fill.[60] Developing countries should therefore build up their own production capacities and develop local know-how in order to benefit from compulsory licensing.

Historical dependence on multinational companies for medicine imports has contributed to the lack of manufacturing capacity in the Global South.[61] Industry groups, including the Pharmaceutical Research and Manufacturers of America ("PhRMA"), suppressed the global movement to develop local pharmaceutical production in the 1970s, arguing that LDCs could not adequately control the quality of medicines.[62] In a few countries, including China and India, local manufacturing has shown to be essential in increasing access to medicines, helping them escape the pharmaceutical industry's tactics.[63] For example, Brazil and South Africa's build-ups of local production facilities were hugely influential in eventually securing a steady pipeline of antiretrovirals during the HIV/AIDS epidemic.[64]

Beyond a dearth of manufacturing capacity, developing countries also suffer from supply chain issues that result in shortages and fake

---

56. *See* James Love, *Buying Know-How to Scale Vaccine Manufacturing*, MEDIUM (Mar. 20, 2021), https://jamie-love.medium.com/buying-know-how-to-scale-vaccine-manufacturing-586bdb304a36 [https://perma.cc/77KJ-7R2D].

57. Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines Via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRAC. 1242 (2021).

58. Anna Mia Ekström et al., *Addressing Production Gaps for Vaccines in African Countries*, 99 BULL. WORLD HEALTH ORG. 910, 910 (2021).

59. Padmashree Gehl Sampath & Jon Pearman, *Local Production of COVID 19 Vaccines: A Strategy for Action*, GLOB. POL'Y 1, 15–16 (Aug. 2021).

60. FIRE IN THE BLOOD (Sparkwater India 2013).

61. Rory Horner, *Pharmaceuticals and the Global South: A Healthy Challenge for Development Theory?*, 10 GEOGRAPHY COMPASS 363, 364–65 (2016).

62. *Id.* at 366–67.

63. Warren A. Kaplan, *Local Production and Access to Medicines in Low- and Middle-Income Countries: A Literature Review and Critical Analysis*, WORLD HEALTH ORG. 1, 11–14 (2011).

64. *Id.* at 16, 31–32.

drugs.[65] Due to a lack of sufficient regulation, supply chains are fragmented in these countries between the public, private, and nonprofit sectors, resulting in stockouts and drug adulteration.[66] Such decentralization can affect distributors, wholesalers, retailers, and ultimately consumers by restricting access to essential medicines.[67] One potential intervention includes a central agency model which eliminates intermediaries, as has been successfully implemented in Zambia.[68] Investing in local capacity and reducing supply chain problems caused by uncoordinated production is therefore a necessary complement to compulsory licensing schemes that permit low-and-middle-income countries to produce patented products.

The COVAX initiative — co-led by the Coalition for Epidemic Preparedness Innovations ("CEPI"), Gavi, and the WHO to increase global access to COVID-19 vaccines — has made strides in this regard, galvanizing factory manufacturing in the Global South through a procurement mechanism that acts as an insurance policy for wealthy donor countries.[69] Specifically, donor countries collaboratively fund manufacturing efforts for a broad portfolio of vaccines in developing countries, thereby improving the likelihood of obtaining successful vaccines and increasing future global supply. While the program ultimately fell short of its goal to distribute two billion doses by the end of 2021, it has bolstered support for the notion that developing countries need to build up their own manufacturing capacities and reduce reliance on the Global North.[70] Similarly, initiatives like the partnership between CEPI and the Institut de Pasteur in Dakar to transfer viral vector solutions for various infectious diseases (i.e., a *platform* technology) allow for the gradual build-up of knowledge in countries like Senegal.[71] Furthermore, South Africa's mRNA hub — a partnership between the WHO and the South African government — presents a sustainable knowledge

65. Angela Acosta et al., *Medicine Shortages: Gaps Between Countries and Global Perspectives*, 10 FRONTIERS IN PHARMACOLOGY 1, 7–8 (2019).

66. *Id.* at 7, 15.

67. Prashant Yadav, *25 Years of Health Product Supply Chain Reform: Market Forms of Organization Versus Public Ownership*, WILLIAM DAVIDSON INST. U. MICH., 2017, at 1, 6, 19.

68. Monique Vledder et al., *Improving Supply Chain for Essential Drugs in Low-Income Countries: Results from a Large Scale Randomized Experiment in Zambia*, 5 HEALTH SYS. & REFORM 158, 158, 162 (2019).

69. *See COVAX*, WORLD HEALTH ORG., https://www.who.int/initiatives/act-accelerator/covax [https://perma.cc/PDP7-Z4LP].

70. Jamie Ducharme, *COVAX Was a Great Idea, but Is Now 500 Million Doses Short of Its Vaccine Distribution Goals. What Exactly Went Wrong?*, TIME (Sept. 9, 2021, 7:00 AM), https://time.com/6096172/covax-vaccines-what-went-wrong/ [https://perma.cc/Z42V-8ZBK] ("COVAX and other global health groups also need to pay more attention to building out manufacturing and public-health infrastructure in countries that need it, rather than simply parachuting in and offering vaccines that many don't have the capacity to use . . . .").

71. Gehl Sampath & Pearman, *supra* note 59, at 16.

transfer method by encouraging local production of cutting-edge vaccine technologies.[72]

In conclusion, it is vital for LMICs to build up both local manufacturing capacity and knowledge about novel technologies for compulsory licensing to be effective. Transfer of production-related insights can come from intergovernmental bodies and nonprofit organizations but would require some buy-in from the pharmaceutical industry, which maintains many trade secrets. In this regard, James Love recommends buyouts of manufacturing know-how from the private sector through collaboration between governments to create a centralized fund.[73] Such buyouts have been proposed by scholars previously as a strategy to overcome the private sector's stronghold on important patents,[74] but they of course require cooperation and adequate funding from national governments.

B. Compulsory Licensing in the Domestic Context

While the United States and large pharmaceutical companies frequently criticize other countries for using compulsory licenses at the expense of innovation,[75] the United States has invoked compulsory licensing extensively in the non-pharmaceutical context. As Fisher and Syed note, "the United States has . . . somewhat more latitude when deviating from the TRIPS Agreement than has been enjoyed by developing countries" given the imbalance in bargaining power between countries.[76] Beyond TRIPS, the United States government has employed other mechanisms for compulsory licensing in different industries, most frequently for military and defense use.[77] Thus, there is a

---

72. *See id.* at 2. The recent partnership between Rwanda and BioNTech to develop an mRNA vaccine manufacturing hub is another such example. *See* Lars Larsson, *Rwanda Aims to Forge Vaccine Production Hub in BioNTech Deal*, AFRICAN BUS. (Mar. 11, 2022), https://african.business/2022/03/agribusiness-manufacturing/rwanda-aims-to-forge-vaccine-production-hub-in-biontech-deal/ [https://perma.cc/449W-7BFK].

73. Love, *supra* note 56 (describing a buyout fund wherein various governments pool money and offer to pay for technology transfer of manufacturing know-how to the public domain).

74. *See, e.g.*, Michael R. Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137 (1998) (proposing an auction mechanism for government buyouts).

75. Carie Steele, *The Biden Administration Supports Waiving Patents on Coronavirus Vaccines. Big Pharma Won't Be Happy*, WASH. POST (May 5, 2021, 5:51 PM), https://www.washingtonpost.com/politics/2021/05/05/biden-administration-supports-waiving-patents-coronavirus-vaccines-big-pharma-wont-be-happy [https://perma.cc/LBX3-ATBS].

76. Fisher & Syed, *supra* note 28, at 25.

77. Jerome Reichman & Catherine Hasenzahl, UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development, Non-voluntary Licensing of Patented Inventions (June 2003) ("While one may concede that statutory compulsory licensing of patents in favour of third parties in the United States is 'virtually non-existent', the truth is more complex and nuanced than would at first appear. For example, the United States government has broad powers to seize and use any invention protected by privately owned patents, subject to

degree of hypocrisy around not publicly supporting compulsory licensing in the pharmaceutical context.

1. The Bayh-Dole Act and March-In Rights

The pharmaceutical sector in the United States relies heavily on research by the government, academic medical centers, and universities.[78] Yet, these institutions often lose control over the final products after they are licensed out to the pharmaceutical industry for clinical development.[79] As an example, while Gilead "benefitted from substantial public sector funding and research collaboration" for the COVID-19 antiviral drug remdesivir — from early research and development to Phase III clinical trial design — the United States government has asserted no ownership rights over the product.[80] As a result, Gilead has a "general entitlement to prevent all other companies from making, using, selling, or importing the compound into the United States," resulting in serious shortages of the drug.[81] To put it bluntly: "Despite the substantial investment made by taxpayers . . . the public exerts no direct control over the price or supply of the medicine."[82] This problem is commonplace, as the government invests billions of dollars in such research every year.[83]

On the one hand, the Bayh-Dole Act has been hailed as a dramatic success in spurring biotechnology innovation in the United States,[84] allowing federally funded research to be patented.[85] However, since the legislation was passed, most of the resulting economic surplus from pharmaceutical products has been captured by the private sector, not the American public.[86] Namely, the availability of patents has

---

the payment of reasonable and entire compensation, and it makes extensive use of this power.").

78. *See* Rajkumar, *supra* note 11, at 2.

79. Bhaven Sampat & Frank Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFF. 332 (2011) (showing less than 10% of all drugs covered by patents owned by the public sector).

80. Amy Kapczynski, *Realizing Public Rights Through Government Patent Use*, 49 J.L. MED. & ETHICS 34, 35 (2021).

81. *Id.* at 35 (citing shortages in thirty-eight hospitals across the country, and in twelve states).

82. *Id.*

83. Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCIENCE (Mar. 9, 2017), https://www.science.org/content/article/data-check-us-government-share-basic-research-funding-falls-below-50 [https://perma.cc/4N84-LYEA].

84. Gabrielle Athanasia, *The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today,* CENTER FOR STRATEGIC & INT'L STUD. BLOG (Jan. 12, 2022), https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today [https://perma.cc/LFE8-VCUW].

85. 35 U.S.C. §§ 200–203, 209 (1980).

86. *See* Peter S. Arno, Dana Neacsu & Kathryn Ardizzone, *March-In Rights Could Ensure Patient Access By Keeping Drug Prices In Check. They're Under Attack*, HEALTH AFFS. (Apr.

encouraged R&D efforts for lifesaving therapies, but once these technologies are licensed out, pharmaceutical companies have nearly unilateral control over final prices and, thereby, access. The statute nominally accounts for this problem by permitting march-in rights, allowing the government to produce the covered federally funded invention in times of necessity without the patent-holder's permission.[87] So far, the United States government has *never* used these march-in rights in the pharmaceutical context.[88] For one thing, the statute restricts march-in rights to inventions "conceived or first actually reduced to practice in the performance of work under a funding agreement,"[89] which does not cover many significant contributions from the government (e.g., identifying disease biomarkers). Additionally, to encourage innovation in the COVID-19 context, it appears that government agencies have actually "used contracts that seem to eliminate even these limited [march-in provisions] for recipients of its funding."[90] Effectively, the government is contracting *away* its march-in rights for federally funded products instead of using its leverage to further control the development of medicines.[91] Access-to-medicines activists such as Amy Kapczynski argue that it is unacceptable for private companies that receive significant support from taxpayer dollars to develop technologies to then restrict public access to these technologies.[92]

At least four reforms could be enacted to overcome this problem. First, the statutory language and regulations that dictate when march-in rights could be applied can be changed. Of course, this would require either an amendment by Congress to the current Bayh-Dole Act or the promulgation of a clarifying regulation by the relevant agency, which presents political obstacles.

Second, government institutions like the National Institutes of Health ("NIH") — which either conduct early-stage R&D for biotechnologies or fund private companies doing this research — should use

---

30, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210428.519540/full/ [https://perma.cc/8P7V-YDPU].

87. 35 U.S.C. § 203(a) (stating that "the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances."). If the patent-holder refuses the request to grant such a license, the federal agency can grant the license itself if "necessary to alleviate health or safety needs which are not reasonably satisfied." *Id.*

88. *Cf.* J.R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 11 (2016).

89. 35 U.S.C. § 201(e) (2018).

90. Kapczynski, *supra* note 80, at 35.

91. *See* Christopher Rowland, *Trump Administration Makes It Easier for Drugmakers To Profit from Publicly Funded Coronavirus Drugs, Advocates Say*, WASH. POST (July 1, 2020), https://www.washingtonpost.com/business/2020/07/01/vaccine-coronavirus-barda-trump/ [https://perma.cc/DFX3-KTWM].

92. *See, e.g.,* Kapczynski, *supra* note 80, at 35.

their leverage when deciding to license out technologies or give out research grants. Unfortunately, despite receiving significant federal assistance, Moderna did not attribute NIH researchers as co-inventors on its COVID-19 vaccine patents,[93] limiting the influence the government can have over the biotechnology company on matters relating to manufacturing and distribution of the vaccine. Contributing to nearly half of all basic research funding,[94] drug patents,[95] and publications underlying final drug approvals,[96] the federal government must attach more strings to its contracts with the private sector (e.g., require companies being funded to voluntarily license their drugs to a fixed list of countries in the Global South).

Third, the government could charge more during out-licensing, and any additional revenue generated can be used to subsidize medicines for poorer populations both in the United States and abroad.

Fourth and lastly, the federal government can directly negotiate with the pharmaceutical industry in its licensing agreements to set a cap on the drug price relative to the amount of federal funding received or the expected costs of clinical development. This model could resemble the National Institute for Health and Care Excellence within the National Health Service in the United Kingdom, which effectively negotiates drug prices for the whole country.[97] While it is usually a payor (e.g., Medicare if the United States took the United Kingdom's approach) that would engage in such negotiations after the drug is approved, similar pressure could be applied *prior* to approval when distributing licenses or grant money through various contractual obligations.[98] The federal government recently placed such contractual requirements on manufacturers in 2020 through Operation Warp Speed — a public-private partnership aimed at accelerating R&D efforts for COVID-19 technologies — through advance purchase

93. Sheryl Gay Stolberg & Rebecca Robbins, *The N.I.H. Says It Isn't Giving Up in Its Patent Fight with Moderna*, N.Y. TIMES (Nov. 10, 2021), https://www.nytimes.com/2021/11/10/us/politics/moderna-vaccine-patent-nih.html [https://perma.cc/8MS5-RX3Q].

94. Mervis, *supra* note 83.

95. Sampat & Lichtenberg, *supra* note 79 (showing, through analysis of patents underlying FDA approval, that indirect government funding is responsible for close to half of all drug approvals).

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

97. *See* DUTFIELD, *supra* note 13, at 441.

98. While there have been recent legislative proposals to authorize Medicare to negotiate drug prices before they hit the market, this does not occur regularly in the United States today. Juliette Cubanski, Tricia Neuman & Meredith Freed, *What's the Latest on Medicare Drug Price Negotiations?*, KAISER FAM. FOUND. (July 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/ [https://perma.cc/6Z5E-NS77].

agreements totaling around $10 billion.[99] But more can be done in return for federal funding beyond merely requiring pharmaceutical companies to allocate future products to the government (and without even a significant discount[100]). Importantly, having the federal government negotiate drug prices with pharmaceutical players is a policy that has already garnered bipartisan support.[101] Overall, the government ought to recognize its crucial role in drug development and leverage it to increase access.

2. Government Patent Use

Beyond march-in rights as established by the Bayh-Dole Act, there is a broader pathway to increase access to medicines through compulsory licensing, known as government patent use or Section 1498.[102] This right "was an outworking of the organization of courts and the logic of sovereign immunity" and has been analogized to eminent domain.[103] Importantly, government patent use has been used frequently in the defense context but has been underutilized for pharmaceuticals more generally. For example, the United States Department of Defense procured generic medicines under the statute during the 1960s and 1970s, and the federal government threatened to invoke the Act to increase access to antibiotics in 2001 following the anthrax attacks (after which the patent-holding pharmaceutical company cut the drug price in half).[104] Government patent use was envisioned "to avoid situations where private rightsholders can hold up the public for more than

99. Noah Higgins-Dunn, *The U.S. Has Already Invested Billions in Potential Coronavirus Vaccines. Here's Where the Deals Stand*, CNBC (Aug. 14, 2020, 9:52 AM), https://www.cnbc.com/2020/08/14/the-us-has-already-invested-billions-on-potential-coronavirus-vaccines-heres-where-the-deals-stand.html [https://perma.cc/E8SS-7BQ7].

100. *Cf.* Jacob S. Sherkow, Lisa Larrimore Ouellette, Nicholson Price & Rachel Sachs, *Multi-Agency Funding for COVID-19 Vaccine Development*, WRITTEN DESCRIPTION (Aug. 19, 2020), https://writtendescription.blogspot.com/2020/08/multi-agency-funding-for-covid-19.html [https://perma.cc/4AXS-CAPZ].

101. *See* Cubanski et al., *supra* note 98. Notably, the U.S. Department of Veterans Affairs ("VA") paid approximately half as much as Medicare Part D for the same drugs in 2017. U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-111, PRESCRIPTION DRUGS: DEPARTMENT OF VETERANS AFFAIRS PAID ABOUT HALF AS MUCH AS MEDICARE PART D FOR SELECTED DRUGS IN 2017 (2020). Accordingly, some Democratic Senators have proposed a bill that pegs the price that Medicare pays for these select drugs to that paid by the VA. Peter Sullivan, *Sanders calls on Democrats to bring up drug pricing bill in Senate,* THE HILL (Feb. 9, 2022, 7:20 PM), https://thehill.com/policy/healthcare/593618-sanders-calls-on-democrats-to-bring-up-drug-pricing-bill-in-senate/ [https://perma.cc/C8ES-SWFN].

102. 28 U.S.C. § 1498 ("Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.").

103. Kapczynski, *supra* note 80, at 36.

104. *Id.*

reasonable compensation."[105] Thus, given the exorbitant price of prescription drugs in the United States, the pharmaceutical sector would be an appropriate use case for Section 1498.

Government patent use could also be a suitable remedy to access the data underlying pharmaceutical patents,[106] which could then be made public to increase competition and lower prices. Modeling the pharmaceutical industry after the defense industry could have significant upsides; for one, greater government control over pharmaceuticals could improve access. Of course, too much regulation might reduce innovation for novel biotechnologies. But greater government pressure (e.g., even through the threat of government patent use) could ensure lower prices during crises like the COVID-19 pandemic. Ultimately, march-in rights and government patent use are ex post remedies, but as proposed above, negotiating early on with companies in the licensing or funding process is the preferable ex ante approach. Nonetheless, President Biden's invocation of the Defense Production Act to forge a partnership between Johnson & Johnson and Merck to engage in vaccine production demonstrates that these ex post pathways are feasible in the pharmaceutical context.[107]

A final strategy to further increase the leverage that the government or universities may have in negotiations with pharmaceutical companies would be to increase the clinical capacity of government and academic labs. Subsidizing early-stage researchers to push them into the clinical trial process could allow them to reach inflection points that would permit them to charge higher fees to pharmaceutical buyers who eventually in-license the technologies.[108] These assets are currently undervalued given the high risk associated with preclinical development and the low percentage of products that eventually get approved.[109] But increasing funding for these innovative government and academic labs to pursue costly clinical research could allow the *true* creators to reap the benefits of their work, rather than having much of this value captured by large pharmaceutical companies.

This notion of pushing early innovators further into the clinical process could also be useful in the antitrust context. Namely, FTC Commissioner Lina Khan has proposed blocking large pharmaceutical

---

105. *Id.*

106. *Id.* at 37.

107. Shayan Karbassi, *Understanding Biden's Invocation of the Defense Production Act*, LAWFARE (Mar. 4, 2021, 8:01 AM), https://www.lawfareblog.com/understanding-bidens-invocation-defense-production-act [https://perma.cc/5XQF-LNB7].

108. *See generally* Margo A. Bagley, *"Just" Sharing: The Virtues of Digital Sequence Information Benefit-Sharing for the Common Good*, 63 HARV. INT'L L.J. (2022) (forthcoming).

109. Tohru Takebe et al., *The Current Status of Drug Discovery and Development as Originated in United States Academia*, 11 CLINICAL AND TRANSLATIONAL SCI. 597 (2018).

companies from acquiring smaller biotechnology companies.[110] One could argue that this would squash innovation by preventing products from reaching clinical development and final approval. But building up clinical capacity even in these small biotechnology firms could be the solution to preventing consolidation in massive pharmaceutical companies while maintaining adequate levels of innovation. Consequently, these companies will not need to be acquired to bring drugs to market. Increasing competition through this approach would ultimately decrease drug prices and increase access to important medicines.

III. THE MERITS AND DRAWBACKS OF VOLUNTARY APPROACHES

Various forms of voluntary licensing have also been proposed in the past to address inequities in access to medicines.[111] Voluntary licenses can involve agreements between innovator pharmaceutical companies and generic players in LMICs, wherein the latter manufactures and distributes the drug at a lower price to its large local population and to those in other similarly situated nations, while the former obtains royalties.[112] Absent reimportation, this arrangement has been hailed as a win-win for the pharmaceutical company as well as people in the Global South.[113] Through differential pricing as a business strategy to employ voluntary licensing, large pharmaceutical companies should be able to increase their overall revenues by expanding the size of the market, while LDCs gain affordable access to the drug. For example, Gilead negotiated voluntary licenses for its Hepatitis C drug Sovaldi in 2014, engaging in a series of deals with generic companies in India.[114] After successfully spearheading this model, the company more recently signed licensing agreements with India, Pakistan, and Egypt for the COVID-19 drug remdesivir, for distribution in 127 developing

110. Zachary Brennan, *Pharma in the Crosshairs: How the FTC is Expanding Its Antitrust Powers Under Its New Chair*, ENDPOINT NEWS (July 2, 2021, 9:51 AM), https://endpts.com/pharma-in-the-crosshairs-how-the-ftc-is-expanding-its-antitrust-powers-under-its-new-chair/ [https://perma.cc/6CKX-G2ZF] ("Khan is rolling back restrictions on antitrust investigations and potentially opening the flood gates on Big Pharma M&A.").

111. *See e.g.*, Daniel D. Kim, *Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing*, 8 INTELL. PROP. BRIEF 63 (2016).

112. Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 548 (2020).

113. *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 195 (2005).

114. *Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries*, GILEAD (Sept. 15, 2014, 6:31 AM), https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries [https://perma.cc/EN88-2XHA].

countries.[115] Proponents of voluntary licensing suggest that it avoids antagonizing the American pharmaceutical industry and permits technology transfer for complex molecules like the COVID-19 vaccine.[116]

A. Price Discrimination

A common fear of the pharmaceutical industry regarding differential pricing is arbitrage; namely, companies are worried that products sold abroad at cheaper prices will be imported back to high-income countries like the United States — at a cost between the low and high prices — and eviscerate the market.[117] However, this fear is unfounded for a few reasons. Absent a black market, there are stringent regulations in the United States on which drugs can be reimported. For example, not only does a drug have to be FDA-approved, but the molecule in question must also have been developed in an approved facility.[118] While there have been legislative proposals by Senator Bernie Sanders to permit the importation of cheaper drugs from countries like Canada,[119] these have yet to make headway in Congress.[120] Finally, some consideration should be given to the recent Supreme Court decision *Impression Products, Inc. v. Lexmark International, Inc*.[121] In this case, the Court held that patent exhaustion applies on first sale regardless of where the product is sold.[122] This holding thus limits the pharmaceutical industry's capacity to sue for patent infringement after importation. However, despite the implications of this decision, pharmaceutical companies can still counter arbitrage effects by engaging in creative contracts during voluntary licensing that prevent any exports back to the United States.

In spite of these benefits, it is not so clear that pharmaceutical companies are willing to share their intellectual property, as they currently

---

115. *Voluntary Licensing Agreements for Remdesivir*, GILEAD, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir [https://perma.cc/8MN4-FMVP] (last updated Jan. 21, 2022).

116. Kim, *supra* note 111, at 68 (citing the "goodwill" towards the pharmaceutical company"); Brook Baker, *The Impracticality of Relying on Compulsory Licenses to Expand Production Capacity for COVID-19 Vaccines*, HEALTH GAP (Jun. 6, 2021), https://healthgap.org/the-impracticality-of-relying-on-compulsory-licenses-to-expand-production-capacity-for-covid-19-vaccines/ [https://perma.cc/26C5-ZL6Y] (noting the supply chain complexities for mRNA vaccines).

117. Outterson, *supra* note 113, at 195–96.

118. *See* 21 U.S.C. § 381(r).

119. The Affordable and Safe Prescription Drug Importation Act, S. 97, 116th Cong. § 2(a) (2019).

120. *See* Berkeley Lovelace, *Sen. Bernie Sanders Says 'We Will End' Big Pharma 'Greed' as Lawmakers Push Bills Aimed at Slashing Prescription Drug Prices*, CNBC (Jan. 10, 2019, 11:46 AM), https://www.cnbc.com/2019/01/10/bernie-sanders-to-introduce-bills-aimed-at-prescription-drug-costs.html [https://perma.cc/Q8NZ-L7LJ].

121. 137 S. Ct. 1523 (2017).

122. *Id.* at 1529.

lack any incentive to do so.[123] On the one hand, "[m]ost economists would agree that, in a perfect world, originator pharmaceutical companies would avoid the risk of compulsory licensing by pricing their products so close to the marginal cost of production that [those in poorer countries] could afford to buy them."[124] In theory, such price discrimination should lower deadweight loss and would be beneficial to the pharmaceutical industry and poorer countries.[125] Yet, other than Gilead, few companies in the pharmaceutical sector engage in such voluntary behaviors.[126] Economists have suggested that originator companies are worried that more affluent countries will use the price for lower-income countries as a "reference price," thereby negotiating down prices with the pharmaceutical player in the higher-income country as well.[127] To avoid this problem, Danzon and Towse suggest a scheme wherein the lower prices are hidden from the rich countries (i.e., through a secret rebate system).[128] Still, fears persist, and the industry has largely stayed away from this approach.

Another suggested explanation for why branded companies are not voluntarily licensing their products to poorer countries at lower prices is known as the "convex demand curve problem."[129] Proposed by economist Aidan Hollis and others, the argument is that pharmaceutical companies would rather sell their drugs at a high price to the highest-income slice of a poor country rather than cheaply to the whole country.[130] This phenomenon occurs in countries like India and South Africa with high levels of inequality.[131] While this strategy creates deadweight loss, it is still profit-maximizing for the company.[132] But as James Love aptly notes, "deadweight loss tends over time to become dead bodies."[133] To conclude, price differentiation will not work in today's environment, and compulsory licensing is likely required to enable open access in poorer nations.

---

123. Reichman, *supra* note 20, at 254 ("Consultation and collaboration with originator pharmaceutical companies only become feasible when the latter are willing to negotiate. The patent-holding drug companies lack an incentive to negotiate so long as there are no clear legal sanctions with which to threaten them in case of refusals to deal.").

124. *Id.* at 251.

125. *See* Frederic M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 WORLD ECON. 1127, 1141 (2004).

126. Patricia Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 425, 441 (Keith Maskus & Jerome Reichman eds., 2005).

127. *Id.*

128. *Id.* at 426, 445.

129. Reichman, *supra* note 20, at 251–52.

130. Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 185 (2009).

131. *Id.* at 189.

132. *Id.*

133. Reichman, *supra* note 20, at 252.

B. Patent Pooling

Beyond price differentiation, voluntary patent pooling has become popular to encourage sharing data, know-how, and even patents in times of crisis.[134] For example, the WHO set up the COVID-19 Technology Access Pool ("C-TAP") to encourage information-sharing between countries during the pandemic.[135] The idea is that bundling such knowledge together can lower transaction costs and more quickly increase access to medicines worldwide.[136] Further, the Medicines Patent Pool ("MPP") is a global intellectual property-sharing platform — backed by the United Nations and funded by Unitaid — that was created in 2010 to increase access to therapies for Hepatitis C, tuberculosis, and HIV.[137] In light of the pandemic, the MPP expanded its mandate to cover COVID-19 technologies and offered its expertise to C-TAP as well.[138]

However, such voluntary sharing arrangements have serious drawbacks. First, the fact that they are voluntary makes pharmaceutical companies and countries with leading biopharmaceutical industries unlikely to join. After C-TAP was created, while more than thirty-five nations joined the effort, absent from the list of members were the United States, United Kingdom, France, China, Russia, India, Germany, Canada, and Saudi Arabia — many of the world's wealthiest countries that are leaders in the space.[139] Thus, much of the essential COVID-19 drug and vaccine know-how is not part of the pool. Further, despite the agreements being voluntary, the International Federation of Pharmaceutical Manufacturers and Associations has argued that C-TAP will

---

134. "Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties." WIPO Secretariat, Patent Pools and Antitrust – A Comparative Analysis 3 (Mar. 2014).

135. *WHO COVID-19 Technology Access Pool*, WORLD HEALTH ORG., https://www.who.int/initiatives/covid-19-technology-access-pool [https://perma.cc/TP5B-E69G].

136. Bashar Malkawi, *Patent Pools and the Pandemic — A Renewed Debate*, THINK GLOB. HEALTH (Aug. 14, 2020), https://www.thinkglobalhealth.org/article/patent-pools-and-pandemic-renewed-debate [https://perma.cc/P9FK-LLZS].

137. MEDS. PAT. POOL, https://medicinespatentpool.org/who-we-are/about-us [https://perma.cc/C9R8-4J8Q].

138. *The Medicines Patent Pool Prepared To Offer Expertise in Licensing and Patent Pooling To Address the Current COVID-19 Crisis*, MEDS. PAT. POOL (May 29, 2020), https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-prepared-to-offer-expertise-in-licensing-and-patent-pooling-to-address-the-current-covid-19-crisis [https://perma.cc/MLK7-HW4Z]; *The Medicines Patent Pool and Unitaid Respond to Access Efforts for COVID-19 Treatments and Technologies*, MEDS. PAT. POOL (Mar. 31, 2020), https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies [https://perma.cc/V55E-4BCL].

139. Ed Silverman, *The WHO Launched a Voluntary Covid-19 Product Pool. What Happens Next?*, STAT NEWS (May 29, 2020), https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/ [https://perma.cc/FFN6-WKC6].

erode the existing global IP framework, and the United States and United Kingdom have publicly pushed against the patent pool as well.[140] Separately, branded pharmaceutical companies have argued that the C-TAP is redundant in light of the pre-existing MPP, with Pfizer CEO Albert Bourla calling the initiative "nonsense" and "dangerous."[141]

Effectively, voluntary agreements provide no assurance from the private sector. When companies do engage, these licenses are narrow in scope and given on a case-by-case basis.[142] For example, Pfizer announced a voluntary license of its oral COVID-19 treatment Paxlovid to the MPP only in November 2021, almost two years into the pandemic.[143] Unfortunately, the deal is very restrictive in that it "only covers 53 percent of the world's population and excludes people in several upper-middle-income countries, leaving this promising medicine out of reach for millions."[144] Responding to the fact that the MPP license includes only ninety-five countries and is solely for treatment, Oxfam noted that Pfizer's license is "far from enough" and "begs the important question: If Pfizer can share data and intellectual property on a medicine, why have they so far categorically refused to do so for their COVID-19 vaccine?"[145] Despite overwhelming pressure from organizations like Doctors Without Borders to share its vaccine, given the immense amount of public funding for the product, Pfizer has refused.[146]

---

140. Sarah Boseley, *US and UK 'Lead Push Against Global Patent Pool for Covid-19 Drugs'*, GUARDIAN (May 17, 2020, 8:08 PM), https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-for-covid-19-drugs [https://perma.cc/JKC8-MFNN].

141. Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on Covid-19 Products*, STAT NEWS (May 28, 2020), https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/ [https://perma.cc/GEU2-BSEZ].

142. *Cf.* Abbott & Reichman, *supra* note 112, at 540.

143. *Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries*, PFIZER (Nov. 16, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing [https://perma.cc/8GGW-AUYY].

144. *MSF Responds to Pfizer and Medicines Patent Pool License for New COVID-19 Treatment*, DRS. WITHOUT BORDERS (Nov. 16, 2021, 6:45 AM), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-responds-pfizer-and-medicines-patent-pool-license-new-covid-19 [https://perma.cc/3EDW-QPBJ].

145. *Reaction to Pfizer's Announcement of Voluntary Licenses of Its COVID-19 Oral Antiviral Treatment Paxlovid to the Medicines Patent Pool*, OXFAM (Nov. 16, 2021), https://www.oxfam.org/en/press-releases/reaction-pfizers-announcement-voluntary-licenses-its-covid-19-oral-antiviral [https://perma.cc/3SZJ-YTZF].

146. *MSF: Following Full FDA Approval, Pfizer-BioNTech Must Share COVID-19 Vaccine Technology To Boost Global Supply*, DRS. WITHOUT BORDERS (Aug. 23, 2021), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-following-full-fda-approval-pfizer-biontech-must-share-covid-19 [https://perma.cc/SQ3C-TRDW].

Given these limitations, Abbott and Reichman suggest *mandatory* patent pools on global and regional bases.[147] In particular, the two argue that "governments should agree that owners of patents *must* place their patents into a 'pool' from which licenses may be freely taken and used by manufacturing companies in return for specified compensation."[148] Such a "Licensing Facility" could be anchored within the WHO's existing architecture or established by countries engaged in pre-existing regional agreements.[149] Contributing patent owners can be compensated through royalties paid for by the countries that enact the compulsory license, with LDCs exempt from having to pay.[150] Additionally, joint manufacturing agreements between countries in the pool can overcome the discussed know-how problems.[151] However, as the authors recognize, "[v]oluntary patent licensing agreements, such as the MPP, do not generate the same political or legal pushback associated with compulsory licensing."[152] Nonetheless, the constraints of voluntary approaches include the private sector's ability to simply decline or severely restrict what can be used and by whom. For example, Brazil was excluded from receiving MPP licenses despite being severely impacted by the COVID-19 pandemic.[153] Countering criticism that mandatory patent pools would deter innovation, Abbott and Reichman argue that "[v]ery little would accordingly be lost by overriding patents" since only a "small portion of global R&D is contributed from drug purchases in countries and by populations with limited incomes."[154] Finally, governments should not abstain from compulsory licensing for fear that it would "antagonize pharmaceutical companies," since to do so would be to imply that they have simply "surrendered their sovereign authority."[155] To conclude, even in the pooling context, voluntary licenses are insufficient and mandatory pools could overcome the primary issues with little to no downside risks.

IV. ALTERNATIVE PARADIGMS TO THE PATENT PROBLEM

While this Note has focused primarily on overcoming patent barriers through the prospects of compulsory licensing in both the global and domestic contexts, more radical proposals suggest a complete overhaul of the intellectual property system for pharmaceutical products. It

147. Abbott & Reichman, *supra* note 112, at 543.
148. *Id.* (emphasis added).
149. *Id.* at 544.
150. *Id.* at 545–46.
151. *See id.* at 550.
152. *Id.* at 548.
153. *Id.* at 549.
154. *Id.* at 541.
155. *Id.* at 549.

would be remiss not to briefly describe some of these progressive solutions that could revolutionize access to medicines.

A. Innovation Prizes

James Love has been a strong proponent of prizes to encourage innovation in the pharmaceutical industry while maintaining adequate access to affordable medicines.[156] Such a "pull" mechanism could change the "expected payoff" of innovation and thereby have a "significant effect on R&D efforts."[157] One possibility would be to link remuneration to global health impact in order to incentivize pharmaceutical companies to create products that improve societal health outcomes.[158] Delinking R&D incentives from drug costs would increase the freedom of innovative companies to invest in cutting-edge technologies that have immense social impact.[159] This approach could change the end goal from market exclusivity — as is permitted through patent monopolies — to social value. A criticism of the proposal could be that such a prize fund would be impossible to establish. However, Senator Sanders has suggested a realistic Medical Innovation Prize Fund,[160] which would receive a portion of national gross domestic product and provide for zero-sum competition among companies that register their products with the Fund.[161] Love argues that a fund, as opposed to a lump-sum prize, is optimal as it increases competition between players and avoids the need to pre-determine prize size (since the number of registered companies and the respective social value of their products determine the individual prize amounts).[162] Another administrability concern is determining how to measure health impact.[163] Proponents propose a pilot program to address these feasibility concerns.[164]

Beyond reimbursement for the social value engendered by approved products, innovation prizes could also be set up to reward intermediary milestones.[165] Encouraging incremental innovation is still

---

156. *See* James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155, 186 (2009).

157. Lisa Larrimore Ouellette, Nicholson Price, Rachel Sachs & Jacob S. Sherkow, *How Should Policymakers Use "Pull" Mechanisms to Improve COVID-19 Innovation Incentives?*, WRITTEN DESCRIPTION (July 30, 2020), https://writtendescription.blogspot.com/2020/07/how-should-policymakers-use-pull.html [https://perma.cc/YD9U-D7ZQ].

158. Thomas Pogge, *The Health Impact Fund: Enhancing Justice and Efficiency in Global Health*, 13 J. HUM. DEV. & CAPABILITIES 537, 537 (2012).

159. *Id.*

160. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 2 (2007).

161. *See id.*

162. Love & Hubbard, *supra* note 156, at 167.

163. Pogge, *supra* note 158, at 553–54.

164. *Id.*

165. *See* Love & Hubbard, *supra* note 156, at 174–77 (providing examples of innovation prizes that reward not only final products but also knowledge, materials, and open research).

valuable, as it would motivate companies to share data and knowledge that could be useful for the final product. While such collaboration is reminiscent of voluntary patent pools, the prize fund creates an additional monetary incentive to encourage sharing and pushes companies to work towards a final product together in a way that free-standing voluntary agreements may not. Innovation prizes could redefine what metrics drive pharmaceutical companies (social value, instead of recouping R&D costs) and allow increased access to care through a centralized fund.

B. A Commons-Based Approach

An even more aggressive approach would involve rethinking the property system that exists for pharmaceuticals. Specifically, a commons-like regime could facilitate open access to necessary medicines while promoting innovation. To note, most biomedical products — vaccines, drugs, medical equipment — are both rival (meaning person A's use precludes person B's use) and excludable (meaning that people can be prevented from accessing the technologies).[166] Though rivalry cannot be overcome until the supply of vaccines overtakes demand, reducing access barriers can resolve problems of excludability. For example, knowledge is a non-rival good (since many people can share it without diminishing each other's use), but it has been made excludable through patents.[167] Naturally, since the marginal cost of knowledge production after initial creation is zero, but the price is non-zero due to intellectual property protection, there is underconsumption of this COVID-related knowledge.

Thus, an open-access commons that allows all parties to share and utilize COVID-related data and knowledge could provide a solution. This approach could potentially increase the freedom to operate by pharmaceutical players as they would not be blocked by patents, and more rapid innovation can result in privatized markets. Of course, unless governments entirely remove incentives from patents for pharmaceutical products, this solution would resemble a voluntary patent pool. But both innovation prizes and funds can be employed instead as a remuneration mechanism. Overall, this approach could motivate early-stage pharmaceutical companies to prioritize exploration, not exploitation, and promote industry growth *and* access to essential medicines.

---

166. *See generally* James Love, *The Use and Abuse of the Phrase "Global Public Good"*, DEV. ECON. (July 16, 2020), https://developingeconomics.org/2020/07/16/the-use-and-abuse-of-the-phrase-global-public-good/ [https://perma.cc/6BXQ-UA3L].

167. Lisa Larrimore Ouellette, Nicholson Price, Rachel Sachs & Jacob S. Sherkow, *Non-excludable Innovations and COVID-19*, WRITTEN DESCRIPTION (May 27, 2020), https://writtendescription.blogspot.com/2020/05/nonexcludable-innovations-and-covid-19.html [https://perma.cc/M7YX-XSCM].

V. CONCLUSION

Ultimately, if poor countries go unvaccinated, both poor and rich countries will have to pay the price.[168] Many have argued that the same holds in the domestic context — the cost of late-stage therapy for lower-income individuals often far outweighs the cost of prevention or early-stage treatment.[169] Thus, increasing access to drugs by overcoming patent barriers can actually be on balance cheaper for *all* taxpayers. It is important to note that beyond patents, there are certainly other obstacles blocking access to care.[170] For example, in the United States, the linkage between the Patent and Trademark Office ("USPTO") and the Food and Drug Administration results in additional pediatric and orphan drug market exclusivities that might impinge access.[171] This problem would require distinct regulatory solutions such as increasing USPTO standards for pharmaceutical products or better incentivizing the production of cheaper generics and biosimilars by amending statutes like the Hatch-Waxman Act[172] and the Biologics Price Competition and Innovation Act.[173] Additionally, there may be concerns around financing public health innovation and using non-IP-related strategies to lower drug costs. In this realm, Abbott and Reichman propose pooled procurement strategies through "Regional Pharmaceutical Supply Centers," wherein regional bodies can come together to increase bargaining power against large pharmaceutical companies.[174]

Nonetheless, patents remain a significant obstacle to accessing medicines both in the United States and abroad. Given the non-binding nature of voluntary licensing agreements, such as through price discrimination and patent pooling, compulsory licensing is the better mechanism to ensure access during times of crisis. Reliance on voluntary methods could leave countries at the whim of the pharmaceutical industry, increasing both uncertainty and transaction costs. Internationally, the TRIPS framework (specifically Article 31*bis* and the proposed

---

168. Peter S. Goodman, *If Poor Countries Go Unvaccinated, a Study Says, Rich Ones Will Pay*, N.Y. TIMES (Jan. 2, 2021), https://www.nytimes.com/2021/01/23/business/coronavirus-vaccines-global-economy.html [https://perma.cc/9EJC-GJ2U].

169. *See, e.g.*, Charlie Sorrel, *One Big Lesson From Obamacare: Preventative Care Saves Lives and Money*, FAST CO. (Jan. 31, 2017), https://www.fastcompany.com/3067684/one-big-lesson-from-obamacare-preventative-care-saves-lives-and-money [https://perma.cc/Z9PR-737F].

170. *See, e.g.*, Daniel Hemel & Lisa L. Ouellette, *Innovation Institutions and the Opioid Crisis*, 7 J.L. & BIOSCIENCES 1, 4 (2020) (noting that in addition to intellectual property law, factors like regulatory structures also contributed to the opioid crisis in America).

171. Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 29.

172. Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355(j) (1984).

173. Patient Protection and Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119, 804 (2010).

174. Abbott & Reichman, *supra* note 112, at 550–51.

waiver) as well as the acceleration of manufacturing know-how transfer could maximize the impact of compulsory licensing regimes. In the domestic context, the United States government should exercise march-in rights as granted by the Bayh-Dole Act, or alternatively bypass patents through Section 1498 to produce biotechnologies as it does for other military and defense products. These compulsory licensing mechanisms are a new way forward to ensure equitable access to lifesaving vaccines and treatments during devastating global pandemics.