SHOT THROUGH THE HEART: HOW THE COVID-19 IP WAIVER GIVES PATENTS A BAD NAME AND HARMS THE ELDERLY

MARIAM KHAN*

This article outlines the ongoing and highly debated COVID-19 IP Waiver from the perspective of one of the most vulnerable COVID-19 populations: the elderly. Although vaccines are often protected by patents, the unpredicted COVID-19 pandemic threatened even intellectual property. This article considers the conflicting views on waiving IP—one that prioritizes property protections and one that prioritizes morality. Considering the moral implications of waiving patents, the article explores the role of limited manufacturing capacity, rather than IP, in stifling vaccine accessibility. This article also examines other methods of expanding vaccine distribution through tech transfer, waiving trade secrets, march-in rights and compulsory licensing. Finally, this article proposes a resolution to the IP waiver debate and outlines additional IP-related measures that governments should consider for the next pandemic.

* Mariam Khan, J.D. Candidate 2024, University of Illinois College of Law; B.S. 2021, University of Houston. This author would like to thank Professor Andrea Augustine at the University of Illinois College of Law for her advice and mentorship. She would like to dedicate this Article to the friends and family who have supported her through her legal journey.

I. INTRODUCTION

When seventy-six-year-old Lindsey Stewart awoke with a tickle in her throat—her heart sank.[1] She had been so careful—only meeting her family and a small group of vaccinated friends, while avoiding her favorite activity: going to baseball games.[2] However, she could never avoid visiting her grandson.[3] Slowly, Stewart and her husband started taking the ferry again and hosting the annual Christmas dinner.[4] But every time COVID-19 infections spiked—her heart sank again.[5]

Stewart is not the only one—ninety-one-year-old Jane Gerechoff, wheelchair-bound and struggling with lung disease, lives with her adult son.[6] While waiting for the doctors to come to her, she prays that her son will not track the virus into their home.[7] Such fears are common amongst seniors.[8] Sixty percent of seniors worry about the surges in COVID-19 infections and hospitalizations.[9] More than forty percent of seniors are concerned that they will get seriously sick.[10] Not surprisingly, these worries have plagued (pun not intended) the elderly population.[11]

---

[1] Deidre McPhillips, *A COVID-19 'senior wave' is driving up hospitalizations*, CNN (Dec. 23, 2022, 6:28 PM), https://www.cnn.com/2022/12/23/health/senior-wave-covid/index.html [https://perma.cc/3M8S-RAZN].
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] Judith Graham, *Homebound seniors are still waiting for COVID-19 vaccines, so doctors and nurses are going to them*, CNN (Feb. 19, 2021, 7:15 AM), https://www.cnn.com/2021/02/19/health/seniors-vaccines-at-home-wellness/index.html [https://perma.cc/KK3X-V3EY].
[7] *Id.*
[8] McPhillips, *supra* note 1.
[9] *Id.*
[10] *Id.*
[11] *Id.*

In Florida, seniors waited over twelve hours to receive the COVID-19 vaccine, only to be denied when the site met capacity.[12] In India, 440 million people above the age of forty-five are awaiting to be "jabbed," but vaccine stocks have been quickly drained.[13] Now, imagine these seniors being strapped with a $175-a-dose bill.[14] These high costs for boosters sound like a nightmare—but such a future remains a very real possibility.[15]

Since the wake of the pandemic, the elderly population has been under threat.[16] The COVID-19 virus is fatal to older Americans, particularly those with comorbidities, and initial efforts to find a vaccine were rushed, resulting in underrepresentation of the senior population in clinical trials.[17] One proposed solution—eliminating the intellectual property (IP) rights of medical

---

[12] Madeline Holcombe, *Florida Seniors Face Long Lines and a Haphazard Registration System to Get COVID-19 Vaccines*, CNN (Jan. 7, 2021, 5:39 AM), https://www.cnn.com/2021/01/07/us/florida-coronavirus-vaccine-rollout/index.html [https://perma.cc/86SN-GUAR].

[13] Aparna Alluri, *India's COVID Vaccine Shortage: The Desperate Wait Gets Longer*, BBC (May 1, 2021), https://www.bbc.com/news/world-asia-india-56912977 [https://perma.cc/DZX2-W6KR].

[14] Chris Morten & Matthew Herder, *We Can't Trust Big Pharma to Make Enough Vaccines*, THE NATION (May 31, 2021), https://www.thenation.com/article/world/covid-vaccines-pharma/ [https://perma.cc/NLD8-SJ2C].

[15] *See id.*

[16] *Guidance for Vaccinating Older Adults and People with Disabilities: Ensuring Equitable COVID-19 Vaccine Access*, CDC (Jan. 20, 2022), https://www.cdc.gov/vaccines/covid-19/clinical-considerations/older-adults-and-disability/access.html [https://perma.cc/6Z7X-VWUT] [hereinafter *Vaccinating Older Adults*]; *Vaccination Resources*, ACL (May 20, 2022), https://acl.gov/covid19/vaccination-resources [https://perma.cc/JL55-BMMM].

[17] Benjamin Helfand et al., *The Exclusion of Older Persons from Vaccine and Treatment Trials for Coronavirus Disease 2019 – Missing the Target*, JAMA NETWORK (September 28, 2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2771091 [https://perma.cc/US73-PDLD].

companies to the COVID-19 vaccine—has ignited controversy.[18] Many IP experts contend that vaccine companies' desire to protect their IP rights diminishes roll out.[19] If countries do not have to worry about infringing a billion-dollar industry's IP rights, these critics argue that future vaccine roll outs will be quicker and vaccines will be more accessible.[20] On the other hand, limited resources for vaccine manufacturing and skepticism surrounding the vaccine have proven to be hurdles in vaccinating the elderly populations.[21] Furthermore, stripping a vaccine company of its IP may disincentivize these companies from reaching groundbreaking pharmaceutical innovations in times of need.[22] Consequently, the proposal to waive these drug manufacturers' IP is controversial.

This Article seeks to outline the complex dichotomy of the IP Waiver debate. In Part II, the Background, this Article will explore the history of vaccine IP protection in the context of one of the most vulnerable COVID-19 populations: the elderly. Considering the moral implications of waiving patents, Part III will analyze the role of limited manufacturing capacity, rather than IP, in stifling vaccine accessibility. The Article will examine the merits of the IP Waiver and whether the waiver expands vaccine

---

[18] *Vaccine IP Under Microscope With Coronavirus Outbreak*, LAW360 (March 4, 2020), https://plus.lexis.com/api/permalink/67379ac0-bf07-4924-905f-be3791268742/?context=1530671 [hereinafter *Vaccine IP*].

[19] *Id.*; *see* Thomas B. Cueni, *Waiving Intellectual Property Rights is a Flawed Solution to Achieving COVID-19 Vaccine Equity*, STAT (June 10, 2022), https://www.statnews.com/2022/06/10/waiving-intellectual-property-rights-is-a-flawed-solution-to-achieving-covid-19-vaccine-equity/ [https://perma.cc/6BB2-39WS].

[20] *Vaccine IP*, *supra* note 18; *see* Cueni, *supra* note 19.

[21] *Vaccine IP*, *supra* note 18.

[22] Amalie Holmgaard Mersch, *WTO Official: IP Waiver on COVID vaccines Would Not Facilitate Access Immediately*, EURACTIV.COM (Apr. 4, 2022), https://www.euractiv.com/section/health-consumers/news/wto-official-an-ip-waiver-on-covid-vaccines-would-not-loosen-up-access-immediately/ [https://perma.cc/2JJB-556R].

accessibility in the United States and globally. This analysis will examine other methods of expanding vaccine distribution through licensing, technology transfer, waiving trade secrets, march-in rights, and compulsory licensing.

Part IV will suggest a resolution to the IP Waiver debate and outline additional IP-related measures that governments should consider for the next pandemic. It will also consider whether the IP Waiver should be extended or expanded to include more technologies, like diagnostic tests or treatments, or additional countries.

II. BACKGROUND

Vaccine IP for the COVID-19 virus is particularly relevant to the local and global elderly population.[23] As a result, waiving IP has been proposed to improve accessibility to the vaccine.[24] The United States government has skirted around this issue by contracting with drug manufacturers, but it has been reluctant to circumvent these drug manufacturers' IP rights.[25] However, many urge the introduction of an IP rights waiver based on moral grounds.[26] Others argue for an IP waiver on more neutral grounds—arguing that IP is inconsequential to federally funded drugs.[27] In contrast, some contend that stripping IP rights does not solve the challenges of supply chain and skepticism toward vaccines.[28] Furthermore, diminishment

[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *See* Brink Lindsey, *Why intellectual property and pandemics don't mix*, BROOKINGS (Jun. 3, 2021), https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-don't-mix/ [https://perma.cc/HG4E-LKXW].
[27] *Id.*
[28] *Id.*

of IP rights now may discourage future drug manufacturers from rushing toward a solution in a future pandemic.[29]

A. Vaccinations for the elderly are particularly vital.

Since the beginning of the pandemic, the elderly have been considered one of the most at-risk populations.[30] As of October 2022, 790,000 of the 1.1 million COVID-19 deaths in the United States were individuals aged sixty-five or older.[31] Even though the elderly population in the United States is approximately 16% of the total population, those ages sixty-five and older account for 75% of all COVID-19-related deaths.[32] Such a drastic increase in elderly COVID-19 deaths during the Summer of 2022 has been attributed to a decrease in booster vaccinations.[33] COVID-19 vaccinations, boosters, and treatments have decreased the instances of severe disease, hospitalizations, and deaths.[34] Even so, the COVID-related deaths from April–July 2022 increased at a rapid rate for all ages, but at a much higher rate for those older than sixty-five.[35]

Along with factors such as low booster uptake and fading vaccine immunity, more transmissible variants, like the Delta or Omicron variants, contributed to these 11,000

---

[29] *Id.*
[30] *Vaccinating Older Adults*, *supra* note 16.
[31] Meredith Freed et al., *Deaths Among Older Adults Due to COVID-19 Jumped During the Summer of 2022 Before Falling Somewhat in September*, KFF (Oct. 6, 2022), https://www.kff.org/coronavirus-covid-19/issue-brief/deaths-among-older-adults-due-to-covid-19-jumped-during-the-summer-of-2022-before-falling-somewhat-in-september/ [https://perma.cc/6727-3D47].
[32] *Id.*
[33] *Id*.
[34] *Id.*
[35] *Id*.

elder deaths.[36] Although Americans have built an immunity wall against the Omicron variant, the immune systems of elderly bodies are still weaker than those of young ages.[37] Since October 2022, the COVID-19 hospitalization rate for elderly has been four times higher than the average COVID-19 hospitalization rate.[38] Even during the first wave of the pandemic, the age gap between hospitalization rates had only been three times higher than that of the average population.[39] This surge in COVID-19 hospitalizations and deaths has been deemed a "senior wave."[40] In California, the only age group seeing a rise in hospitalization rates was the seventy-plus group.[41] Such sharp increase in infections undoubtedly plague the minds of seniors, who fear for their safety.[42] Indeed, the unpredictably of COVID-19 deaths continues to pose a danger to the elderly population.[43]

Furthermore, the elderly population also experienced unique virus-related challenges.[44] Unlike other age groups, elderly individuals suffer from atypical symptoms—including oversleeping, not eating, confusion, dizziness, or fainting.[45] This unresponsiveness arises from the fact that older bodies respond differently to infection.[46] This masking of typical COVID-19 virus symptoms prevents

---

[36] *Id.*
[37] McPhillips, *supra* note 1.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] Rong-Gong Lin II, *California Senior Citizens are Hard Hit as COVID-19 Surges This Winter*, LOS ANGELES TIMES (Dec. 5, 2022, 9:10 AM), https://www.latimes.com/california/story/2022-12-05/senior-california-covid-19-hospitalization-rates-spike [https://perma.cc/A9ZU-RRGL].
[42] *See* McPhillips, *supra* note 1.
[43] *See* Freed et al., *supra* note 31.
[44] Graham, *supra* note 6.
[45] *Id.*
[46] *Id.*

those older than sixty-five from receiving the treatment they desperately need.[47]

Despite this, many of these older individuals are reluctant to obtain boosters.[48] Nearly 25% of seniors have plans to obtain a booster.[49] According to the CDC, only 26.7% of elder individuals have obtained two boosters,[50] while 40.5% of the elder individuals have obtained one booster, as of January 2023.[51] In California, only 35% of the vaccinated senior population have obtained the updated booster.[52] While this figure is shocking, the reports for other age groups are much lower in California.[53] Less than 10% of adults and 5% of children have obtained a second booster.[54] Some doctors have suggested that the state has done a "pathetic job of protecting seniors (and age 50+) from severe COVID."[55] Regardless of who fails to obtain a booster, seniors are affected.[56] Family, friends, grandchildren, and the general public can expose seniors to the virus.[57] Those in nursing homes are particularly

---

[47] Judith Graham, *Seniors With COVID-19 Show Unusual Symptoms, Doctors Say*, KFF (Apr. 24, 2020) [hereinafter *Unusual Symptoms*], https://kffhealthnews.org/news/seniors-with-covid-19-show-unusual-symptoms-doctors-say/#:~:text=%E2%80%9CUnderlying%20chronic%20illnesses%20can%20mask,able%20to%20-communicate%20their%20symptoms.%E2%80%9D [https://perma.cc/4PHQ-RLU5].

[48] McPhillips, *supra* note 1.

[49] *Id.*

[50] Ralph Ellis, *Elderly Still Make Up Most of the COVID-19 Deaths*, WEBMD, (May 27, 2022), https://www.webmd.com/covid/news/20220526/elderly-still-make-up-most-covid-deaths [https://perma.cc/6JVL-2PTG].

[51] *Maps of COVID-19 Vaccinations by Age and Sex over Time*, CDC, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-maps [https://perma.cc/5QSQ-9ESU] (last visited Nov. 3, 2023).

[52] Lin II, *supra* note 41.

[53] *Id.*

[54] McPhillips, *supra* note 1.

[55] Lin II, *supra* note 41.

[56] McPhillips, *supra* note 1.

[57] *Id.*

vulnerable.[58] In spite of these slow booster rates, boosters do not solve all of the problems faced by seniors during a virus outbreak.[59]

Other challenges to vaccines include older Americans being homebound and unable to access the vaccine.[60] One study in April 2021 showed that 1.6 million seniors are homebound, with approximately 51% of these adults facing additional barriers to accessing the vaccine.[61] Such barriers include lack of access to technology, poor social support, lack of access to transportation, and limited economic resources.[62] These accessibility limits are also exacerbated along racial lines.[63] As opposed to their White, American Indian, and Pacific Islander counterparts, Hispanic older adults are twice as likely to be homebound.[64] While the elderly vaccination rate, for at least the first dose, has been relatively high in the United States,[65] there also remains a disparate impact among impoverished communities and southern states.[66] Similarly, rushed

---

[58] *Id.*

[59] *See generally* Emma Nye & Martin Blanco, *Characterizing Homebound Older Adults: Potential Barriers to Accessing the COVID-19 Vaccine Issue Brief*, ASPE (Apr. 15, 2021), https://aspe.hhs.gov/reports/characteristics-homebound-older-adults-potential-barriers-accessing-covid-19-vaccine-issue-brief [https://perma.cc/Q2FB-YGCP].

[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] John Elfein, *Percentage of adults 65 years and older in the United States with at least one does or were fully vaccinated against COVID-19 as of April 26, 2023*, STATISTA (May 2, 2023), https://www.statista.com/statistics/1254250/share-of-older-us-adults-fully-or-partially-vaccinated-against-covid/ [https://perma.cc/F89Y-4NZ9].

[66] Meredith Freed et al., *Vaccination Rates are Relatively Higher for Older Adults, But Lag in the Counties in the South, in Counties with the*

vaccine trials underrepresented senior citizens.[67] Consequently, the future effects of those vaccines on the elderly population are still to be determined.[68] For example, a study in September 2020 revealed that one COVID-19 trial had a median age of forty years, suggesting that hardly any participants would be over seventy-five.[69] These exclusionary medical trial practices resulted from fear for the health of seniors, especially when the effects of COVID-19 were first being determined.[70]

Recognizing the dangers to particularly vulnerable populations, governments have had to make critical choices regarding whether to protect the elderly or other vulnerable people.[71] As the vaccines developed, countries decided who to prioritize first: the United States chose to protect the elderly populations first, China protected those with high-risk jobs, and Indonesia prioritized the non-elderly population whom they were concerned would spread the

---

High Poverty Rates and in Counties that Voted for Trump, KFF (May 13, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/vaccination-rates-are-relatively-high-for-older-adults-but-lag-in-counties-in-the-south-in-counties-with-higher-poverty-rates-and-in-counties-that-voted-for-trump/ [https://perma.cc/J4PL-W6AN].

[67] Nicola Veronese et al., *Underrepresentation of Older Adults in Clinical Trials on COVID-19 Vaccines*, NATIONAL LIBRARY OF MEDICINE (Sep. 3, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8413602/ [https://perma.cc/LM9R-BXC8].

[68] *Id.*

[69] Benjamin Helfand et al., *The Exclusion of Older Persons from Vaccine and Treatment Trials for Coronavirus Disease 2019 – Missing the Target*, JAMA Network (September 28, 2020), https://jamanetwork.com/journals/-jamainternalmedicine/fullarticle/2771091 [https://perma.cc/4FEN-N235]; David R. Boulware et al., *A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for COVID-19*, 383 NEW ENG. J. MED. 517, 522 (2020).

[70] Hefland et al., *supra* note 69.

[71] *See* Abby Goodnough & Jan Hoffman, *Frontline Workers and People Over 74 Should Get Shots Next, C.D.C. Panel Says*, NEW YORK TIMES (Dec. 20, 2020), https://www.nytimes.com/2020/12/20/health/covid-vaccine-first-elderly-workers.html [https://perma.cc/7PBJ-ALSR].

virus at a higher rate.[72] In countries that are concerned with protecting the economy from a recession, global elderly populations are particularly vulnerable.[73]

Other solutions to vaccine accessibility challenges have included in-home vaccination services.[74] Homebound adults struggle to travel to vaccination sites.[75] According to the Centers for Medicare & Medicaid Services, "homebound" means "unable to leave home unassisted and for whom leaving the house would take considerable and taxing effort."[76] Such homebound adults face higher rates of multiple health conditions, higher rates of depression and anxiety, and higher rates of hospitalization.[77] Consequently, many localities are providing in-home healthcare services in an effort to reach such homebound seniors.[78] For example, the Nevada Senior Service provides vaccines to their active clients; in Maryland, some counties are sending emergency medical technicians to vaccinate within the home; and the Ventura County Area Agency on Aging uses public health nurses to vaccinate homebound older adults.[79] Such infrastructure has the potential to create routine healthcare administration for future booster doses and other vaccines.[80]

---

[72] Veronese et al., *supra* note 67; Stanford Graduate School of Business, *Podcases: Case Studies, Reimagined, Intellectual Property and COVID Vaccines*, STANFORD BUSINESS (May 5, 2022), https://www.gsb.stanford.edu/business-podcasts/podcase-intellectual-property-covid-vaccines [https://perma.cc/24ZD-UZFF] [hereinafter Podcases].
[73] Podcases, *supra* note 72.
[74] James G. Hodge, Jr. et al., *Vaccinating Urban Populations in Response to COVID-19: Legal Challenges and Options*, 49 FORDHAM URBAN LAW JOURNAL 1 (2021).
[75] Nye & Blanco, *supra* note 59.
[76] *Id.*
[77] *Id.* at 1–2.
[78] *Id.* at 7.
[79] *Id.* at 7.
[80] *Id.* at 7.

The United States government also attempted to provide aid to urban areas.[81] Dubbed the "great equalizer,"[82] COVID-19 hit urban populations the hardest, especially considering the prevalence of multi-generational and multi-family housing; public transportation; and individuals residing, working, and socializing in close quarters.[83] While 83% of Americans live in urban areas, approximately 89% of U.S. COVID deaths in January 2021 occurred there.[84] As the Pfizer, Moderna, and Johnson & Johnson vaccines rolled out, the White House coordinated federally-operated vaccine sites, specifically prioritizing at-risk populations.[85] From February to June 2021, ten billion dollars were allocated to protect such at risk individuals, minorities, and low-income populations.[86] Points of distributions (PODs) for vaccines exploded in different urban areas: Disneyland in Anaheim, California, and State Farm Stadium in Glendale, Arizona.[87] Such PODs vaccinated thousands of people per day.[88] Other challenges included slow websites (which elderly persons lacking computer skills find especially difficult), inclement weather, cold storage measures, and vial distribution limitations.[89]

Combatting vaccine hesitancy was also a major concern, as anti-vax misinformation spread.[90] Whether in urban or rural populations, millions of Americans are hesitant to obtain the vaccines, stemming from religious or

---

[81] Nye & Blanco, *supra* note 59, at 6.
[82] *See* Stephen A. Mein, *COVID-19 and Health Disparities: The Reality of "The Great Equalizer"*, 35 J. GEN. INTERNAL MED. 2439, 2439–40 (2020).
[83] Hodge et al., *supra* note 74, at 5–6.
[84] *Id.* at 5.
[85] *Id.* at 2–10.
[86] *Id.*
[87] *Id.* at 10.
[88] *Id.*
[89] Hodge et al., *supra* note 74, at 10–12.
[90] *Id.* at 12–13.

political beliefs, anti-vax information, and a general distrust of the government.[91] Notably, after the J&J vaccine produced side effects like blood clotting, vaccine hesitancy increased in April 2021.[92] In a 2021 decision, the Supreme Court countered with broad interpretations on religious liberty.[93] Another decision from a federal district court in Texas encouraged nurses who were displeased with work vaccination mandates to "simply . . . work somewhere else."[94] The words of the Supreme Court in 1890 echoed in 2020:

> Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is, then, liberty regulated by law.[95]

Such a shifting political landscape was ripe for vaccine hesitancy—encouraging social media sites to crackdown on misinformation, and federal authorities to limit some media messages.[96] These challenges to accessibility have plagued the elderly population.[97]

---

[91] *Id.* at 13.
[92] Alex Reinhart, *Vaccine Hesitancy and the J&J Vaccine Suspension*, CARNEGIE MELLON UNIVERSITY: DELPHI GROUP (Apr. 23, 2021), https://delphi.cmu.edu/blog/2021/04/23/vaccine-hesitancy-and-the-jj-vaccine-suspension/[https://perma.cc/5QP8-DTM7].
[93] *See* South Bay United Pentecostal Church v. Newsom, 141 S. Ct. 716, 716 (2021).
[94] Bridges v. Hous. Methodist Hosp., 543 F. Supp. 3d 525, 528 (S.D. Tex. 2021).
[95] Jacobsen v. Massachusetts, 197 U.S. 11, 26–27 (1905) (citing Crowley v. Christensen, 137 U.S. 86, 89 (1890)).
[96] Hodge et al., *supra* note 74, at 28.
[97] Nye & Blanco, *supra* note 59.

B. The IP Waiver for COVID-19 tools was proposed as a solution to encourage accessibility globally.

In response to the issues with accessibility, many IP scholars and politicians have proposed waiving the intellectual property rights to COVID-19 vaccines.[98] This Trade-Related Aspects of Intellectual Property (TRIPS) waiver, or the IP Waiver, would allow governments to manufacture their own vaccines without infringing the IP of vaccines giants, like Pfizer or Moderna.[99] In October 2020, India and South Africa proposed the TRIPS waiver to temporarily waive restrictions on patents to encourage global access for vaccines and boost research efforts.[100] In June 2022, the World Trade Organization (WTO) negotiated a deal allowing "those developing countries that exported less than 10% of the world's coronavirus vaccine doses in 2021 to authorize a patented vaccine without the patent owner's consent."[101]

This move was controversial. On one hand, members of the WTO saw the deal as a step toward building manufacturing facilities in developing countries.[102] On the other hand, other WTO members hoped for a broader deal that covered more than COVID-19 vaccines, including diagnostics and treatments.[103] Furthermore, the original proposals waived rights to not just patents, but also trade

---

[98] *See* John Zarocostas, *Mixed Response to COVID-19 Intellectual Property Waivers*, 399 LANCET 1292, 1292–93 (Apr. 2, 2022).
[99] *COVID vaccine IP waiver agreed*, 40 NATURE BIOTECHNOLOGY 443 (2022) [hereinafter *IP waiver agreed*].
[100] *Id.*
[101] *Id.*
[102] Andrew Green, *WTO Finally Agrees on a TRIPS Deal. But Not Everyone is Happy.*, DEVEX (June 17, 2022), https://www.devex.com/news/wto-finally-agrees-on-a-trips-deal-but-not-everyone-is-happy-103476 [https://perma.cc/2KNK-WXK4].
[103] *Id.*

secrets, copyrights, and designs.[104] The deal offered little that is different from already available WTO exemptions—but it provides a narrower limitation: the deal only applied to low-income and middle-income countries.[105] It also specifically excluded China from exercising provisions of the waiver and prevented the reexporting of vaccines, except for humanitarian purposes.[106] These limitations likely resulted from the influence of the Global North countries, especially the United States, the European Union, the United Kingdom, and Switzerland.[107]

Despite urging from Democratic senators, the Biden administration was originally reluctant to support the TRIPS waiver.[108] In October 2022, Democratic congresspeople urged the United States to publicly support the WTO agreement.[109] They also urged Biden to expand the agreement to include therapeutics and diagnostics.[110] Without the United States' support, low-income countries may be hesitant to act under the WTO agreement.[111] Support from the Biden administration would indicate that the United States will not use diplomatic or trade-related pressure to prevent these countries from utilizing WTO provisions.[112]

Previously, the Biden administration had expressed an open approach to an IP waiver.[113] In May 2021, the United States Trade Representative, Katherine Tai, released

---

[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] Green, *supra* note 102.
[108] *See* Rae Ann Varona, *Senators Want Info As US Ponders Extending COVID IP Waiver*, LAW360 (Oct. 20, 2022, 3:25 PM), https://www.law360.com/articles/1541616/senators-want-info-as-us-ponders-extending-covid-ip-waiver- [https://perma.cc/SBS3-UBYQ].
[109] *Id.*
[110] *Id.*
[111] *See id.*
[112] Varona, *supra* note 108.
[113] *Id.*

a statement announcing the Biden-Harris administration's support for waiving IP enforcement rights for COVID-19 vaccines.[114] Tai expressed open support for an IP waiver and optimism towards the WTO negotiations:

> This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines.[115]

However, controversy amongst lawmakers regarding the future implications of the waiver continues to present challenges to its use.[116] In October 2022, bipartisan congresspeople worried that the scope of the IP Waiver would diminish U.S. authority as an innovation powerhouse.[117] Instead of a waiver, these legislators relied on the cooperative agreements made by American companies, finding that countries who proposed the waiver are not indicating that domestic demand is overwhelming their vaccine supply.[118] Collectively, the senators wrote:

> [t]he United States is a global leader in research and development (R&D) and innovation in part because of our strong protections for IP. Additionally, the United States will continue its leadership with our partners across the globe to ensure developing countries have access to the tools and treatments needed to combat COVID, and we believe this can be accomplished

[114] Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver [https://perma.cc/Z6GL-KAE6].
[115] *Id.*
[116] *See* Varona, *supra* note 108.
[117] *Id.*
[118] *Id.*

> without undermining U.S. leadership in medical innovation[.][119]

U.S. support alleviates some of the concerns from low-income countries about overstepping the IP of big pharmaceutical countries.[120]

The IP of COVID-19 vaccines has been a source of debate since the beginning of the pandemic.[121] In December 2022, shareholders of Pfizer, Inc. asked their board of directors to consider transferring IP related to vaccines to low-income and middle-income countries.[122] In contrast, some members of the House proposed a bill opposing an IP waiver for COVID-19 vaccines in June 2021.[123] This bill has been in committee since June 2022.[124]

In March 2023, the ITC held an all-day hearing featuring testimony from WTO stakeholders on whether the TRIPS waiver should be extended.[125] In June 2023, the House of Representatives held yet another hearing to determine a TRIPS extension and interestingly, to discuss

---

[119] Press Release, Tom Carper, Carper, Toomey Highlight Importance of Protecting Medical Innovation, Request Additional Information About Possible Expansion of WTO Intellectual Property Waiver (Oct. 19, 2022), https://www.carper.senate.gov/newsroom/press-releases/carper-toomey-highlight-importance-of-protecting-medical-product-innovation-request-additional-information-about-possible-expansion-of-wto-intellectual-property-waiver/ [https://perma.cc/BV39-UVTJ].

[120] Varona, *supra* note 108.

[121] *See* Zarocostas, *supra* note 98.

[122] Letter from S. E. C. Rule 14a-8 Review Team to Margaret M. Madden, Pfizer Inc., (Feb. 23, 2022) (Westlaw WL 6126552).

[123] H.R. 484, 117th Cong. (2021).

[124] *Id.*

[125] Eileen McDermott, *Industry, NGOs Spar Over Need to Extend TRIPS COVID-19 Waiver at ITC Hearing*, IPWATCHDOG (March 29, 2023), https://ipwatchdog.com/2023/03/29/industry-ngos-spar-need-extend-covid-ip-waiver-itc-hearing/id=158595/ [https://perma.cc/23CW-7H34].

whether the waiver should have been implemented at all.[126] There, the IP Subcommittee's Chair, Darrel Issa, introduced another bill that would require the president to receive congressional approval before waiving relevant portions of the TRIPS Agreement in a future emergency situation.[127] Another concern raised at the hearing included that the waiver is giving China (which is still considered a developing country) a leg up in COVID-19 innovation.[128]

The core of the IP debate is rooted in the quid pro quo of the patent.[129] In October 2020, Moderna pledged to not enforce its patents against any other vaccine competitors.[130] However, in August 2022, Moderna sued both Pfizer and Biotech for infringing its mRNA vaccine patents.[131] In fact, litigation regarding vaccine patent infringement has skyrocketed.[132] This uptick in lawsuits and the back–and–forth between policymakers and

---

[126] *Id.*
[127] *Id.*
[128] *Id.*
[129] *See* Adam Mossoff, *The COVID-19 IP Waiver: Threats to U.S. Innovation, Economic Growth, and National Security,* 290 HERITAGE FOUNDATION 1, 5 (2021).
[130] Jorge L. Contreras, *No-Take Backs: Moderna's Attempt to Renege on its Vaccine Patent Pledge,* BILL OF HEALTH (Aug. 29, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/ [https://perma.cc/6UYL-CLW4].
[131] *Id.*; Complaint, ModernaTX, Inc. v. Pfizer Inc., No. 22CV11378, 2020 WL 3701751 (D. Mass. filed Aug. 26, 2022).
[132] *See* Adam Zamecnik, *COVID-19 Patent Lawsuits: Will Vaccine Producers Have to Pay the Bill?*, PHARMECEUTICAL TECHNOLOGY (May 13, 2022), https://www.pharmaceutical-technology.com/news/covid-19-patent-lawsuits-will-vaccine-producers-have-to-pay-the-bill/ [https://perma.cc/LWP9-YM8J]; *see also HDT Bio Corp. v. Emcure Pharmas, LTD* No. C22-0334JLR, 2022 WL 2106160, at *1, *2 (W.D. Wash. Jun. 10, 2022) (asserting misappropriation of trade secrets where licensees to arrangement for selling COVID-19 vaccines allegedly sold the vaccines and filed patent applications in India without the licensor's permission).

pharmaceutical companies reflects the importance of clinging onto one's IP. In an effort to avoid stepping on the toes of these pharmaceutical powerhouses, governments have looked to other ways of scaling up vaccine distribution, without going after lucrative IP.[133]

C. Historically, the U.S. government has looked for alternatives to an IP waiver.

Avoiding the issue of IP, the U.S. and other countries have opted for other approaches to vaccine security.[134] In an effort to boost production, the Trump administration enacted Operation Warp Speed, in May 2020.[135] Along with organizations like the Center for Disease and Control (CDC), U.S. Food and Drug Administration (FDA), the National Institute for Health (NIH), the federal government aimed at producing 300 million doses of vaccines.[136] Despite this private-public partnership,[137] the government failed to maintain common government rights to IP.[138] In November 2020, the Department of Health and Human Services (HHS) announced Pfizer's vaccine supply contract under Operation Warp Speed.[139] Under the $1.95 billion

---

[133] *See infra* Section II(C).

[134] *See* Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members, *Operation Warp Speed: Implications for Global Vaccine Security,* 9 LANCET E1017, E1017, E1020 (July 2021).

[135] Podcases, supra note 72.

[136] *Id.*

[137] Department of Health & Human Services, *Explaining Operation Warp Speed* https://www.nihb.org/covid-19/wp-content/uploads/2020/08/Fact-sheet-operation-warp-speed.pdf [https://perma.cc/7R2U-LFZS] (last visited Nov. 2, 2023).

[138] Sydney Lupkin, *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NPR (Nov. 24, 2020, 4:46 PM), https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections [https://perma.cc/F3B4-4BGJ].

[139] *Id.*

contract, the Trump administration purchased 100 million vaccine doses for $19.50 a piece, including an option to buy an additional 500 million doses.[140] It also offered narrow protections for taxpayers by excluding IP rights that are typically found in federal contracts.[141] Importantly, the government failed to provide funding for the research and development used to create the Pfizer/BioNTech vaccine.[142] Other vaccine contracts under the Operation did not require prior FDA approval.[143]

As millions of people died from the virus, these companies took a (surprisingly) humanitarian approach to their IP in early 2020.[144] Despite the immense value of the COVID-19 vaccine, such manufacturers took the initiative to waive their monopoly on their patented tech.[145] In July 2020, AstraZeneca and Johnson & Johnson pledged to Congress that they would not profit financially from their vaccines.[146] Shortly after, Moderna made a similar "patent pledge," stating that "while the COVID pandemic continues, Moderna will not enforce [their] COVID-19 related patents against those making vaccines intended to combat the pandemic."[147] While AstraZeneca was producing the vaccine without generating a profit, even companies like Pfizer and Moderna were selling vaccines below their commercial market value.[148] These manufacturers viewed the first wave of vaccine delivery as

---

[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] Podcases, *supra* note 72.
[145] *See id.*
[146] *Id.*
[147] Andrew Alexander, *Did Moderna Sink Its Own Ship by Making a "Patent Pledge?"*, JDSUPRA (Oct. 14, 2022), https://www.jdsupra.com/legalnews/did-moderna-sink-its-own-ship-by-making-5067968/ [https://perma.cc/A97G-VCR6].
[148] Podcases, *supra* note 72.

an act of public service, implying that such acts were part of the social contract that society has with these biotech companies.[149] However, these so-called patent pledges were short-lived.[150]

The possibility that the COVID-19 virus will become as routine as the common cold drove drug companies to protect their IP in non-emergency times.[151] In August 2022, Moderna caused shockwaves by suddenly breaking its patent pledge and filing a mega-suit against Pfizer and BioNTech.[152] On October 2022, Moderna backtracked this move by updating their patent pledge—boldly stating that they would never enforce their patents against the ninety-two low-income and middle-income countries that are part of the Gavi COVAX Advance Market Commitment (AMC).[153] These conflicting moves illustrate the moral challenges of vaccine IP.[154] Many argue that voluntarily licensing, donations, and patent pledges fail to offer protection to the global population.[155] Barriers like IP should be removed to provide room for a generic competitor.[156]

Once these vaccines proved effective, governments instituted services to administer them both locally and globally.[157] On a state level, local governments turned to

---

[149] *Id.*
[150] Alexander, *supra* note 147.
[151] Podcases, *supra* note 72.
[152] Contreras, *supra* note 130.
[153] Dan Shores, *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?*, IPWATCHDOG, https://ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/ [https://perma.cc/F2W8-KL4R] (last visited Nov. 3, 2023); Alexander, *supra* note 147.
[154] Zarocostas, *supra* note 98, at 1292.
[155] *Id.*
[156] *Id.* at 1293.
[157] *See e.g.,* Comprehensive Plan for Vaccinating Residents of the State Against COVID-19, Md. Code Ann., Health-Gen. § 18-9A-03 (West).

other means to protect vulnerable populations.[158] States subsequently enacted regulations for vaccine administration, including guidelines on reporting vaccination data in nursing facilities,[159] policies on vaccine roll-out,[160] and special considerations for elderly prisoners.[161] While the IP Waiver debate centers on whether pharmaceutical companies should hide away valuable vaccine patents, limited manufacturing capacity continues to strain vaccine accessibility.

III. ANALYSIS

Evidence of a large disparity in vaccine distribution between low-income countries and their wealthier counterparts suggests the need for morally driven government action. Despite the extraordinary push for the IP Waiver, it does not solve the use of obtaining valuable "know-how," the knowledge on how to implement the patent, that is necessary to achieve vaccine efficacy. In fact, many of the challenges low-income countries face are not access to knowledge but limited manufacturing capacity, a lack of skilled workers, and short vaccine lifespans.[162]

Recognizing these challenges, pharmaceutical companies have already volunteered their patents to low-income countries, which are still struggling with vaccine distribution.[163] Furthermore, similar IP remedies have persisted prior to the COVID-19 pandemic including compulsory licensing provisions in the original 1995 TRIPS

---

[158] *See id.*; *see also* Reporting of COVID-19 Vaccination Data in Nursing Facilities, Assisted Living Facilities, and Residential Care Facilities, Or. Admin. R. 411-061-0010 (2022); *see also* Motions for compassionate release for individuals convicted of felony offenses., DC CODE § 24-403.04 (West 2021).
[159] OR. ADMIN. R. 411-061-0010 (2022).
[160] MD. CODE ANN., HEALTH-GEN. § 18-9A-03 (West 2021).
[161] DC CODE § 24-403.04 (West 2021).
[162] *See infra* Section (III)(B)(1).
[163] *See* Shores, *supra* note 153.

agreement.[164] Consequently, government funding for vaccine manufacturing is far more necessary than an IP waiver. Since an IP waiver does not address the challenges that older Americans currently face, the government should not extend or expand the IP Waiver as a solution to the vaccine issue.[165]

A. The push for an IP waiver is rooted primarily in morality.

Labelled as the "vaccine apartheid," the global inequity of vaccine distribution is lethal.[166] If COVID-19 vaccines were shared equitably with lower-income countries in 2021, more than one million lives could have been saved."[167] Additionally, between December 2020 and May

---

[164] *Part II – Standards concerning the availability, scope and use of Intellectual Property Rights*, WORLD TRADE ORG., https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm [https://perma.cc/494M-QKCS] (last visited Nov. 2, 2023) [hereinafter *Part II*].

[165] *See infra* Section (IV).

[166] Press Release, United Nations, UN expert urges States to end 'vaccine apartheid (Jun. 14, 2022) https://www.ohchr.org/en/press-releases/2022/06/un-expert-urges-states-end-vaccine-apartheid#:~:text=%E2%80%9CThe%20current%20status%20quo%20amounts,access%20to%20life%2Dsaving%20treatments [https://perma.cc/X3W7-S5ZJ] [hereinafter UN Press Release].

[167] Heidi Ledford, *COVID vaccine hoarding might have more than a million lives*, NATURE (Nov. 2, 2022), https://www.nature.com/articles/d41586-022-03529-3 [https://perma.cc/5E9P-7VRJ]; *see e.g.*, Melody Schreiber, *US Throws Out Millions of Doses of COVID Vaccine as World Goes Wanting*, GUARDIAN (Oct. 16, 2021), https://www.theguardian.com/world/2021/oct/16/us-throws-out-millions-doses-covid-vaccine-world-shortages [https://perma.cc/688M-EQXX]; Joshua Eaton, *The U.S. Has Wasted Over 82 Million COVID Vaccine Doses*, NBC (Jun. 6, 2022, 3:27 AM), https://www.nbcnews.com/news/us-news/covid-vaccine-doses-wasted-rcna31399 [https://perma.cc/WW9B-99TL].

2022, the U.S. wasted 82.1 million COVID vaccine doses.[168] A study relying on a mathematical model suggests that if wealthier countries had simultaneously maintained mitigation measures, like limiting the number of people who could gather at once and enforcing mask mandates for a longer period, this number of lives saved could have risen to 3.8 million.[169] These studies reflect the death toll if vaccines had been distributed based on need, not on wealth.[170] At the end of 2021, the vaccine rates were 75% in wealthier countries.[171] In poorer countries, the vaccination rate was less than 2%.[172] Furthermore, the United States and other wealthier countries were left with a surplus of vaccines.[173] Issues with the ability to refrigerate these vaccines and their short lifespans plagued the United States.[174] Elsewhere, poorer countries were unable to vaccinate even the most vulnerable populations.[175]

Moreover, the gap in vaccine distribution has proven to be racially discriminatory.[176] Racially marginalized people have been most harmed by inequitable vaccine distribution.[177] One United Nations (UN) expert attributes this injustice to inequalities in wealth, power, and healthcare resources, which stem from racist and colonialist histories.[178] She points to other racially discriminatory outcomes of the pandemic including economic, social, and health harms, as well as movements like the 2020 racial

[168] Eaton, *supra* note 167.
[169] Ledford, *supra* note 167.
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.*; Eaton, *supra* note 167.
[174] Eaton, *supra* note 167.
[175] Ledford, *supra* note 167.
[176] UN Press Release, *supra* note 166.
[177] *Id.*
[178] *Id.*

justice uprising.[179] This includes the stockpiles of vaccines in the Global North, in contrast to the need in the Global South.[180]

As a result, a number of parties have encouraged an IP waiver as a moral solution.[181] These include the Indian and South African governments, organizations like UNICEF,[182] the World Health Organization,[183] and Prep4All;[184] over 150 U.S. leaders,[185] and the United Nations AIDs charity (UNAIDS).[186] However, this move has been met with opposition by incumbent drug manufacturers.[187] Some scholars pose that vaccine manufacturers are not eager to increase supply as quickly as possible.[188] As drug companies sell more doses, they make more money.[189] By partnering with competitors, these companies can manufacture far more doses.[190] However, such partnerships require the manufacturer to share trade secrets, which may include the ingredients and instructions to produce the drug.[191] Although this may involve non-

[179] *Id.*
[180] *Id.*
[181] *See A Patent Waiver on COVID Vaccines is Right and Fair*, 593 NATURE 478, 478 (May 27, 2021) [hereinafter *A Patent Waiver*].
[182] *COVAX: ensuring global equitable access to COVID-19 vaccines*, UNICEF, https://www.unicef.org/supply/covax-ensuring-global-equitable-access-covid-19-vaccines [https://perma.cc/C5LW-MMXN] (last visited Nov. 3, 2023).
[183] *A Patent Waiver*, *supra* note 181.
[184] Morten & Herder, *supra* note 14.
[185] Jeffrey D. Sachs, *Share the Intellectual Property on COVID-19*, PROJECT SYNDICATE (Apr. 29, 2021), https://www.project-syndicate.org/commentary/covid19-intellectual-property-waiver-is-a-moral-imperative-by-jeffrey-d-sachs-2021-04 [https://perma.cc/JT8R-TAYF].
[186] *A Patent Waiver*, *supra* note 181.
[187] Morten & Herder, *supra* note 14.
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.*

disclosure agreements, the concern of leaks remains.[192] Consequently, these so-called incumbent drug manufacturers have little incentive to partner with others.[193] Moderna and BioNTech, whose proprietary mRNA technology led to their version of the COVID-19 vaccine, are using that technology to roll out new treatments related to cancer, influenza, HIV, and other diseases.[194]

Furthermore, rapid spread of the virus keeps demand for the vaccine high, and these companies know it.[195] As scholars note, this ghoulish concept stems from the idea that more profits can be made over a long-term endemic, which is both recurring and perhaps permanent.[196] In fact, companies like Pfizer have been rumored to retract their low-cost pricing in favor of $175 per injection.[197] As long as variants keep emerging, the incumbents have some incentive to keep production slow.[198] Although this prospect seems macabre, this is not the first time that the ethics of drug producers have been called into question.[199]

Contrary to this accusation, these incumbents made bold moves at the beginning of the pandemic.[200] In fact, drug manufacturers like Moderna, Johnson & Johnson, and AstraZeneca recognized the ongoing catastrophe of COVID-19 and attempted to be their own ethics monitors.[201] In October 2020, Moderna pledged to "not enforce [its] COVID-19 related patents against those making vaccines intended to combat the pandemic."[202] The company also

---

[192] *Id.*
[193] Morten & Herder, *supra* note 14.
[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] *Id.*
[198] *Id.*
[199] Morten & Herder, *supra* note 14.
[200] *See* Shores, *supra* note 153.
[201] *See e.g.*, *id.*
[202] *Id.*

promised to "eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post-pandemic period."[203]

Similarly, Pfizer Inc. agreed to a voluntary licensing agreement for a COVID-19 oral antiviral treatment with the Medicines Patent Pool (MPP), a UN public health organization, which can grant sub-licenses to medicine manufacturers globally.[204] Companies who pledged patents include Medtronic and Smiths Group, AbbVie, Labrador Diagnostics, and Innovative Genomics Institute for University of California Berkeley.[205] In April 2020, the Open COVID Pledge was formed.[206] Tech firms and laboratories contributed over 500,000 patents.[207] In March 2022, the MPP signed sub-licenses with over thirty manufacturers in twelve different countries to produce the treatment ritonavir, an oral COVID-19 treatment.[208] Nevertheless, Pfizer's licensing agreement spans only 53% of the global population and excludes some middle-income

---

[203] *Id.*

[204] Press Release, Pfizer, 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 (Nov. 16, 2021, 6:45 AM), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing [https://perma.cc/2GDE-QXXP] [hereinafter Pfizer MPP]; *MSF Responds to Medicines Patent Pool Deal With 35 Manufacturers to Produce COVID-19 Treatment Nirmatrelvir/ Ritonavir*, RELIEFWEB (Mar. 17, 2022), https://reliefweb.int/report/world/msf-responds-medicines-patent-pool-deal-35-manufacturers-produce-covid-19-treatment [https://perma.cc/XQ9N-TSQV].

[205] Contreras, *supra* note 130.

[206] Jorge L. Contreras, *The Open Covid Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 21 UTAH L. REV. 833, 842 (2021).

[207] *Id.*

[208] Pfizer MPP, *supra* note 204.

countries such as Brazil, China, Malaysia, and Thailand.[209] In lieu of an IP waiver, these patent pledges and licensing agreements were meant to override the incumbents' patents, diminish enforcement of patents, and prevent the rejection of patent applications at the Patent Office.[210]

Evidence of backtracking was revealed in subsequent pledging efforts.[211] Moderna's motivations for their pledge included: altruism, corporate social responsibility, to demonstrate that they are using federal government spending, and to avoid controversy with the National Institute of Health (NIH).[212] Another motive includes deterring third-party patentees from enforcing their own patents against Moderna, instead of licensing their technology, for fear of public backlash.[213] In March 2022, Moderna updated its Patent Pledge promising "to never enforce [their] patents for COVID-19 vaccines against companies manufacturing in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries."[214] There, it "expects those using Moderna-patented technologies will respect the Company's intellectual property," which includes Pfizer and BioNTech.[215] However, this lack of clarity in what it means to "respect"

---

[209] *Id.*

[210] Shores, *supra* note 153.

[211] Contreras, *supra* note 130.

[212] *Id.*

[213] Shores, *supra* note 153.

[214] Press Release, Moderna, Moderna's Updated Patent Pledge (Mar. 7, 2022), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/ [https://perma.cc/9NQE-G5DX].

[215] *Id.*; Gene Quinn, *Moderna Sues Pfizer, BioNTech Over COVID-19 mRNA Vaccine Patents*, IPWATCHDOG (Aug. 26, 22), https://ipwatchdog.com/2022/08/26/moderna-sues-pfizer-biontech-mrna-vaccine-patents/id=151121/ [https://perma.cc/A5MK-L74G].

Moderna's patents, and the vagueness of when it will be willing to license its patents, breeds uncertainty.[216]

Next, these drug manufacturers enforced their patents against each other.[217] In August 2022, Moderna filed a patent infringement suit against Pfizer and BioNTech in federal district court, claiming that the Pfizer-BioNTech COVID-19 vaccine Comirnaty® infringes multiple patents regarding Moderna's mRNA technology.[218] Moderna alleged that this mRNA technology was critical to developing Moderna's Spikevax®, its own COVID-19 vaccine.[219] Moderna claimed that it took a decade to develop this mRNA technology, whereas it only took Pfizer-BioNTech a few weeks to develop a vaccine with the aid of Moderna's tech.[220] Moderna emphasized that this technology was created prior to the pandemic and required billions of dollars of investment.[221] The company uses this tech in developing medicines for HIV, influenza, cardiovascular diseases, autoimmune disorders, and some cancers.[222] Moderna is not seeking an injunction to prevent the sale of Comirnaty®, nor is it seeking damages for the sales in countries protected by the COVAX alliance.[223] However, it is seeking damages for sales in other medium- and high-income countries made after March 8, 2022.[224]

Threats of price hikes and lawsuits express doubt as to whether drug manufacturers are maintaining ethical

---

[216] *See* Contreras, *supra* note 130.
[217] *See generally* Lynn Lehnert & Sara Pilson, *The Role of Morality in IP Suits Over COVID-19 Vaccines*, IPWATCHDOG (Aug, 5, 2022), https://www.law360.com/articles/1518423/the-role-of-morality-in-ip-suits-over-covid-19-vaccines [https://perma.cc/JA7N-FNGX].
[218] Quinn, *supra* note 215.
[219] *Id.*
[220] *Id.*
[221] *Id.*
[222] *Id.*
[223] *Id.*
[224] Quinn, *supra* note 215.

practices.[225] In October 2020, Allele Biotechnology and Pharmaceuticals filed cases against Pfizer, BioNTech, and Regeneron.[226] In February 2022, Arbutus Biopharma Corporation and Genevant Sciences GmbH alleged that Moderna infringed its five patents through the use of Moderna's mRNA-1271 COVID-19 mRNA LNP[7] vaccine product.[227] In March 2022, Alnylam Pharmaceuticals filed two separate lawsuits against Moderna and Pfizer.[228] These claims were directed at delivery technology that transports the mRNA vaccine throughout the body.[229] In July 2022, Pfizer-BioNTech filed a complaint for declaratory judgment of noninfringement against CureVac AG.[230] As early as October 2020, Allele Biotechnology and Pharmaceuticals filed cases against Pfizer, BioNTech, and Regeneron, but these cases were later voluntarily dismissed.[231] Although these companies are not seeking injunctions, they are seeking significant monetary damages, which is not surprising considering that Pfizer made $32 billion in COVID-19 vaccine sales for 2022 and Moderna made $19 billion in sales.[232] This complete reversal of an initially moral approach to vaccine accessibility questions whether these drug companies should be relied on for ethical policing.[233]

Rather than focusing on morality, some scholars find the TRIPS waiver to be a logical step during a pandemic.[234] Instead of relying on the patent system as an incentive, some

[225] *See* Lehnert & Pilson, *supra* note 217.
[226] *Id.*
[227] *Id.*
[228] *Id.*
[229] *Id.*
[230] *Id.*
[231] Lehnert & Pilson, *supra* note 217
[232] *Id.*
[233] *See generally id.*
[234] *See* Lindsey, *supra* note 26.

scholars propose direct support as an alternate regime.[235] This approach offers advantages to the federal government as well as the drug companies.[236] The government can urge the drug companies to speed up their vaccine creation while insulating these companies from financial risk.[237] Once a company has developed an effective vaccine, the government can step in to buy bulk quantities of the vaccine. As a result of these benefits, these pharmaceutical companies would no longer need patent support.[238] Since IP is no longer the driving incentive, IP waivers would then become insignificant to these drug companies.[239] Regardless of the drive behind the IP Waiver, it does not resolve the true hurdle in the race to achieving global vaccination: a lack of vaccine manufacturing facilities.

B. Some argue that waiving IP fails to solve challenges to accessibility.

The IP Waiver allows low-income to middle-income countries to develop their own vaccines.[240] However, many of these countries lack the facilities to perform these operations.[241] Some of these countries are only capable of "fill and finish" facilities—where the actual vaccine is merely placed into the syringe unit.[242]

---

[235] *Id.*
[236] *See id.*
[237] *Id.*
[238] *Id.*
[239] *Id.*
[240] *IP waiver agreed*, *supra* note 99.
[241] Derek Lowe, *Waiving IP*, SCIENCE (May 6, 2022), https://www.science.org/content/blog-post/waiving-ip [https://perma.cc/DZM2-VVCP].
[242] *Id.*

One medicinal chemist and IP policy expert, Derek Lowe[243], argues that the factors constraining supply include hardware concerns where limits on cell culture tanks, filtration apparatuses, and mixing equipment have created a bottleneck on vaccine production.[244] Other concerns include limits on cell culture bags and other consumable equipment, as well as key enzymes and lipids.[245] Moderna has also explained that it is in short supply of trained individuals who guide the production of these vaccines.[246]

Additionally, since most countries do not have cell culture or fill–and–finish facilities, building such mechanisms for vaccine production would cost significant time and money.[247] The ninety-two low-income and middle-income countries that are protected by the COVAX alliance are unlikely to produce such facilities on their own.[248] In its updated patent pledge, Moderna has promised to produce a mRNA manufacturing plant in Kenya—offering a drop in a bucket to what is actually needed.[249] In other countries, vaccine doses remain in refrigerators due to issues with healthcare systems.[250] Reportedly, a lack of trained staff, the lack of coordination, and the complexity of handling the vaccines pose barriers to delivering vaccines to older adults.[251]

In contrast, some countries like India and South Africa have benefited from COVID-19 partnerships that

---

[243] Derek Lowe is an organic chemist who received his PhD from Duke University and is a columnist for the Royal Society of Chemistry's "Chemistry World." *See id.*
[244] *Id.*
[245] *Id.*
[246] *Id.*
[247] Lowe, *supra* note 241.
[248] Press Release, Moderna, Moderna's Updated Patent Pledge, *supra* note 214.
[249] *Id.*
[250] Cueni, *supra* note 19.
[251] *Id.*

allow technology transfers.[252] As a result, India is the third-largest manufacturer of COVID-19 vaccines.[253] This suggests that those countries that have the capacity to manufacture vaccines will benefit from an IP waiver.[254] Whether other low-income or middle-income countries have this capacity remains a challenge to improving accessibility for vulnerable populations.[255] Although most European countries have been opposed to sharing IP, European Union members have accelerated this process.[256] Nevertheless, fewer than 15% of people in low-income countries have had at least one dose, while wealthy countries have offered their citizens four doses.[257]

Ultimately, the effects of the limited TRIPS waiver are still up in the air.[258] The International Trade Commission (ITC) plans to investigate the effects by consulting with stakeholders like foreign governments, organizations like the MPP, health advocates, and the manufacturers themselves.[259] The investigation will also consider whether

---

[252] *Id.*
[253] *Id*. (describing how India's production has boosted from the over 380 COVID-19 vaccine partnerships and transfer of vaccine know-how from the large drug manufacturers).
[254] *Id.*
[255] *See id.*
[256] *Time is Running Out For COVID Vaccine Patent Waivers*, 603 NATURE 764, 764 (Mar. 29, 2022) [hereinafter Time is Running Out].
[257] *Id.*
[258] *See* Matthew J. Rizzolo & Brendan McLaughlin*, U.S. International Trade Commission to Investigate COVID-19 Diagnostics and Therapeutics Market and Potential TRIPS Waiver; Public Hearing in March 2023*, ROPES & GRAY (Feb. 6, 2023), https://www.ropesgray.com/en/newsroom/alerts/2023/02/us-international-trade-commission-to-investigate-covid-19-diagnostics-and-therapeutics-market-and [https://perma.cc/GC9E-L2L3].
[259] *Id.*

the existing TRIPS waiver, passed in 1995,[260] contains enough flexibilities to remain efficacious.[261] Although extension of this limited waiver is on the table, broadening the waiver to include more countries or other forms of IP are not.[262] Some proponents are also advocating for an extension to tests and treatments for COVID-19.[263]

1. In the United States, the issue is not supply but demand.

One of the driving forces behind the push for an IP waiver was to lower costs for consumers.[264] As of February 2022, Pfizer has manufactured more than 3 billion mRNA vaccines.[265] In 2021, the booming drug manufacturer earned a net profit of $22 billion.[266] An IP waiver would theoretically allow manufacturers around the world to produce vaccines without the threat of legal retaliation from

---

[260] *Overview: the TRIPS Agreement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm [https://perma.cc/4V47-NPCB] (last visited Nov. 2, 2023).
[261] *See generally* Rizzolo & McLaughlin, *supra* note 258.
[262] *See id.*
[263] Eileen McDermott, *As IP Waiver Deadline Approaches, Advocacy Groups Call on WTO Director-General to Step In*, IPWATCHDOG (Dec. 14, 2022, 12:52 PM), https://ipwatchdog.com/2022/12/14/ip-waiver-extension-deadline-approaches-advocacy-groups-call-wto-director-general-step/id=154193/ [https://perma.cc/YW4W-HXUE]; Bryce Bashuk, *US Won't Back 2022 Patent Waivers for COVID Tests and Treatments*, BLOOMBERG (Dec. 6, 2022, 5:57 AM), https://www.bloomberg.com/news/articles/2022-12-05/us-won-t-back-2022-patent-waivers-for-covid-tests-and-treatments#xj4y7vzkg [https://perma.cc/5UP6-HMKE].
[264] *See* Mikel Berdud et al., *Would Waiving COVID-19 Vaccines Patents Save Lives?*, OHE (May 18, 2021), https://www.ohe.org/insight/would-waiving-covid-19-vaccines-patents-save-lives/ [https://perma.cc/5ZB9-7GZ9].
[265] Time is Running Out, *supra* note 256.
[266] *Id.*

powerful pharmaceutical companies.[267] These manufacturers would also be able to avoid expensive licensing costs.[268] Additionally, local vaccine manufacturers would only face production costs, allowing affordable vaccine prices.[269] Such saving costs are merely speculative.[270] In fact, many are skeptical of these predictions.[271]Although data on the effects of the IP Waiver is limited, many predicted that the effects on pricing would be minimal.[272] Moderna CEO, Stéphane Bancel, recognized that patents were not vital to maintaining Moderna's dominance in the vaccine market.[273] Consequently, the company pledged not to enforce its patent portfolio for its COVID-19 vaccine against manufactures in low- and middle-income countries.[274] However, its lucrative mRNA vaccine still remains a mystery—the vaccine kingpin refused to share its secret know-how with the WHO's South African hub.[275] Pfizer also made charitable moves—licensing Paxlovid™ patents to the MPP and generously pricing its

---

[267] *Id.* ("More companies in more countries must be able to make vaccines without the threat of being sued by high-powered legal teams representing the pharmaceutical firms that dominate vaccine supply.").
[268] *See* E. Richard Gold, *What The COVID-19 Pandemic Revealed About Intellectual Property,* NATURE BIOTECHNOLOGY 40, 1428 (2022) (describing how Pfizer donated its patents to the Medical Patent Pool).
[269] Berdud et al., *supra* note 264.
[270] *See id.* (merely presenting both sides of the IP Waiver debate).
[271] *See e.g.*, Gold, *supra* note 268, at 1429 (describing how Pfizer donated its patents to the Medicines Patent Pool); Berdud et al., *supra* note 264; Jacob S. Sherkow, Lisa Larrimore Ouellette, Nicholson Price & Rachel Sachs, *Are patents the cause of—or solution to—COVID-19 Vaccine Innovation Problems? (No!)*, WRITTEN DESCRIPTION (Mar. 4, 2021), https://writtendescription.blogspot.com/2021/03/are-patents-cause-ofor-solution-tocovid.html [https://perma.cc/W6RD-FK38]; Lowe, *supra* note 241.
[272] *See e.g.*, Gold, *supra* note 268, at 1429; Berdud et al., *supra* note 264; Sherkow, *supra* note 271; Lowe, *supra* note 241.
[273] Gold, *supra* note 268, at 1429.
[274] *Id.*
[275] *Id*.

vaccines and drugs.[276] It has also promised 10 million courses of Paxlovid™ for distribution via UNICEF and the Global Fund for low-income countries.[277] Since pharmaceutical powerhouses like Pfizer and Moderna have already taken steps to combat the struggles of lower income countries, the effect of the IP Waiver is limited.[278]

Others find that the limited IP Waiver is not enough.[279] Even proponents of the IP Waiver find that the limited version passed in June 2022 has denied meaningful access to vaccines, treatments, and tests.[280] Mark Lawson, Co-Chair of the People's Vaccine Alliance and Head of Inequality Policy at Oxfam, described the waiver as a "technocratic fudge aimed at saving reputations, not lives."[281] Since the limited IP Waiver specifically excluded trade secrets, drug manufacturers will not have the valuable know-how to actually construct the vaccine.[282] Even

---

[276] *Id*.

[277] Deborah Gleeson, Dianne Nicol & James Scheibner, *Intellectual property waiver for COVID vaccines should be expanded to include treatments and tests,* THE CONVERSATION (Nov. 21, 2022, 2:03 PM), https://theconversation.com/intellectual-property-waiver-for-covid-vaccines-should-be-expanded-to-include-treatments-and-tests-194918 [https://perma.cc/DQ4V-PBEC].

[278] Gold, *supra* note 268, at 1429. *See generally* Gleeson, *supra* note 277.

[279] *See generally* Press Release, Oxfam, WTO Agrees a Deal On Patents For COVID Vaccines – But Campaigners Say This Is Absolutely Not The Broad Intellectual Property Waiver The World Desperately Needs (Jun. 17, 2022), https://www.oxfam.org/en/press-releases/wto-agrees-deal-patents-covid-vaccines-campaigners-say-absolutely-not-broad [https://perma.cc/Z6WZ-BTCG].

[280] *Id.*

[281] *Id.*

[282] Ian Lopez & Matthew Bultman*, Covid Vaccine Waiver Deal Threatens Investment for Future Crises,* BLOOMBERG LAW (Jun. 21, 2022, 5:15 AM), https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X7KEM7C8000000?bna_news_filter=health-law-and-business#jcite [https://perma.cc/6ZFY-ZFV2].

proponents of the IP Waiver acknowledged that price shifts were unlikely.[283]

Lowe and other opponents of the IP Waiver insist that both the price and availability of the vaccines are bottlenecked by supply chain concerns.[284] Since vaccine manufacturing is dependent on the availability of raw materials, waiving IP can result in higher prices and increased demands.[285] As a result, more established and precise vaccine manufacturers could be hindered by such a move.[286] According to Dr. Ranjeev Venkayya, President of the Global Vaccine Business Unit at Takeda Pharmaceuticals, vaccines are complex biologics and changes in the manufacturing process can affect the efficacy of the vaccine, requiring further testing.[287] Tight control of the raw materials, lab equipment, production process, training of vaccines, and operating procedures must be maintained and supervised by Good Manufacturing Practice (GMP).[288] Additionally, last-mile distribution challenges result in unused vaccines and turned away donations.[289]

---

[283] *See* Gold, *supra* note 268, at 1428.
[284] Lowe, *supra* note 241.
[285] *Id.*
[286] *Id.*
[287] @rvenkayya, X (Feb 1, 2021, 12:00 PM), https://twitter.com/rvenkayya/status/1356286201309900800 [https://perma.cc/5F2S-8A55]. *See* Samantha Putterman, *Can Pfizer and Moderna end the pandemic by sharing their vaccine designs? It's not that simple.*, POLITIFACT (Feb. 15, 2021), https://www.politifact.com/factchecks/2021/feb/09/facebook-posts/can-pfizer-and-moderna-end-pandemic-sharing-their-/ [https://perma.cc/RQ2G-6EZ7]. *See generally* Sherkow, *supra* note 267.
[288] @rvenkayya, *supra* note 287. *See generally Good Manufacturing Practice (GMP) Resources*, INT'L SOC'Y FOR PHARM ENG'G, https://ispe.org/initiatives/regulatory-resources/gmp [https://perma.cc/CJ5W-HJ3R] (last visited Nov. 2, 2023).
[289] *PhRMA Statement on the TRIPS Waiver Agreement*, PHRMA (Jun. 17, 2022), https://phrma.org/en/resource-center/Topics/Trade/PhRMA-

Rather than IP barriers, other holdups in the manufacturing process have constrained vaccine accessibility.[290] These include: (1) shortages of raw material, (2) limited production capabilities, and (3) a complex manufacturing process for mRNA vaccines.[291] The technological process for creating such biosimilars demands high costs for production relative to generic small-molecule drugs.[292] Since both mRNA and vector vaccines have high production costs, some argue that drug manufacturers will need to operate as for-profit companies.[293] Since challenges to vaccines are diverse, it is unlikely that sharing patents will tackle all of these obstacles.[294]

2. The limited IP Waiver has made little impact so far.

Declining to extend the IP Waiver in December 2022, some senators pointed to the lack of results since the waiver was first adopted by the WTO.[295] Since the adoption of the MC12 waiver, the United States Trade Representative's Office has not revealed much data on how the waiver has improved COVID-19 vaccine accessibility across the globe.[296] The senators further argued that the other barriers to effective vaccine distribution, including a shortage of workers and a limited capacity to hold such

---

Statement-on-the-TRIPS-Waiver-Agreement [https://perma.cc/GX5L-WYW5].

[290] *See* Reto M. Hilty, Pedro Henrique D. Batista, Suelen Carls, Diaria Kim, Matthias Lamping & Peter R. Slowinski, *COVID-19 and the Role of Intellectual Property*, MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION 3–4 (2021).

[291] *Id.* at 2.

[292] *Id.* at 4.

[293] *Id.* at 3–4.

[294] *See e.g.*, Gold, *supra* note 268, at 1429.

[295] Varona, *supra* note 108.

[296] *Id.*

vaccines, do more to hinder vaccine distribution than patent protections.[297]

As a result, these senators demanded data.[298] Specifically, in a letter addressed to United States Trade Representative, Katherine Tai, the legislators demanded all findings and analysis undertaken by the office regarding the impact of the TRIPS waiver including a list of countries expressing use of American IP for COVID-related therapeutics and diagnostics, either publicly or privately.[299] The senators also considered whether any of the countries have the capacity for this level of production; any alternatives to the TRIPS extension, such as voluntary licensing at the WTO; and existing agreements made by manufacturers.[300] Other demands included a definition of therapeutics and diagnostics, as well as economic data points regarding the impact on American jobs, and data points on the future of research and development investment for vaccines, therapeutics, and diagnostics which are not made to treat COVID-19.[301] Finally, the senators questioned whether the United States Trade Representative's Office has met its legal requirements to be transparent.[302] Subsequently, in June 2023, United States Ambassador to the WTO Dennis Shea described the TRIPS waiver as a "solution in search of a problem," after finding that "no compelling evidence has been put forward to show that IP protections have hindered global access to these vaccines."[303]

Since the adoption of the WTO IP agreement, the narrow limitations suggest that even low-income and

---

[297] *Id.*
[298] *Id.*
[299] *Id.*
[300] *Id.*
[301] Varona, *supra* note 108.
[302] *Id*.
[303] McDermott, *supra* note 126.

middle-income countries would be hesitant to act under its provisions.[304] Firstly, the provisions were far more limited than these countries had hoped.[305] After the WTO endorsed a diminished version of the original proposals, some feared that the deal would not do much to boost the production of vaccines.[306] The original proposal, made by India and South Africa, was intended to protect therapeutics and diagnostics along with COVID-19 vaccines.[307] However, the original proposal did not extend waiving IP rights to other forms of IP, including trade secrets.[308] The waiver of trade secrets would be an alarming move to the medical technology world, specifically because it would reveal previously secret information to multiple different global manufacturers.[309] Since waiving IP rights is off the table, drug manufacturers can still restrain their critical technologies from the world.[310]

One of the concerns with extending the waiver is the slippery slope of allowing use of patent technology over the objections of others.[311] The IP Waiver presents a strong challenge to the international patent system, specifically because such limitations on patent rights could extend to other global emergencies like climate change and patents on energy alternatives.[312] Since the proposed IP Waiver does not provide the teeth necessary to combat capitalistic motivations and weakens faith in the patent system, this debate must be resolved before another pandemic arrives.

---

[304] Ryan Davis, *WTO Vax Patent Deal Seen As Doing Little To Boost Access*, LAW360 (Jun. 17, 2022, 10:13 PM), https://www.law360.com/articles/1503943/wto-vax-patent-deal-seen-as-doing-little-to-boost-access [https://perma.cc/77ZF-5TAD].
[305] *Id.*
[306] *Id.*
[307] *Id.*
[308] *Id.*
[309] *Id.*
[310] Davis, *supra* note 304.
[311] *Id.*
[312] *Id.*

C. The IP Waiver sets a dangerous precedent for future pandemics.

Patents are monopolies on the right to exclude others from using a particular invention.[313] Medical companies, referring to a patriotic duty, made pledges to not enforce their patents against other manufacturers during the COVID-19 pandemic.[314] One of these efforts, known as the Open COVID Pledge (OCP), includes over 500,000 patents.[315] Despite these pledges, lawsuits between these companies were initiated.[316]

Opponents of patent protection argue that there is a greater incentive for vaccine development than patents: public funding.[317] Key mRNA vaccine technology, as well as the lipid nanoparticle container—which are critical components of both the Pfizer/BioNTech and Moderna vaccines—were publicly funded.[318] Pfizer's COVID-19 treatment, Paxlovid™, was first developed in 2003 when Pfizer created an intravenous protease inhibitor after it acquired Agouron Pharmaceuticals.[319] Although Pfizer abandoned the protease inhibitor shortly after the SARS coronavirus outbreak ended, the company began retesting the molecule and developed it for oral consumption.[320] This new molecule, a mixture of Paxlovid™ and ritonavir, was

[313] Podcases, *supra* note 72.
[314] Contreras, *supra* note 206, at 839.
[315] *Id*. at 833.
[316] Britain Eakin, *Moderna Lobs COVID Vaccine IP Suit At Pfizer, BioNTech*, LAW360 (Aug. 26, 2022, 9:46 AM), https://www.law360.com/articles/1524762/moderna-lobs-covid-vaccine-ip-suit-at-pfizer-biontech [https://perma.cc/KL4T-95JX].
[317] Gold, *supra* note 268, at 1429.
[318] *Id.* at 1428.
[319] *Id.*
[320] *Id.*

developed without reliance on patents, but based on Pfizer's accumulated knowledge.[321]

Grants also highly incentivize vaccine development.[322] Moderna received a grant of $1.7 billion from the United States Government, while BioNTech received a total of £475 million from the German government and European Commission—such grants were later amplified by procurement contracts.[323] The grants boosted their sales and encouraged pharmaceutical innovations.[324] Furthermore, Oxford researchers developed a vaccine almost entirely through government and philanthropic efforts, which was later licensed to AstraZeneca under conditions that the drug company would further license it to others and sell the vaccine at cost.[325] One unpatented vaccine, Corbevax, developed by Texas Children's Hospital and Baylor College of Medicine, cost only $7 million of university funding to develop and has been transferred to companies in lower-income countries.[326] Such findings demonstrate that strict patent monopolies are not the key to boosting vaccine research and development.[327]

Organic chemist Lowe also argues that patents incentivize innovation.[328] Eliminating IP rights for vaccines would disincentivize medical companies from creating vaccines in times of public health emergencies.[329] In future pandemics, this could pose a problem for incentivizing new vaccines.[330] Companies, like Pfizer and Moderna, may see no financial incentive to take on the expensive task of

---

[321] *Id.*
[322] *Id.*
[323] Gold, *supra* note 268.
[324] *Id.*
[325] *Id.*
[326] *Id.*
[327] *Id.*
[328] Lowe, *supra* note 241.
[329] *Id.*
[330] *Id.*

treating a new virus.[331] Thus, the IP Waiver may create the opposite effect from what it intended.[332] Furthermore, such companies see a moral and patriotic incentive to not enforce their patents.[333] Although such an effort may have been undertaken to garner a good reputation in the public's eye, patent pledges suggest that companies understand the immediate need for the medical treatment and that they are willing to voluntarily waive their own IP rights.[334]

Other proponents argue that without patent protection, these vaccines would not exist in the first place.[335] They suggest that IP rights play an enabling role, rather than a limiting one, during the COVID-19 pandemic.[336] First, IP rights encourage drug manufacturers to collaborate with each other.[337] Although fierce competition usually arises in the pharmaceutical sectors, contractual agreements based on IP rights have increased rapidly after COVID-19.[338] Such partnerships for the joint development of COVID-19 vaccines include BioNTech with Pfizer and CureVac with GSK.[339] Partnerships for COVID-19 vaccine production include BioNTech, Pfizer, Sanofi, and Novartis; CureVac and Bayer; and Moderna and Lonza.[340] As an example, in May 2023, the WHO endorsed 7 out of 899 COVID-19 therapeutics candidates, which were brought

[331] *See generally id.*
[332] *Id.*
[333] *Id.*
[334] Contreras, *supra* note 206, at 872.
[335] *See* Hilty, *supra* note 290, at 3 ("A patent waiver, however, would remove an incentive of the developers of the original products to provide such information to manufacturers of biosimilars.").
[336] *Id.* at 1.
[337] *Id.* at 2.
[338] *Id.*
[339] *Id.*
[340] *Id.*

to life by such partnerships.[341] Proponents of maintaining IP rights suggest that waiving IP rights would discourage some corporate cooperation.[342] Instead, voluntary patent licensing encourages drug manufacturers to contractually transfer knowledge on vaccine development.[343]

1. A moral solution to the COVID-19 IP crisis includes licensing and technology transfer agreements.

Patent licensing shares more knowledge than the IP Waiver.[344] While conducting research and development, these drug companies accumulate know-how on vaccine production.[345] When a voluntary patent license is agreed upon, this contractual transfer is accompanied by the know-how necessary to implement such licensed technology.[346] This knowledge is not published, especially not within these patents themselves.[347] Upon expiration of the patent license, the knowledge is transferred through non-disclosure agreements.[348] Such technology transfers contribute to the collective knowledge of vaccine development, more than the IP Waiver allows.[349] Waiving IP would allow simple sharing of the patented technology without forcing companies to provide the same know-how they would otherwise share through patent licensing.[350]

---

[341] *Impact of a waiver of intellectual property rights for COVID-19 therapeutics*, INT'L FED'N OF PHARM. MFRS. AND ASS'NS (Dec. 5, 2023), https://www.ifpma.org/resources/impact-of-a-waiver-of-intellectual-property-rights-for-covid-19-therapeutics/ [https://perma.cc/Q5GA-6VS7].
[342] Hilty, *supra* note 290, at 2.
[343] *Id.*
[344] *Id.* at 2–3.
[345] *Id.* at 2.
[346] *Id.*
[347] *Id.*
[348] Hilty, *supra* note 290, at 2–3.
[349] *Id.* at 3.
[350] *Id.*

Furthermore, expansions in the MPP signal that drug manufacturers' comprehend the moral urgency of a pandemic.[351] In December 2021, MSD's molnupiravir and Pfizer's PF-07321332 (nirmatrelvir) joined the MPP, allowing nearly 100 low- and middle-income countries access to the anti-viral pills.[352] Such a massive license is anticipated to enable mass production and low-cost distribution.[353] Interestingly, MSD and Pfizer refused royalties on vaccines sales during the COVID-19 public health emergency.[354] The World Intellectual Property Organization (WIPO) is a major supporter of the MPP, stating that it promotes "voluntary licensing practices of pharmaceutical companies."[355] Licensing—the most common tool for transferring IP—presents some limitations involving market failures.[356] A standard licensing model accounts for the market failures by offering provisions that concentrate product distribution to places where consumers pay a premium and limit a licensee's ability to manufacture the invention in massive quantities.[357] Technology transfer agreements offer a solution to this problem.[358]

Technology transfer agreements can multiply the number of manufacturing plants and foster a collaborative process that shares IP and research, accumulated by research institutions, universities, and private labs to the public.[359] The World Health Organization (WHO) has created its own

---

[351] Jhon Carmona & Edward Harris, *Improving access to COVID-19 treatments: how IP makes it possible*, WIPO MAGAZINE (Dec. 2021), https://www.wipo.int/wipo_magazine/en/2021/04/article_0003.html [https://perma.cc/5LPF-WDGY].
[352] *Id.*
[353] *Id.*
[354] *Id.*
[355] *Id.*
[356] *Id.*
[357] Carmona & Harris, *supra* note 351.
[358] *Id.*
[359] *Id.*

patent pool for distribution and sales in low- and middle-income countries.[360] The COVID-19 Technology Access Pool (C-TAP) also promotes sharing the IP.[361] In November 2021, the C-TAP completed its technology transfer agreement with the Spanish Research Institute, which involved a non-exclusive voluntary license for a COVID-19 antibody test.[362] Another recent contributor is the United States National Institutes of Health (NIH).[363]

The NIH licensed some of its COVID-19 technologies to the C-TAP through the MPP, showing that the NIH will not take action to exclude those sublicensees from making, using, or selling its technologies.[364] Such technologies, like the stabilized spike protein, include inventions eligible for patent protection, as well as known biological compounds developed by NIH scientists, which are not eligible for patent protection.[365] While most NIH technology will not be subject to royalties, the NIH's crown jewel—the patented stabilized spike technology—will be subject to a royalty rate of 0.0–0.5% in Least Developed

---

[360] *See WHO Director-General's Remarks at Launch of the WIPO Patent Landscape Report on COVID-19 – 10 March 2022*, WORLD HEALTH ORGANIZATION (Mar. 10, 2022), https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-launch-of-the-wipo-patent-landscape-report-on-covid-19-10-march-2022 [https://perma.cc/96FP-9VYP] [hereinafter WHO Director General's Remarks]; *see generally Patent Landscape Report: COVID-19-related vaccines and therapeutics*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (2022) [hereinafter Patent Landscape Report].

[361] WHO Director-General's Remarks, *supra* note 360. *See generally* Patent Landscape Report, *supra* note 360.

[362] WHO Director-General's Remarks, *supra* note 360.

[363] *Id.*

[364] *NIH Contributions to WHO COVID-19 Technology Access Pool and Q&As*, NATIONAL INSTITUTE OF HEALTH (May 12, 2022), https://www.techtransfer.nih.gov/policy/ctap [https://perma.cc/4RS5-ZEA5].

[365] *Id.*

Countries (LDCs).[366] The NIH notes that generic versions of COVID-19 vaccines could be created through public domain technology donations if other manufacturers contribute other tools and know-how on vaccine development.[367] Through these technology transfer efforts, the WHO intends to achieve the joint target of vaccinating 70% of the global population.[368]

2. Trade secrets can shield vaccine manufacturers from limited patent rights—even during a pandemic.[369]

In lieu of patent rights, other forms of IP still protect drug manufacturers' critical technologies.[370] The original proposal for the TRIPS waiver hoped to waive not just patent protections, but also trade secret protections.[371] A trade secret is technological information that is not disclosed to either the government nor the public.[372] After two years of negotiations, the WTO failed to adopt this provision and focused on patent rights instead.[373] Although this was a key

---

[366] *Id.*
[367] *Id.*
[368] WHO Director-General's Remarks, *supra* note 360. *See generally* Patent Landscape Report, *supra* note 360, at 16.
[369] *See Ethics Talk: Equity and Intellectual Property Protection of COVID Vaccines*, AMA J. OF ETHICS (June 3, 2021), https://edhub.ama-assn.org/ama-journal-of-ethics/video-player/18615220 [https://perma.cc/XTC7-V9F9]; Andrew J. Koopman & Jonathan H. Spadt, *The "Moral" Waiver of IP Protection for COVID-19 Vaccines*, THE TEMP. 10-Q, https://www2.law.temple.edu/10q/the-moral-waiver-of-ip-protection-for-covid-19-vaccines/ [https://perma.cc/55KY-KVJQ] (last visited Nov. 3, 2023).
[370] Davis, *supra* note 304.
[371] *Id.*
[372] *See Trade secrets remain the sticking point in global debate over a vaccine IP waiver*, OSBORNE CLARKE (Dec. 3, 2021), https://www.osborneclarke.com/insights/trade-secrets-remain-sticking-point-global-debate-over-vaccine-ip-waiver [https://perma.cc/HD4K-KA6K] [hereinafter *Trade Secrets*].
[373] *Id.*

win for drug makers, it effectively crushed the weight of the waiver.[374]

Since trade secrets are key to vaccine production, their absence hinders third-party vaccine production.[375] The value of trade secrets is in the name — this knowledge must remain confidential.[376] Once the secret is out, then its value is lost.[377] Since many pharmaceutical technologies are protected by trade secrets, drug manufacturers are reluctant to reveal them.[378] Disclosure could jeopardize their future sales, such as other technologies beyond the scope of COVID-19.[379] This valuable know-how is arguably more critical to the vaccine production process than patents themselves.[380]

However, others believe that proponents of trade secret disclosures overestimate their contributions to vaccine production.[381] Transferring trade secret information to scale up production would require significant time and skill.[382] Even if the confidential information could be transferred in a timely fashion, skilled workers will be needed for the vaccine production process.[383] Even without a trade secret waiver, a shortage of these skilled workers persists.[384]

---

[374] *Id.*
[375] Lopez & Bultman, *supra* note 282. *See* Olga Gurgula & John Hull, *Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer*, 16 J. INTELL. PROP. L. & PRAC. 1242, 1252 (2021).
[376] *Trade Secrets*, *supra* note 372.
[377] *Id.*
[378] *Id.*
[379] *See id.*
[380] *See id.*; Lopez & Bultman, *supra* note 282.
[381] *See Trade Secrets, supra* note 372; Lopez & Bultman, *supra* note 282.
[382] *Trade Secrets, supra* note 372.
[383] *Id.*
[384] *Lowe*, *supra* note 241; *see* Megan McArdle, *Waiving intellectual property rights is popular policy. It won't get more vaccines in arms.*, WASH. POST (May 7, 2021, 9:46 AM), https://www.washingtonpost.com

Furthermore, multiple pharmaceutical companies have already donated licenses for both patents and critical know-how to the MPP.[385] Although these pharmaceutical companies have foregone royalties on any future licensing agreements, these licenses will be significantly limited in scope.[386] In contrast, others find another major hurdle of the pandemic rooted in contracts, rather than IP.[387]

3. Bayh-Dole Rights, or march-in rights, are a contractual remedy to the IP Waiver controversy.

Where the government has funded vaccine research and development, it may set price ceilings and authorize private manufacturing.[388] Historically, such contracts have been coupled with the Bayh-Dole Act[389] to offer another solution: march-in rights.[390] March-in rights, also known as "Bayh-Dole" rights, allow the government to take over a drug if the manufacturer refuses to provide reasonable terms.[391] Unlike the Pfizer-BioNTech deal, these rights are reserved for those vaccines that have received federal

/opinions/2021/05/07/intellectual-property-rights-vaccines-policy-politics/ [https://perma.cc/6G7Y-A4W8].

[385] *Trade Secrets, supra* note 372; *see* Lopez & Bultman, *supra* note 282.

[386] *Trade Secrets, supra* note 372.

[387] *See* Alexander Kersten & Gabrielle Athanasia, *March-in Rights and U.S. Global Competitiveness*, CTR FOR STRATEGIC & INT'L STUDS. (Mar. 24, 2022), https://www.csis.org/analysis/march-rights-and-us-global-competitiveness#:~:text=A1%3A%20The%20concept%20of%20march,businesses%20to%20meet%20agency%20missions [https://perma.cc/S732-4FEX]; Adam Mossoff, *Pandemic*, *Patents, and Price Controls*, THE HERITAGE FOUNDATION (May 13, 2021), https://www.heritage.org/economic-and-property-rights/report/pandemics-patents-and-price-controls [https://perma.cc/J65U-DYKJ].

[388] Kersten & Anthanasia, *supra* note 387; Mossoff, *supra* note 387.

[389] Bayh-Dole Act, 35 U.S.C. §§ 200-212 (1980).

[390] March-in rights, 35 U.S.C. § 203 (1980).

[391] Lupkin, *supra* note 138.

funding.[392] However, even those companies that received federal funding to produce a COVID-19 vaccine leveraged diminished rights.[393] Johnson & Johnson's 100 million dose government contract included limited march-in rights, which permit only a small window for the government to step in.[394] Although march-in rights were intended to alleviate the health or safety needs that the manufacturer falls short on, these limited government rights only kick-in while the COVID-19 virus presents a public health emergency or endemic.[395]

Diminished Bayh-Dole rights raise concerns for taxpayers.[396] Originally, the Bayh-Dole Act aimed to provide an alternative solution to private-public partnerships, where the government previously retained the patents to federally funded products.[397] By removing march-in provisions, some argue that the government has handed over thousands of billions of dollars to drug manufacturers in the rush to find an effective vaccine.[398] The HHS rejects this notion, arguing that the government has no rights to the technology created prior to contracting.[399] Still, the Pfizer-BioNTech reveals that the manufacturers

---

[392] *Id.*
[393] Kersten & Anthansia, *supra* note 387.
[394] Sydney Lupkin, *HHS Released More Coronavirus Vaccine Contracts As Election Results Unfolded*, NPR (Nov. 8, 2022, 2:16 PM), https://www.npr.org/sections/health-shots/2020/11/08/932793698/hhs-released-more-coronavirus-vaccine-contracts-as-election-results-unfolded/ [https://perma.cc/9FRE-YKWV].
[395] Kersten & Anthanasia, *supra* note 387.
[396] *See* Lupkin, *supra* note 138.
[397] Erin Herdeman, *Bayh-Dole and COVID-19: Here Comes the March-In Rights*, PATTERSON THUENTE IP (Sep. 15, 2020), [https://web.archive.org/web/20221003084943/https://www.ptslaw.com/blog/2020/09/bayh-dole-and-covid-19-here-come-the-march-in-rights/].
[398] Lupkin, *supra* note 394.
[399] *Id.*

will maintain the rights to any future developments.[400] Further inspection of such contracts reveals other limited rights.[401] Johnson & Johnson's contract encompasses a smaller scope of data rights, which typically involve the disclosure of cell lines, key studies, clinical data, and technical know-how.[402] In contrast, including march-in provisions may cause a spike in vaccine costs,[403] despite the fact that Bayh-Dole rights have never been exercised.[404] This reluctance to invoke the Bayh-Dole Act stems from a fear of stifling innovations.[405]

One scholar suggests that the Bayh-Dole Act does not even allow price control for vaccine patents.[406] While some politicians suggest that the Bayh-Dole Act provides the government with the power to price control vaccines, neither the Bayh-Dole Act nor march-in-rights provide American consumers with these protections.[407] According to Adam Mossoff, an IP policy law professor, the Bayh-Dole Act does not mention the term "market price" as a condition that allows the government to "march in" and license.[408] While Congress has the power to create a price control statute, Congress did not do so in the Bayh-Dole Act.[409] Mossoff contends that this is the logic behind some Congressional bills, which require the United States government to use drug prices set forth by foreign governments as a reference

---

[400] Lupkin, *supra* note 138.
[401] *See* Lupkin, *supra* note 394.
[402] *See id.*
[403] Lupkin, *supra* note 138.
[404] Kersten & Anthanasia, *supra* note 387.
[405] Nancy L. Urizar, *"March-In" Rights in the Era of COVID-19, An Unlikely Scenario for Remdesivir*, GOODWIN PROCTER (Aug. 24, 2020), https://www.goodwinlaw.com/publications/2020/08/marchin-rights-in-the-era-of-covid19--an-unlikely [https://perma.cc/3SCL-HJHB].
[406] Mossoff, *supra* note 387.
[407] *Id.*
[408] *Id.*
[409] *Id.*

point.[410] While price control under the Bayh-Dole Act is highly debated,[411] it clearly allows compulsory licensing.[412]

4. Compulsory licensing is both a sword and a shield against the financial interests of drug manufacturers.

Even without the IP Waiver, the threat of compulsory licensing encourages drug companies to initiate their own philanthropic IP-sharing endeavors.[413] The original TRIPS waiver, passed in 1995, contains flexibilities including compulsory licensing.[414] Compulsory licensing occurs when the government licenses a patent for use by another company, without the consent of the patent owner.[415] Section 31 of the TRIPS agreement allows for other use of the subject matter of a patent without the authorization of the right holder, including both government use and compulsory licensing.[416]

Normally, this use is limited.[417] The licensor usually must meet two criteria: 1) it must have unsuccessfully attempted to license the technology from the original patent owner and 2) it must adequately compensate the original

---

[410] *Id.*
[411] *See e.g.,* The Editorial Board, *How the Government Can Lower Drug Prices*, N.Y. TIMES (June 20, 2021), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html [https://perma.cc/WUN4-P9F2]; Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 277 (2016); Mossoff, *supra* note 387.
[412] The Editorial Board*, supra* note 411; Brennan et al., *supra* note 411, at 301; Mossoff, *supra* note 387.
[413] *See generally Part II, supra* note 164.
[414] *Id.*
[415] *Part II*, *supra* note 164; Olga Gurgula, *Compulsory Licensing vs. The IP Waiver: What is the Best Way to End the COVID-19 Pandemic?*, 104 SOUTH CENTRE: POLICY BRIEF 1, 3 (2021) [hereinafter *Compulsory Licensing*].
[416] *Part II*, *supra* note 164; *Compulsory Licensing*, *supra* note 415, at 3.
[417] *Part II*, supra note 164; *Compulsory Licensing*, *supra* note 415, at 3.

patent owner for its use.[418] These requirements are waived in a "national emergency or other circumstances of extreme use."[419] Some additional requirements still apply, including that the original patent owner cannot be prevented from using their own patent and usually the product must be supplied mainly for the domestic market.[420] This has since been resolved by the Doha Declaration and subsequent revisions that prioritized public health and waived exporting constraints for least-developing and least-developed countries.[421]

The pandemic is a national emergency.[422] The United States government has invoked TRIPS flexibilities before, as seen in the opioid and Anthrax contexts.[423] During a pandemic, governments have a right to compulsory license patents related to COVID-19 tools to facilitate access to affordable vaccines and treatments.[424] In early May 2021, several European companies sought to clarify and simplify the compulsory licensing process.[425] Some scholars have suggested that trade secret compulsory licensing is a necessity during a public health emergency.[426]

---

[418] *Part II*, supra note 164; *Compulsory Licensing*, *supra* note 415, at 4.
[419] *Part II*, supra note164; *Compulsory Licensing*, *supra* note 415, at 4.
[420] *Part II*, *supra* note 164.
[421] *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/2KVZ-JTRP] (last visited Nov. 2, 2023).
[422] Proclamation No. 9994, 85 Fed. Reg. 15337 (Mar. 18, 2020).
[423] *The TRIPS Flexibilities Database*, MED. L. & POL'Y, http://tripsflexibilities.medicineslawandpolicy.org/ [https://perma.cc/AU6T-BVLA] (last visited Nov. 3, 2023) (cataloging several instances where TRIPS flexibilities have been executed including Anthrax and opioid treatments as well as pending COVID-19 treatments).
[424] Gurgula & Hull, *supra* note 375, at 1252.
[425] *A Patent Waiver on COVID Vaccines is Right and Fair*, NATURE (May 25, 2021), https://www.nature.com/articles/d41586-021-01242-1 [https://perma.cc/5EAB-EC6V].
[426] Gurgula & Hull, *supra* note 375, at 1243.

Even so, executing TRIPS flexibilities proposes some challenges.[427] The compulsory licensing process has been described as "burdensome and arduous."[428] Countries must jump through a significant number of hoops to compulsory license a patent, such as: 1) both the exporting and importing countries must execute a license; 2) the importing company must demonstrate an "insufficient manufacturing capacity;" and 3) the countries must meet administrative requirements such as provide notice to the WTO and reporting the quantity of doses needed and the drug's purpose.[429] These requirements alone are costly to the exporting country because the exported product must be distinguishable from its patented counterpart.[430] Likely to appease WTO members who favor strict IP protection measures, this requirement forces the exported version to be distinguished in label as well as color, shape and packaging.[431] Although time is of the essence during a public health emergency, these regulatory hoops slow down vaccine distribution.[432]

Nevertheless, this TRIPS flexibility is enough to keep drug manufacturers on their toes.[433] Many have criticized the IP Waiver for being virtually identical to the Section 31 of the original TRIPS agreement.[434] Neither

---

[427] Lowri Davies, *Compulsory Licensing: An Effective Tool for Securing Access to COVID-19 Vaccines for Developing States*, 43 LEGAL STUDIES 86, 87 (2022).
[428] *Id.* at 92.
[429] *Id.*
[430] *Id.*
[431] *Id.*
[432] *Id.*
[433] Davies, *supra* note 427.
[434] *Proposed TRIPS waiver a Hollow Diplomatic Compromise With Little Practical Impact*, MEDS. L. & POL'Y (Apr. 12, 2022), https://medicineslawandpolicy.org/2022/04/proposed-trips-waiver-a-hollow-diplomatic-compromise-with-little-practical-impact/

option provides a path to accessing the technological know-how lingering behind COVID-19 patents. As discussed above, this information is far harder to determine. Furthermore, these IP sharing measures are worthless unless global manufacturers are capable of keeping up with demand.

IV. RECOMMENDATION

Much of the confusion surrounding this back and forth between drug manufacturers and the government stems from a lack of clarity on what we expect from drug manufacturers.[435] During a pandemic, a drug manufacturer is expected to do what it does best: manufacture drugs.[436] But what about its role in distribution and the commercialization of that new drug?[437] While the goal of

[https://perma.cc/MA69-JUW8]; *MSF Responds to Potential Compromise on the 'TRIPS Waiver'*, MSF (Mar. 16, 2020), https://msfaccess.org/msf-responds-potential-compromise-trips-waiver [https://perma.cc/5G4T-8AYP]. *See* Zarocostas, *supra* note 98; Davies, *supra* note 427, at 87.

[435] *See* Ezekiel J. Emanuel et al., *What are the Obligations of Pharmaceutical Companies in a Global Health Emergency?*, 398 THE LANCET 1015, 1015 (noting that pharmaceutical companies have ethical obligations during emergencies); Priya Joi, *Are Vaccines a Global Public Good?*, GAVI (Sept. 11, 2020), https://www.gavi.org/vaccineswork/are-vaccines-global-public-good [https://perma.cc/7FQY-ES6U] (arguing that COVID-19 vaccines are public good that must be non-rivalrous).

[436] *See* Emanuel et al., *supra* note 435, at 1015.

[437] *See* Thomas J. Bollyky et al., *The Equitable Distribution of COVID-19 Therapeutics and Vaccines*, JAMA NETWORK (May 7, 2020), https://jamanetwork.com/journals/jama/fullarticle/2765944 [https://perma.cc/MS62-35GH] (emphasizing that vaccine distribution must be a collaborative effort). *See e.g,.* Madlen Davies et al., *'Held to Ransom': Pfizer Plays Hardball in COVID-19 Vaccine Negotiations with Latin American Countries*, STAT (Feb. 23, 2021), https://www.statnews.com/2021/02/23/pfizer-plays-hardball-in-

WTO has been to vaccinate 70% of the world's population,[438] it is unclear who is responsible for distributing these essential doses: the government or the drug manufacturers.[439] Rather than only funding the production of the vaccine, the United States government must also fund distribution by promoting drug facilities.[440]

The IP Waiver debate makes it clear that both the public and the government expect Pfizer, Moderna, Johnson & Johnson, and countless other vaccine manufacturers to do more than simply make drugs, including commercializing them as well.[441] Intuitively, these vaccine companies know this and have pooled their vaccine IP together,[442] pledged to create vaccine facilities in low-income countries,[443] and

---

covid19-vaccine-negotiations-in-latin-america/ [https://perma.cc/DD9Q-GL64] (confirming "bullying" rumors against Pfizer during vaccine negotiations with Latin American countries).

[438] WHO Director-General's Remarks, *supra* note 360.

[439] *See* Emanuel et al., *supra* note 435, at 1015 (noting that pharmaceutical companies have ethical obligations during emergencies); Joi, *supra* note 435.

[440] *See* Lindsey, *supra* note 26 (arguing that what is needed is an "Operation Warp Speed for the *world*") (emphasis added).

[441] *See e.g.,* Michael Erman & Blacke Brittan, *Analysis: U.S. Move to Loosen Patents Will Cause More Companies to Bargain – Lawyers*, REUTERS (May 7, 2021, 12:00 AM), https://www.reuters.com/business/healthcare-pharmaceuticals/us-move-loosen-vaccine-patents-will-draw-drug-companies-bargain-lawyers-2021-05-07/ [https://perma.cc/S4ZL-7JQX] (noting that the Biden administration's support for the IP waiver "pushes the drug companies to be more open to partnerships, and other licensing on favorable terms, in a way that perhaps they otherwise wouldn't be.").

[442] *See e.g.*, Gold, *supra* note 268, at 1429 (describing how Pfizer donated its patents to the Medicines Patent Pool); Kate Silver, *Shot of a Lifetime: How Pfizer and BioNTech Developed and Manufactured a COVID-19 Vaccine in Record Time*, PFIZER, https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_pfizer_and_biontech_developed_and_manufactured_a_covid_19_vaccine_in_record_time [https://perma.cc/ALK3-TKQ2] (last visited Nov. 3, 2023).

[443] Press Release, Moderna, Moderna's Updated Patent Pledge, *supra* note 214.

lowered costs for each vaccine dose.[444] In a future pandemic, this expectation must be clear from the start. In India, this approach has proven fruitful and bolstered the country as the third largest vaccine distributer.[445] Until these vaccine manufacturers know the role they play in a pandemic, the goal of vaccinating 70% of the global population will never be achieved.[446]

The COVID-19 IP Waiver is a red herring. Sharing patents does not solve issues of accessibility. Issues with the supply chain will continue to hinder the vaccine accessibility rate. Although the COVID-19 IP Waiver bolsters corporate reputations and makes a showing of morality, its effects are illusory. If the global community wants to take steps to combat the vaccine gap, it should rely on IP-related measures that have teeth: compulsory licensing and march-in rights. Additionally, federal funding of vaccine research and development will enable the government to have a stake in the resulting IP.

Most importantly, governments must subsidize vaccination facilities in low-income and developing countries, prevent the spread of misinformation amongst the elderly, and encourage more clinical trials to study the effects of vaccines on the elderly.[447] Allowing drug

---

[444] *See* Berdud et al., *supra* note 264.

[445] Cueni, *supra* note 19 (describing how India's production has boosted from the over 380 COVID-19 vaccine partnerships and transfer of vaccine know-how from the large drug manufacturers).

[446] *See generally* Lindsey, *supra* note 26 (arguing that what is needed is an "Operation Warp Speed for the *world*") (emphasis added); Emanuel et al., *supra* note 435, at 1015 (noting that pharmaceutical companies have ethical obligations during emergencies).

[447] *Lack of a real waiver on COVID-19 tools is a disappointing failure for people*, MSF, https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people [https://perma.cc/G9RD-YB5J] (last visited Nov. 2, 2023) ("Without agreement on a true global solution to ongoing access challenges, we now urge governments to take immediate

manufacturers to make their own ethical decisions invites abuse of the patent system and exposes vulnerable populations, such as the elderly, to become victims of capitalistic motivations.[448] Thus, march-in rights should become staple contract provisions, even during public health emergencies. Since an IP waiver does not address the challenges that older Americans currently face, the government should not extend or expand the IP Waiver as a solution to vaccine accessibility issues.[449]

V. CONCLUSION

In essence, the choice to waive the intellectual property for COVID-19 is a solution rooted in morality rather than efficiency. While the IP Waiver presents a moral approach to addressing vaccine distribution, this does not mean it is the *only* moral solution to such a virus-related crisis. Since the elderly population has been particularly victimized by vaccine accessibility challenges, the United States government must employ IP policies with teeth, unlike the IP Waiver. Hollow IP policies, like the IP Waiver, fail to provide the valuable know-how that generally accompanies a patent, nor does it address issues with the supply chain.

---

steps at the national level to make sure people have access to needed COVID-19 medical tools. Governments should consider using all available legal and policy options. This includes suspending intellectual property on COVID-19 medical tools, issuing compulsory licenses on key medical technologies to overcome patent barriers, and adopting new laws and policies to ensure the disclosure of essential technical information needed to support generic production and supply.").

[448] *See e.g.,* Gold, *supra* note 268, at 1429 (explaining how Moderna has kept its proprietary mRNA vaccine know-how under lock and key); Morten & Herder, *supra* note 14 (describing how Big Pharma companies rely on the spread of a virus for demand of the vaccine).

[449] *See* Morten & Herder, *supra* note 14.

Consequently, vaccine companies should maintain their own IP and fight their own infringement battles. This will incentivize competition and ensure that, in a future pandemic, these companies will be incentivized to research and develop vaccination solutions. This approach does not allow these vaccine companies to ethically police themselves. Instead, the United States government can rely on tried-and-true alternatives to merely waiving patents. Standard march-in rights in government contracts will allow over the government to take over patent licensing for drug manufacturers in the wake of another public health emergency. Furthermore, compulsory licensing through existing TRIPS flexibilities provides another government mechanism—one that is virtually the same as those provided by the IP Waiver.

Finally, the government must also target the other avenues to remedying vaccine distribution, such as subsidizing vaccine production facilities, incentivizing more drug research through public funding, allowing more contractual rights for the government, and supporting patent pools. By carving out a role for these drug manufactures in the post-production processes—including vaccine distribution, administration, scaling up, and commercialization—the government can set expectations for the next pandemic.