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THE FUTURE OF PANDEMIC VACCINE ACCESS†

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Now over two years since the pandemic began, new COVID-19 cases are plateauing or declining and deaths rates are following. The gradual spread of vaccine access to low- and middle-income countries, coupled with the emergence of the comparatively mild omicron variant of SARS-CoV-2, has raised hopes that the COVID-19 public health emergency may now be moving to a "post-pandemic period." While this comes as welcome news,

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worrying signs indicate that complacency about future pandemics is already spreading. Negotiations for a new pandemic treaty have stalled. Demand for vaccinations is declining. And perhaps most alarmingly, governments in wealthy countries appear ready to move on from the pressing issue of inequitable access and distribution of COVID-19 vaccines, a key failure in the global response. This Article argues that it is more important now than ever to prepare for global vaccine access, with a focus on development and manufacturing capacity in low- and middle-income countries. COVID-19 vaccines, especially the most effective ones, produced in Europe and North America, are shielded by a range of intellectual property protections: patents, trade secrets, and proprietary know-how essential to low-cost manufacturing elsewhere. Surveying the major barriers to vaccine development and manufacturing capacity worldwide, this Article recommends adapting international agreements to facilitate greater capacity for vaccine production worldwide; creating a scientific corps of advisors to assist low- and middle-income countries in becoming producers of next generation vaccines; and exercising both public and private legal mechanisms to achieve global access.

I. INTRODUCTION

"On March 30, 2021, the heads of state of 26 nations, joined by the executive director of the World Health Organization (WHO) and the president of the European Council, called for an international treaty on pandemic prevention and preparedness—the highest level of coordinated political action to avert and respond to future health crises."[1] In a historic move, "194 countries passed a World Health Assembly (WHA) resolution to host a special session devoted solely to an international pandemic agreement."[2] However, with the decline in COVID-19 cases, hospitalizations, and deaths worldwide, global interest has increasingly shifted from pandemic survival to moving on.[3] This emerging complacency is dangerous and

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1. Lawrence Gostin, Sam Halabi & Kevin Klock, *An International Agreement on Pandemic Prevention and Response*, 326(13) JAMA 1257 (2021), https://jamanetwork.com/journals/jama/fullarticle/2784418 [https://perma.cc/JMM8-LR6M], *citing*, *Global Leaders Unite in Urgent Call for International Pandemic Treaty*, WORLD HEALTH ORGANIZATION [WHO] (Mar. 30, 2021), https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty [https://perma.cc/S9WX-DHNJ]

2. Gostin, Halabi & Klock, *supra* note 1, *citing* World Health Assembly [WHA], 74th Session, Special Session of the World Health Assembly to Consider Developing a WHO Convention, Agreement or Other International Instrument on Pandemic Preparedness and Response, WHO Doc. A74/VR/7 (May 31, 2021).

3. *See* Priti Patnaik, *Game on at WHO: International Health Regulations vs. The Pandemic Treaty*, GENEVA HEALTH FILES (Mar. 3, 2022), https://geneva

misguided. Greater attention must be drawn to the significant toll that COVID-19 imposed on the world's poorest populations, and the need to ensure they do not remain vulnerable in the future.

It is worth remembering how the worldwide health threat emerged, and the devastation it wrought. Atypical cases of pneumonia circulated in Wuhan, China since at least November, 2019.[4] In late December of 2019, the first cases of COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), were described in the city of Wuhan in Hubei province, China, as distinguished from the atypical pneumonia used to describe the disease before.[5] City and provincial officials struggled with how to manage the novel pathogen and whether and how to report it to national authorities.[6] National authorities, in turn, did not effectively report the urgency and impact of the virus to the World Health Or-

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healthfiles.substack.com/p/game-on-at-who-international-health?s=r[https://perma.cc/X27J-75JV] (tracking the launch of global negotiations for a new treaty to govern health crises and acknowledging the potential derailment of such negotiations in light of the humanitarian crisis in Ukraine).

4. *Cf.* Scott LaFee, *Novel Coronavirus Circulated Undetected Months before First COVID-19 Cases in Wuhan, China,* U.C. SAN DIEGO HEALTH (Mar. 18, 2021), https://health.ucsd.edu/news/releases/Pages/2021-03-18-novel-coronavirus-circulated-undetected-months-before-first-covid-19-cases-in-wuhan-china.aspx [https://perma.cc/3GM9-T2E6] ("Using molecular dating tools and epidemiological simulations, researchers at University of California San Diego School of Medicine, with colleagues at the University of Arizona and Illumina, Inc., estimate that the SARS-CoV-2 virus was likely circulating undetected for at most two months before the first human cases of COVID-19 were described in Wuhan, China in late-December 2019.").

5. Marco Cascella, et al., *Features, Evaluation, and Treatment of Coronavirus (COVID-19), in* Statpearls (Jan. 5, 2022), https://www.ncbi.nlm.nih.gov/books/NBK554776/ [https://perma.cc/X8XB-SXRL] ("Genomic characterization of the new HCoV, isolated from a cluster-patient with atypical pneumonia after visiting Wuhan, had 89% nucleotide identity with bat SARS-like-CoVZXC21 and 82% with that of human SARS-CoV. Hence, it was termed SARS-CoV-2 by experts of the International Committee on Taxonomy of Viruses.").

6. Sam Halabi and Kumanan Wilson, *The Independence of National Focal Points Under the International Health Regulations (2005)*, 63 HARV. INT'L L.J. 135, 137 (2022) ("When atypical cases of pneumonia arose in Wuhan—the early warning signs of a COVID-19 pandemic—hospitals 'deferred to local health officials who, over a political aversion to sharing bad news, withheld information about cases from the national reporting system—keeping Beijing in the dark and delaying the response.'").

ganization.[7] ProMED, an infectious disease surveillance and reporting service, communicated cases diagnosed in Taiwan in travelers from the mainland.[8] The World Health Organization only received official information about the disease from government of the People's Republic of China after two requests.[9]

On January 11, 2020, PRC researchers made the genetic sequence of the virus available, thus setting off a race to develop diagnostics, therapeutics, and vaccines that might address the unfolding public health threat.[10] On January 20, the World Health Organization declared COVID-19 a public health emergency of international concern—he most significant alert it is legally authorized to issue—and on March 11, 2020, it declared COVID-19 a pandemic, a classification that

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7. *Id.* (indicating that local health officials, who are responsible for China's implementation of the IHRs, withheld information from China's national reporting system).

8. *See* Sheng-Fang Su & Yueh-Ying Han, How Taiwan, a non-WHO member, takes actions in response to COVID-19, 10 J. Glob. Health 1, 2 (2020), http://jogha.org/documents/issue202001/jogh-10-010380.pdf [https://perma.cc/23C7-2YXF] ("On 31 December 2019, epidemic prevention physicians of the Taiwan Centers for Disease Control (CDC) were alerted by seven cases with suspected atypical pneumonia from Wuhan, China of whom all had exposure history to the Huanan Seafood Market of Wuhan. Immediately on that day (31 December, 2019) Taiwan CDC sent an email to WHO International Health Regulations (IHR): 'News resources today indicate that at least seven atypical pneumonia cases were reported in Wuhan, China. Their health authorities replied to the media that the cases were believed not SARS; however, the samples are still under examination, and the cases have been isolated for treatment."); ProMED is a web service used to identify unusual health events related to emerging and re-emerging infectious diseases. *About ProMED*, ProMED, https://promedmail.org/about-promed/ [https://perma.cc/8T2W-RPC9] (last visited Sept. 23, 2022).

9. *WHO Revises Coronavirus Timeline to Clarify Its China Office Raised Alert, not Authorities*, S. China Morning Post (July 4, 2020), https://www.scmp.com/news/china/science/article/3091820/who-revises-coronavirus-timeline-clarify-its-china-office-raised [https://perma.cc/T8UX-D8D8] ("The World Health Organi[z]ation was alerted by its own office in China, and not by Chinese authorities, to the first cases in the early stages of the coronavirus pandemic, according to an updated account from the UN health body. . . . Information was provided by Chinese authorities on January 3, after two requests from the organisation.").

10. Lisa Schnirring, *China Releases Genetic Data on New Coronavirus, Now Deadly*, Ctr. for Infectious Disease Rsch. & Pol'y (Jan. 11, 2020), https://www.cidrap.umn.edu/news-perspective/2020/01/china-releases-genetic-data-new-coronavirus-now-deadly [https://perma.cc/L8E4-NYF2].

remains without clear criteria or effect.[11] By May 17, 2022, COVID-19 had killed approximately 1.01 million people in the United States and 6.33 million worldwide.[12]

Despite the near-miraculous timeframe within which safe and efficacious vaccines were developed and authorized for emergency use, by the end of 2021 more than 95% of the global population lacked access to the first dose of life-saving COVID-19 vaccines, even as governments in wealthy countries recommended and mandated booster vaccines for those already inoculated.[13] The availability of diagnostics, therapeutics, and especially vaccines, has defined the inequality in the

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11. Jon Cohen, *Chinese researchers reveal draft genome of virus implicated in Wuhan pneumonia outbreak*, SCIENCE, January 11 2020, https://www.science.org/content/article/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak [https://perma.cc/3FGZ-S6MK]; Laurel Wamsley, March 11, 2020: The D*ay Everything Changed*, NPR, March 11, 2021, https://www.npr.org/2021/03/11/975663437/march-11-2020-the-day-everything-changed [https://perma.cc/CRM8-3FB5]; Clare Wenham et al., *Problems with Traffic Light Approaches to Public Health Emergencies of International Concern*, 397 THE LANCET 1856 (2021).

12. *Cumulative Confirmed COVID-19 Deaths*, OUR WORLD IN DATA, https://ourworldindata.org/explorers/coronavirus-data-explorer [https://perma.cc/VYZ8-3GA4] (last visited May 17, 2022) (citing Johns Hopkins CSSE COVID-19 Data); Rob Stein, *In Wave After Deadly Wave, COVID Has Claimed 1 Million Lives in the U.S.*, SHOTS: HEALTH NEWS FROM NPR (May 17, 2022), https://www.npr.org/sections/health-shots/2022/05/17/1093651037/us-one-million-deaths. For data current as of November 3, 2022, see *WHO Coronavirus (COVID-19) Dashboard*, WHO, https://covid19.who.int/; *COVID Data Tracker*, CDC, https://covid.cdc.gov/covid-data-tracker/#datatracker-home [https://perma.cc/4HHU-M78G].

13. Helen Branswell, *Why Covid-19 Vaccines are a Freaking Miracle*, STAT NEWS (Feb. 14, 2022), https://www.statnews.com/2022/02/14/why-covid-19-vaccines-are-a-freaking-miracle/ [https://perma.cc/ZGT9-KXU8]; Anna Rouw et al., *Tracking Global COVID-19 Vaccine Equity*, KAISER FAMILY FOUNDATION (July 21. 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/tracking-global-covid-19-vaccine-equity/ [https://perma.cc/5M6F-YSGR]; Pfizer *and Biontech to Submit Emergency Use Authorization Request Today to the U.S. FDA for Covid-19 Vaccine*, PFIZER (Nov. 20, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-emergency-use-authorization [https://perma.cc/R4NP-5KH4]; Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization, Moderna (Nov. 30, 2020), https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Primary-Efficacy-Analysis-in-Phase-3-COVE-Study-for-Its-COVID-19-Vaccine-Candidate-and-Filing-Today-with-U.S.-FDA-for-Emergency-Use-Authorization/default.aspx [https://perma.cc/KQ26-YBUU].

global response to the COVID-19 pandemic.[14] Before the availability of vaccines, wealthy countries developed systems for mass testing, implemented vast contact tracing systems, and invested billions of dollars in accelerating the processes leading to safe and effective vaccines.[15] After those vaccines were available, they immunized their populations at a galloping pace.[16] In the United States, as of November 2022 approximately 87% of adults had received at least one vaccine dose, and approximately 85% were fully immunized.[17] In the European Union, problems with vaccine development and procurement caused some delays, but the rates of people in the 27-member body with at least one dose climbed from less than 4% in mid-February 2021 to over 60% in early August 2021, while rates in the

14. Anna Rouw et al., *Tracking Global COVID-19 Vaccine Equity*, KAISER FAMILY FOUNDATION (July 21. 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/tracking-global-covid-19-vaccine-equity/ [https://perma.cc/55BH-HNR2] ("As of July 7, 2021, of the estimated 3.3 billion COVID-19 vaccine doses administered globally, most had been provided in a small number of countries only. For much of the world, particularly for those living in low- and middle-income countries, COVID-19 vaccines remain out of reach. While international efforts, such as COVAX and additional vaccine donations are seeking to increase global vaccine access, several estimates suggest that many countries may not achieve substantial levels of vaccination until at least 2023.").

15. Simi V. Siddalingaiah, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS, 1-2 (2021); Amy Dighe et. al., *Response to COVID-19 in South Korea and Implications for Lifting Stringent Interventions*, 18 BMC MED 321, 329-30 (2020) (noting that, "[t]he rapid expansion of test capacity, early localised strengthening of social distancing measures in Daegu, voluntary reduction in movement prior to the mandated enhanced national social distancing campaign, and continued case-based contact tracing across the large clusters in Seoul Metropolitan Region have all likely contributed to help contain South Korea's epidemic").

16. John Cohen and Kai Kuperferschmidt, *Fairer Shares: Rich Countries Corned the Marketplace for COVID-19 Vaccines. Here are Four Strategies to Protect the Rest of the World*, SCIENCE (May 26, 2021), https://www.science.org/content/article/rich-countries-cornered-covid-19-vaccine-doses-four-strategies-right-scandalous [https://perma.cc/XY2X-WZRW] (highlighting that "some rich countries are vaccinating children as young as 12 years old, who are at extremely low risk of developing severe COVID-19, while poorer countries don't even have enough shots for health care workers").

17. *COVID-19 Vaccination Coverage and Vaccine Confidence Among Adults*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Nov. 4, 2022), https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html [https://perma.cc/3SSZ-QV3H].

United States rose from 12% to almost 58% in the same time period.[18]

International efforts to coordinate vaccine procurement attempted to address disparities in access, however, challenges remain. The Access to COVID-19 Tools (ACT) Accelerator—arguably the world's most effective effort so far to facilitate access to COVID-19 diagnostics, therapeutics, and vaccines for low and middle-income countries—"brings together governments, scientists, businesses, civil society, [ ] philanthropists," and global health organizations.[19] COVAX, the ACT Accelerator's vaccine pillar, is co-led by global health organizations CEPI, Gavi, and WHO, alongside key delivery partner, UNICEF.[20] In the Americas, the PAHO Revolving Fund is the recognized procurement agent for COVAX.[21] COVAX aimed to supply 2 billion doses in 2021 to the world's poorest countries, but by January 2022, COVAX had distributed only half that many.[22] Many governments, including the United States,

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18. Robert Preidt and Robin Foster, *EU Passes U.S. in COVID Vaccination Rates*, HEALTHDAY (May 24, 2022), https://consumer.healthday.com/b-8-9-eu-passes-u-s-in-covid-19-vaccination-rates-2654597462.html [https://perma.cc/RSL7-UWQF] ("European authorities attribute their success to nationalized health care and a history of public confidence in the safety of shots. The EU's slower approval process set the bloc back at the beginning, but that is now instilling more confidence in the rapidly developed vaccine formulas, Dr. Peter Liese, a European Parliament member from Germany, told the AP. While the United States and Britain issued emergency authorizations of vaccines to get shots into arms quickly, the EU went through the longer process of granting full approvals.").

19. *ACT*-Accelerator update: Publication of investment cases, WHO (June 26, 2020), https://www.who.int/news-room/detail/26-06-2020-act-accelerator-update [https://perma.cc/PPF7-DZ3S]; see, e.g., Jonathan C. Carlson, Strengthening the Property-Rights Regime for Plant Genetic *Resources: the Role of the World Bank*, 6 TRANSNAT'L. L. & CONTEMP. PROBS. 91, 112-13 (1997) (identifying the evolving role of the World Bank from discrete project funding to broader, structural efforts).

20. *ACT-Accelerator update: Publication of investment cases*, *supra* note 19.

21. *PAHO Steps Up COVID-19 Surveillance and Vaccine Procurement to Fight Surging Infections, PAHO Director Reports*, PAN AM. HEALTH ORG. (Mar. 31, 2021), https://www.paho.org/en/news/31-3-2021-paho-steps-covid-19-surveillance-and-vaccine-procurement-fight-surging-infections [https://perma.cc/R6VL-MM2J].

22. *Compare, Call to Action to Equip COVAX to Deliver 2 Billion Doses in 2021*, GAVI (last visited Sept. 25, 2022), https://www.gavi.org/news/media-room/call-action-equip-covax-deliver-2-billion-doses-2021?gclid=CJ0KCQjwvZCZBhCiARIsAPXbajuyq1p9tRvaYQkO78pFVackTqno59_FACdyu9wpUOjiq1

Japan, and the European Union, chose to circumvent COVAX in favor of bilateral deals directly with pharmaceutical companies.[23]

Even as vaccines are needed worldwide, the spread of the omicron variant of SARS-CoV-2, with less severe outcomes than its alpha and delta predecessors, is fueling complacency about the continuing pandemic.[24] Hans Kluge, the World Health Organization's Regional Director for Europe, stated that European nations could soon be entering a "long period of tranquillity" as the pandemic abates.[25] Noting that mortality from COVID-19 seemed to be plateauing, he suggested the continent was approaching a "plausible endgame" and an "enduring peace."[26] Meanwhile in the United States, COVID-19 public health measures are being rolled back, from mask mandates to social distancing.[27]

Yet even in Europe, there is little reason for such celebration:

> Hospitalisations and deaths are still increasing in some areas. With over 5000 deaths each day, COVID-

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UmvsAqyVcaAmdDEALw_wcBl [https://perma.cc/2BFB-X46N] and, COVAX Has so far Shipped over 1 Billion COVID-19 Vaccines to 144 Participants, GAVI (last visited Sept. 25, 2022), https://www.gavi.org/covax-vaccine-roll-out [https://perma.cc/5WLE-K9B8] ("COVAX has so far shipped over 1 billion COVID-19 vaccines to 144 participants.").

23. *Nationalism vs Solidarity – in the Race to Vaccine the World*, Innova Health (Feb. 15, 2021), https://innovahealthtec.medium.com/vaccine-nationalism-and-the-race-to-vaccinate-the-world-d210cdb7af7e [https://perma.cc/TJZ6-CWVS].

24. *See* A. Danielle Luliano et al., *Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS-CoV-2 High Transmission Periods — United States, December 2020–January 2022*, MMWR Morbidity and Mortality Weekly Report, 146–52 (Jan. 28, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e4.htm [https://perma.cc/V4J2-ZAAC] (explaining that the emergence of the less severe Omicron variant has resulted in a rapid increase in COVID-10 cases).

25. Richard Horton, *Complacency Threatens Progress Against COVID-19*, 399 The Lancet 10325 (Feb. 12, 2022), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00266-5/fulltext [https://perma.cc/G46J-G5M4].

26. *Id.*

27. *Covid News: C.D.C. Director Says Agency Is Working on 'Relevant' Health Guidance*, N.Y. Times, Feb. 28, 2022 ("A growing number of U.S. states and cities have lifted restrictions, as have two of the biggest U.S. music festivals.").

> 19 remains the second largest killer after ischaemic heart disease. Health systems will experience particular pressure in the next few weeks, not least because of shortages of health workers. . . . Although the aftermath of the omicron wave will most likely usher in a relatively quiet spring and summer, IHME predicts that "COVID-19 will return". Waning immunity and an approaching winter will create conditions for a further surge of infections later in 2022. There is no immediate endgame in sight. The available data point to a much more uncertain future.[28]

The situation is even more severe in some regions outside of Europe and the United States, like South Asia and Brazil, where cases, hospitalizations, and deaths continue to climb, but where access to vaccines remains suppressed.[29]

One way to address this inequity is for wealthy countries that have stockpiled COVID-19 doses, and maintain contracts to further hoard, to facilitate their donation, sale, and transfer to nations in need. But another, longer-term solution, is for those governments to commit to ensuring that if another pandemic comes, populations in poorer countries will not have to wait until those in richer countries are protected and more before enjoying access to lifesaving medicines.[30] Making this

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28. Horton, *supra* note 25.

29. Lisa Schnirring, *Global COVID-19 Cases Continue to Spike, with Deaths Stable*, CTR. FOR INFECTIOUS DISEASE RSCH & POL'Y (Jan. 12, 2020), https://www.cidrap.umn.edu/news-perspective/2022/01/global-covid-19-cases-continue-spike-deaths-stable [https://perma.cc/4AAK-Z3XU] (finding that cases in WHO's Southeast Asia region including India, were up 418% compared with previous week in January 2022, with similar increases of cases and hospitalizations in Brazil); *Covid map: Coronavirus cases, deaths, vaccinations by country*, BBC NEWS (July 5, 2022), https://www.bbc.com/news/world-51235105 [https://perma.cc/Q2CF-SZDM] (page may be updated in future, providing an in-depth data visualization tool broken down by country) ("Nearly every nation in the world is now administering vaccines and publishing rollout data, while at least 113 countries and territories have moved on to booster jabs.").

30. *Cf.*Sam Halabi and Ana Santos Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, 36 EMORY INT'L. L. R. 101 (2022) ("Vaccine nationalism reemerged again during the COVID-19 pandemic. The policy followed by the United States is instructive. The U.S. relied on a public-private partnership known as "Operation Warp Speed" (OWS) as the primary mode to procure COVID-19 vaccines. The partnership supported work on six vaccine candidates through

solution a reality requires three key global commitments: 1) supporting waivers of intellectual property protections for potentially pandemic diseases under the world's major multilateral intellectual property treaty (the WTO's Agreement on Trade-Related Aspects of Intellectual Property, or "TRIPS"), as well as in bilateral and regional investment and trade treaties; 2) making bilateral and regional investments in the manufacturing capacity of low- and middle-income countries, comparable to similar accomplishments in the context of influenza vaccines; and 3) developing an international corps of scientific advisors and technical support personnel to facilitate the establishment of vaccine research and development centers of excellence on every continent. Beyond these core requirements, wealthy governments could also commit to both know-how and supply chain guarantees vital for manufacturing capacity to develop in regional hubs across the world. These kinds of measures and investments, described in greater detail below, could play a key role in helping to prevent and prepare for future pandemics.

Part II of this Article highlights and analyzes the major barriers to vaccine access experienced over the course of the COVID-19 pandemic, with an emphasis on the barriers erected by the United States, the European Union, and the United Kingdom. Part III turns to solutions, offering specific recommendations to promote a future where access to vaccines during pandemics is not contingent upon the existing, extensive research infrastructure concentrated in Europe, North America, and East Asia, but is instead more equitably and rationally distributed. In doing so, Part III analyzes the public law tools available to governments where technology transfer requires coordination with private sector actors. Part IV provides a brief conclusion.

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the provision of direct funding, as well as the use of APAs to secure millions of doses of vaccine: by March 2021, these contractual agreements accounted for the purchase of over 1 billion doses by the U.S. government, all of which were dedicated to the U.S. market. While making OWS its primary vaccine procurement tool, the U.S. government sought to further diversify its vaccine candidate portfolio during the earlier stages of the pandemic. In March 2020, the German press reported that the White House approached German biotech company CureVac in an attempt to guarantee exclusive access to its vaccine. The German government warded off this effort by a foreign government to lay claims to CureVac's vaccine candidate.").

II. The Hoarding of Vaccine Technology

Drawing on evidence from the vaccines for which information is most available—AstraZeneca's, Johnson & Johnson's (Janssen), Moderna's, and Pfizer-BioNTech's—this section provides a roadmap to the barriers that intellectual property, uneven scientific expertise, and inequitable access to key resources erected to global vaccine availability. The United States, the European Union, and the United Kingdom are the primary governments of analysis, as they presided over most of the upstream development of the aforementioned vaccines, and have historically championed strong intellectual property protections worldwide, especially for pharmaceuticals.[31] But the challenges examined here are not limited to those governments or to intellectual property alone; they also involve the consolidated structure of global vaccine development and production, and thus the reach of antitrust and competition law and regulation.

Generally, vaccines are produced in three main steps: (1) raw material manufacturing; (2) drug-substance manufacturing; and (3) fill and finish.[32] The supply of raw materials needed for COVID-19 vaccines in particular depend on sources across the globe, and came under pressure during the initial phases of the pandemic.[33] Drug substance manufacturing is the most complex step of the process, and for vaccines incorporating novel technologies—for example, mRNA and viral vector vaccines—the capacity to manufacture drug substances is concentrated in a few high-income countries.[34] The

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31. Suma Athreye, Lucia Piscitello, & Kenneth C. Shadlen, *Twenty-five Years Since TRIPS: Patent Policy and International Business*, 3 J. Int'l Bus. Pol'y 315, 320 (2020).

32. *Cf.* Phillip L. Gomez & James M. Robinson, *Vaccine Manufacturing*, *in* Plotkin's Vaccines, 51, 51–54, (Walter Orenstein et al. eds., 7th ed. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7152262/pdf/main.pdf [https://perma.cc/B9VG-G9QC] (detailing a number of steps, some of which are synthesized in the text above).

33. *See* WTO, Developing and Delivering COVID-19 Vaccines Around the World: An Information Note about Issues with Trade Impact, 16 (Dec. 22 2020), https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf [https://perma.cc/N2QQ-8ZVH] (stating vaccine raw materials are difficult to substitute in a timely manner).

34. *See* Gomez & Robinson, *supra* note 32, at 58 (stating most supply of vaccines is concentrated in a few developing countries).

fill and finish stage includes packaging, inspecting, and labeling the drug substance in advance of final distribution.[35]

As a regulatory matter, medicines may be divided into two categories: small-molecule compounds generated through chemical synthesis and biologics, larger molecule therapies and vaccines derived from living organisms.[36] According to the FDA,

> Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.[37]

The former are far easier to copy than the latter which explains, in part, why commercial, competition, and intellec-

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35. *Id.* at 56; Cynthia A. Challener, *Focus on Fill and Finish*, BIOPHARM, October 1, 2022, https://www.biopharminternational.com/view/focus-on-fill-and-finish [https://perma.cc/4FEB-KCGR].

36. Levon Khachigian, *Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent*, 25 DRUG DISC. TODAY 1135 (2020); Aakash Shah, Jonathan Warsh & Aaron Kesselheim, *The Ethics of Intellectual Property Rights in an Era of Globalization,* 41 J. L. MED. ETHICS 841 (2013); Frederick M. Abbott, Access to Medicines and Intellectual Property Rights, Presentation hosted by the Permanent Representatives of India, Brazil, and South Africa, Geneva (Oct. 15, 2010) (transcript available, http://www.law.nyu.edu/sites/default/files/ECM_PRO_074747.pdf [https://perma.cc/773V-5Z3N]); Linda Kesselring, *The Differences Between Small Molecule Drugs and Biological Drugs?*, Emory Technology Transfer Blog, February 16, 2021, https://scholarblogs.emory.edu/techtransfer/2021/02/the-differences-between-small-molecule-drugs-and-biological-drugs/ [https://perma.cc/S7RE-GTEC]. For all else relevant to this sentence, *infra* note 37.

37. *What Are "Biologics" Questions and Answers*, FDA (Feb. 6, 2018) https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers [https://perma.cc/5R7H-C8BA].

tual property protections for vaccines are so controversial.[38] Vaccines are vital for the protection of individual and public health, but they require vast financial resources to develop; intellectual property rights offer incentives to do so, although how well-tailored those incentives are remains the subject of heated debate.[39]

A. *Patents, Market Exclusivity, and Trade Secrets*

While copyright and trademark protections play some role in the intellectual property protection of vaccine technology—for example, copyright can protect some forms of product information and trademark and trade dress can protect the visual appearance of the product—the primary forms of protection are patents, regulatory market exclusivity, and trade secrets, which include the knowledge generated by the people companies hire.[40] At base, patents are government-provided legal monopolies given to the inventors of new, useful, and non-obvious products, including vaccines and incorporated technologies like adjuvants, in exchange for disclosing the technology to the inventive and research communities so that technologies can continuously improve.[41] Regulatory market exclusivity refers to a separate set of government-provided monopolies, intended to incentivize companies to produce the safety and efficacy data necessary to license the vaccines for sale.[42] The most expensive data to produce relates to Phase

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38. Favour Danladi Makurvet, *Biologics vs. small molecules: Drug costs and patient access*, 9 MEDICINE in Drug Discovery 100075 (2021), https://www.sciencedirect.com/science/article/pii/S2590098620300622 [https://perma.cc/4KJ3-SZEC]; Kesselring, *supra* note 36.

39. Sam Meredith, *Covid vaccine front-runners: How much they cost, who's bought them and how they're stored*, CNBC (Nov. 17, 2020), https://www.cnbc.com/2020/11/17/covid-vaccines-how-much-they-cost-whos-bought-them-and-how-theyre-stored.html [https://perma.cc/JE9Z-WM6R].

40. *See, e.g.*, Olga Gurgola, *Strategic Patenting by Pharmaceutical Companies — Should Competition Law Intervene?*, 51 INT'L REV. INDUS. PROP. & COPYRIGHT L. 1062 (Oct. 28, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/pdf/40319_2020_Article_985.pdf [https://perma.cc/5AEH-ZBGY] (arguing that strategic patenting requires a long-overdue intervention by competition authorities).

41. SAM F. HALABI, INTELLECTUAL PROPERTY AND THE NEW INTERNATIONAL ECONOMIC ORDER 22 (2018).

42. *See generally*, Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE

III clinical trials, in which thousands of volunteers are enrolled to receive either an experimental vaccine or a placebo.[43] Phases I and II are smaller, oriented toward identifying correct dosages and any safety problems, but are also costly.[44] Once this data is generated and submitted to regulators, other companies are generally not allowed to use it for their own applications for licensure for several years—typically twelve in the United States and ten to eleven in the European Union.[45] This means that COVID-19 vaccines approved during the pandemic may not be copied for a decade or more.[46]

Trade secrets, meanwhile, are a form of legal protection for something used in a company's business that is not known or accessible by competitors, has commercial value or that provides a competitive advantage in the marketplace, and is protected from disclosure by its owner through reasonable efforts to maintain its secrecy.[47] All three of these kinds of legal protections are included in the TRIPS Agreement analyzed below.

i. *Patents*

The patent is the fundamental form of intellectual property that governments offer to vaccine developers, along with all other inventors who meet criteria for novelty, usefulness, and non-obviousness.[48] TRIPS codified these protections—20-

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J. L. & TECH. 1 (2018) (examining the role of market exclusivity in drug repurposing).

43. *See* Roger Collier, *Rapidly Rising Clinical Trial Costs Worry Researchers*, 180(3) CANADIAN MED. ASS'N J. 277, 278 (2009) (noting the steps which companies take to avoid failures ahead of costly Phase III trials).

44. *Id.*

45. Zachary Brennan, *New Study Questions the Need for 12 Years of Market Exclusivity for Biologics*, REGULATORY FOCUS (June 21, 2019), https://www.raps.org/news-and-articles/news-articles/2019/6/new-study-questions-the-need-for-12-years-of-marke [https://perma.cc/KP6T-BRNX] (highlighting a study questioning the need for twelve years of market exclusivity in the United States); Dana P. Goldman et. al., The *Benefits from Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity over Clinical Trial Data*, 30:1 HEALTH AFFAIRS 84, 84-85 (2011).

46. Brennan, *supra* note 45.

47. *Trade Secrets*, WORLD INTELL. PROP. ORG., https://www.wipo.int/tradesecrets/en/ [https://perma.cc/V898-UGCN] (last visited Sept. 21, 2022).

48. Roseann B. Termini & Amy Miele, *Copyright and Trademark Issues in the Pharmaceutical Industry—Generic Compliance or Brand Drug Imitating—"Copycat or Compliance"*, 84 PA. B.A. Q. 34 (2013).

year exclusivity, criteria for patent grants, and other features—as international floors as part of the establishment of the World Trade Organization in 1994.[49] The patent represents a bargain: the successful applicant is legally entitled to prevent others from using their invention without (often compensated) permission, while society benefits from the full disclosure of the new and useful technology.[50] The promise of such compensation, the argument goes, provides an important incentive for research and innovation of medical products that are costly to develop, frequently fail to meet standards for safety and therapeutic efficacy, and, even when finally allowed onto market, subject the manufacturer to significant liability for injuries or deaths attributable to the medicine or vaccine.[51]

Because patents cover products, processes, and methods, more than one—and for vaccines, many more than one—patent may cover a single vaccine. In the case of mRNA vaccines like Pfizer-BioNTech's and Moderna's for example, patents cover the lipid nanoparticle technology that allows the mRNA to be effectively and safely delivered into human cells, as well as the modified mRNA technology itself which instructs cells to generate proteins that will elicit a protective biological response.[52] In total, dozens of patents protect these vaccine components, each with a 20-year life.[53] The upshot of these protec-

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49. *See* Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 61 (1998) (explaining the technology gap disfavoring the production of biotechnology inventions in developing countries).

50. Mario Gaviria and Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, 546-548 (2021).

51. *See, e.g.*, Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507-508 (2009) (describing the purpose of the patent system to allow pharmaceutical companies to recoup costly investments in research and development and thus encourage them to invest in socially beneficial medicines they would otherwise not invent).

52. *See* Cecilia Martin & Drew Lowery, *mRNA Vaccines: Intellectual Property Landscape,* 19 NATURE REVIEWS DRUG DISCOVERY 578 (2020) (noting the various patent applications by Moderna and Pfizer BioNTech, among other pharmaceutical companies, for not only mRNA vaccinations, but also for delivery efficiency for such vaccines, including lipid nanoparticles).

53. Vivencio O. Ballano, *Analyzing the Morality of Owning and Suspending Patent Rights for COVID-19 Vaccines in the Light of Catholic Social Teaching*, 89 LINACRE Q. 47, 54 (Feb. 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8935135/ [https://perma.cc/F32P-JPBR].

tion is that "[v]accine patent holders have the ability to refuse licensing their technology to others, even against a backdrop of vaccine scarcity."[54] Even for a would-be patent holder, though, patents are not without their drawbacks: though generally regarded as the foundational and most important protection, vaccine patents are of limited duration, may be costly to enforce and, *ex ante*, are expensive to obtain.[55]

ii. *Regulatory Market Exclusivity*

Beyond the role of patents, intellectual property protections also cover the investments companies make in producing the data necessary to obtain regulatory approval for vaccines, including information relevant to the manufacture of their underling compounds.[56] Some of these protections take the form of statutory protections specific to the compound itself. In the United States, for example, regulatory exclusivities may offer 6-month or multi-year protections, depending on how the data is characterized and how it was approved.

Even where a vaccine or its associated technologies are not patentable or patents have expired, U.S. and E.U. law, among others, allow firms to exclude others from using the data that support their new drug applications: five years for new pharmaceutical chemical entities, seven years for drugs designated to treat "orphan" diseases, three years for new indications for pharmaceutical drugs, and twelve years for biologic products, the classification into which vaccines fall.[57]

Exclusivity periods granted by government agencies such as the Food and Drug Administration (FDA) or European Medicines Agency (EMA) allow pharmaceutical manufacturers

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54. Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, BILL OF HEALTH, (May 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/ [https://perma.cc/A8XN-GUXU].

55. Aaron S. Kesselheim et al., *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177(11) JAMA INTERN. MED. 1658 (2017).

56. Arti K. Rai and Grant Rice, *Use Patents Can Be Useful: The Case of Rescued Drugs*, 6 SCI. TRANSLATIONAL MED. 248, 248 (2014); Michael J. Keiser et al., *The Chemical Basis of Pharmacology*, 49 BIOCHEMISTRY 10267 (2010).

57. *See* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 253 (2012) (describing the role of the Hatch-Waxman Act in shaping the timelines for new drug applications).

to market drugs without competition.[58] Meanwhile, knowledge related to manufacturing processes themselves may be protected by trade secrets and other contractual restraints, many of which may be of indefinite duration.[59]

iii. *Trade Secrets*

Trade secrets are protected by law when they represent knowledge used in a company's business that is not known or readily accessible by competitors, has commercial value, or provides a competitive advantage in the marketplace, and the owner of the information protects from disclosure through reasonable efforts to maintain its secrecy.[60] Information comprising trade secrets can involve almost any aspect of business that provides an economic or competitive advantage over a

58. Kesselheim et al., *supra* note 55, at 1658.

59. Tara Nealey, Ronald M. Daignault, & Yu Cai, *Trade Secrets in Life Science and Pharmaceutical Companies*, COLD SPRING HARB. PERSPECT. MED. 1, 3 (2015), http://perspectivesinmedicine.cshlp.org/content/5/4/a020982.short [https://perma.cc/URJ6-DTLG] ("Nonexclusive examples of trade secrets are manufacturing, industrial, or commercial secrets; supplier or client lists; sales and distribution methods; consumer profiles and lists; marketing and advertising strategies; and (perhaps most significantly for pharmaceutical and other biotech companies) manufacturing processes, formulas, and development research, including preclinical data. Moreover, a trade secret may take any of a multitude of forms, including plans, designs, lists, computer software, data, or physical devices. Further, the "know-how" residing with an individual employee or team of employees may be a trade secret. A compilation of otherwise known facts can be a trade secret if the compilation is kept secret and provides a competitive advantage. .").

60. *Id.* ("Generally, then, a trade secret is any confidential business information that provides a business with a competitive advantage. It is information that (1) is not generally known to the public; (2) provides the competitive advantage or economic benefit by virtue of it not being publicly known (i.e., not just from the value of the information itself); and (3) is subject to reasonable efforts to maintain it as a secret. The Restatement further provides six factors to be weighed in determining whether certain information actually qualifies for protection as a trade secret: (1) the extent to which the information is known outside the claimant's business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken by the claimant to guard the secrecy of the information; (4) the value of the information to the business and its competitors; (5) the amount of effort or money that the business spent in developing the information in the first instance; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others, taking into account what the business has publicly disclosed, for example, in a patent application or in marketing materials.").

company's competitors.[61] The law that governs them protects a wide range of valuable information, including information that would not be eligible for protection under patent law or regulatory exclusivities.[62] Trade secrets may include:

> formulae and recipes, proprietary databases, business processes and methods, information about costs, pricing, margins, overhead, manufacturing processes, proprietary computer software programs, customer lists, and strategic plans and marketing programs. Often the owners of these trade secrets may not even know that this type of information is protectable by trade secret laws. Such overlooked trade secrets may include customer lists, supply chain information, or even business development and financial plans.[63]

iv. *The Cumulative Barriers Posed by Intellectual Property*

This thicket of intellectual property protections explains why establishing COVID-19 manufacturing centers in low- and middle-income countries has proven so difficult.[64] For example, Moderna promised in October 2020 that it would not enforce its patents related to its COVID-19 vaccine.[65] On August

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61. Cf. BRIAN T. YEH, CONG. RSCH. SERV. R43714, PROTECTION OF TRADE SECRETS: OVERVIEW OF CURRENT LAW AND Legislation 1 (April 22, 2016), https://sgp.fas.org/crs/secrecy/R43714.pdf [https://perma.cc/GTC7-3H8R] ("A trade secret is confidential, commercially valuable information that provides a company with a competitive advantage, such as customer lists, methods of production, marketing strategies, pricing information, and chemical formulae.").

62. *Id.* at 4-5.

63. Michael J. Kasdan, Kevin M. Smith & Benjamin Daniels, *Trade Secrets: What You Need to Know*, NAT'L L. REV. (12 December 2019), https://www.natlawreview.com/article/trade-secrets-what-you-need-to-know [https://perma.cc/2ZBC-T5KK].

64. *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & BIOSCIS. 590, 593 (2018) (noting that in "discussing the pharmaceutical industry, the broader term 'intellectual property' should be used"); Avani Laad, *Vaccine Nationalism, the TRIPS Waiver Proposal and Public International Law*, OPINIO JURIS, August 23, 2021, https://opiniojuris.org/2021/08/23/vaccine-nationalism-the-trips-waiver-proposal-and-public-international-law/ [https://perma.cc/27KX-C6HU] (noting, *inter alia*, that the "thicket of intellectual property that surrounds a vaccine causes major encumbrances for manufacturers in developing countries").

65. Jorge L. Contreras, *No Take-Backs: Moderna's Attempt to Renege on Its Vaccine Patent Pledge*, HARV. L. PETRIE-FLOM CTR.: BILL OF HEALTH (Aug. 29,

26, 2022, it sued Pfizer and BioNTech for patent infringement.[66] Then, the World Health Organization initiated an effort to establish a "vaccine hub" in South Africa, intended to help supply the vaccine to the African continent where only 23% of people are fully vaccinated against COVID-19 as of November 2022.[67] But despite WHO action and Moderna's apparent good will, Moderna has continued to protect its manufacturing and testing processes via trade secrets and efforts to negotiate their release have failed.[68] WHO's vaccine hub in South Africa, intended to establish mRNA vaccine manufacturing capacity, provides a clear illustration. The partnership has faced substantial obstacles stemming from Moderna's intransigence. Moderna implied support for technology transfer to low- and middle-income countries, but failed to deliver. Though the hub has managed to create its own vaccine, a lack of access to proprietary information, including manufacturing trade secrets, means that scaled up manufacturing will remain a challenge.[69] As noted by Kate Stegman of the MSF Access

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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/NPL6-MR5N], citing Press Release, Moderna, Inc., Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic (Oct. 8, 2020), https://investors.modernatx.com/Statements—Perspectives/Statements—Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx [https://perma.cc/EMU7-9JAT].

66. Moderna v. Pfizer, No. 22-cv-11378, 2022 WL 3701751 (D. Mass. filed Aug. 26, 2022).

67. Wendell Roelf, *WHO-Backed Vaccine Hub for Africa to Copy Moderna COVID-19 Shot*, REUTERS (Sept. 15, 2021), https://www.reuters.com/world/africa/exclusive-who-backed-vaccine-hub-africa-copy-moderna-covid-19-shot-2021-09-14/ [https://perma.cc/J7T2-ZNVB]; COVID-19 Vaccination, Africa CDC, (Nov. 2, 2022), https://africacdc.org/covid-19-vaccination/ [https://perma.cc/V4L3-9JC3].

68. *See* David Meyer, *Moderna Wouldn't Share its Vaccine Technology, so South Africa and the WHO Made a Covid Jab Based on it Anyway*, FORTUNE (Feb. 24, 2022), https://fortune.com/2022/02/04/south-africa-afrigen-moderna-covid-vaccine-mrna-who-hotez-corbevax/ [https://perma.cc/Y7HE-A55P] (stating that Moderna has refused to share its vaccine knowledge with the WHO).

69. *See* Chidi Victor Nweneka & Tolu Disu, *The Future of Vaccine Manufacturing in Africa, in* FORESIGHT AFRICA TOP PRIORITIES FOR THE CONTINENT IN 2022 39, 39–41 (Aloysius Uche Ordu ed., 2022), https://www.brookings.edu/wp-content/uploads/2022/01/foresightafrica2022_fullreport.pdf [https://perma.cc/R4FK-NL59] (discussing the WHO hub in Africa and the strug-

Campaign "While the hub is undoubtedly an important initiative today and for future pandemic preparedness, the fastest way to start vaccine production in African countries and other regions with limited vaccine production is still through full and transparent transfer of vaccine know-how of already-approved mRNA technologies to able companies, with existing capacity that can be retrofitted to produce mRNA vaccines."[70]

Despite these obstacles raised by protections, proponents of protections continue to insist that they provide key incentives for development, and that without those incentives, the global community would not have had any COVID vaccines at all. These incentives, the companies and many scholars argue, encourage pharmaceutical companies to continually innovate to develop medicines and vaccines to fight common and rare diseases, identify promising new medicines researched in the academy and small biotechnology companies, and facilitate the later entry of less expensive generics that use the information disclosed by the patent and the regulatory process.[71] However, many critics argue that the incentives do precisely the opposite: they encourage investment in incremental changes that just barely qualify for costly patent protection, keep drug prices high and out of the reach of many who need them most, and impose significant barriers to entry for other manufacturers.[72]

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gles in African vaccine manufacturing in light of low interest from global vaccine stakeholders).

70. *MSF Responds to WHO Announcement That 6 Countries Will Receive Tech From mRNA COVID-19 Hub*, MÉDECINS SANS FRONTIÈRES (Feb. 18, 2022), https://msfaccess.org/msf-responds-who-announcement-6-countries-will-receive-tech-mrna-covid-19-hub [https://perma.cc/6C3B-EQ6M].

71. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 505 (2009) (noting that pharmaceutical companies are encouraged to invest in expensive R&D for new medicines, which ultimately benefit society by the protection and opportunity for profit offered by patents); *see also*, U.S. Food and Drug Admin., Office of Generic Drugs, "Hatch-Waxman" Opinion Letter on Buprenorphine and Naloxone Sublingual Film (July 19, 2018) (highlighting Congress's "efforts to balance the need to 'make available more low cost generic drugs by establishing a generic drug approval procedure' with new incentives for drug development in the form of exclusivity and patent term extension").

72. *See, e.g.*, Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE J. L. & TECH. 1, 73 (2018) ("new-use incentives . . . may in fact erect additional barriers to patient access to medicines while complicating academic research

Critics further argue that those protections in turn precede other critical investments like equipment and people. Pfizer-BioNTech, for example, estimates that it cost $1 billion to develop Comirnaty, the trade name of its COVID-19 vaccine. Developing a vaccine requires dozens of scientists, industrial engineers, and other skilled and semi-skilled workers to ensure on an ongoing basis that vaccine inputs are of sufficient quality and purity, are processed correctly, and are properly bottled, packaged, and labelled. Each of these steps requires intensive capital and human resources.

After securing access to intellectual property, trade secrets, and other information, vaccine capacity expansion will require:

> (1) advanced research infrastructure;
>
> (2) significant pools of capital resources from both private and public sector sources—needed to invest in often risky and failed clinical trials for medicines and vaccines; and
>
> (3) highly trained personnel to guide the scientific process from hypothesis to finished products, which includes navigating strict regulatory requirements and composing information on safe and effective use to accompany these products.

For years, debates have stirred around the proper balance between IP protections and the need for widespread access to vaccines. Then, with the onset of COVID-19, the debate took on a new urgency.

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efforts"); *See also*, KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV. R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 16–17 (Feb. 11, 2020), https://fas.org/sgp/crs/misc/R46221.pdf [https://perma.cc/9N9S-V33G] (discussing the practice of "evergreening" wherein drug manufacturers maintain their patents by adding incremental changes); Sy Mukherjee, Protect at All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-High, Fortune (July 18, 2019), https://fortune.com/longform/abbvie-humira-drug-costs-innovation [https://perma.cc/73GD-RNLN] (detailing "[h]ow a blockbuster medication became a case study in what's killing drug innovation).

B. *How Intellectual Property has Limited Access to COVID-19 Vaccines in Low- and Middle-Income Countries*

Companies carefully plan intellectual property protections for their products in an effort to preserve and maximize resulting revenues. Typically, major global vaccine developers are legally accountable to investors, who expect the companies to maximize returns, even under the circumstances of an international public health emergency.[73] Developers and manufacturers would therefore be unlikely to share these life-saving technologies, even if low- and middle-income countries around the world had the capacity necessary to fully implement them through their own manufacturing processes. Of course, many countries lack capacity in the first place.

Vaccine research, development, and manufacturing capacity is overwhelmingly concentrated in just a handful of wealthy countries.[74] When COVID-19 hit, the governments in those countries acted quickly to ensure that even if vaccine companies were inclined to share technology or finished doses more evenly with the global community, they would be prevented from doing so. Take the United States, for example. Its flagship vaccine effort was Operation Warp Speed (OWS), an 18 billion dollar interagency effort to coordinate government activities and funding for the development and manufacturing of COVID-19 vaccines (and the right to lay exclusive claim to them).[75] But the U.S. government also sought to diversify its vaccine candidate portfolio during earlier stages of the pan-

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73. Sophie Harman, et. al, *Global vaccine equity demands reparative justice — not charity*, BMJ GLOBAL HEALTH, June 4, 2021, https://gh.bmj.com/content/bmjgh/6/6/e006504.full.pdf [https://perma.cc/6V5H-5ASH] ("Given that they are accountable to shareholders and boards—not patients—financial incentives will drive transfer decisions, not public health demand.").

74. Jon Smith et al., Vaccine production, distribution, access, and uptake, Lancet 428, 428, 434 (2011) https://doi.org/10.1016/S0140-6736(11)60478-9 [https://perma.cc/79BQ-9DUE].

75. *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,'* U.S. DEP'T OF HEALTH & HUM. SERVS. (May 15, 2020), https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%C2%A0About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html [https://perma.cc/XR6H-LSSJ] (explaining that OWS is "the administration's national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics").

demic.[76] In March 2020, the German press reported that the White House had approached German biotech company CureVac in an attempt to guarantee exclusive access to its vaccine.[77] The German government warded off this effort to lay claim to CureVac's vaccine candidate,[78] noting that "Germany is not for sale" and that "if a vaccine is developed in Germany, then it is for Germany and the world".[79] A few months later, the German government invested €300 million (roughly $337 million) to guarantee a 23% stake in CureVac, ensuring that domestic supply would be substantial.[80] German Chancellor Angela Merkel declared, "[w]e also have an obligation towards our own citizens. . . There has to be a balance. . . not a single German vaccination appointment will be endangered."[81]

In a similar story, the French government also intervened to halt negotiations between the French pharmaceutical com-

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76. *Id.* ("The 14 vaccine candidates are being winnowed down to about eight candidates, which will go through further testing in early stage small clinical trials.").

77. Andy Gregory, *'This Should Be Worldwide, Not Regional': German Drug Firm Chief Rebukes Trump 'Attempt to Monopolise Vaccine,'* THE INDEPENDENT (Mar. 16, 2020), www.independent.co.uk/news/world/europe/coronavirus-vaccine-trump-germany-us-dietmar-hopp-carevac-a9404646.html [https://perma.cc/7VG8-D6VN].

78. Hans Von Der Burchard & Jakob Hanke Vela, *EU Weighs into German-American Spat over Vaccine Company*, POLITICO (Mar. 16, 2020), www.politico.eu/article/eu-weighs-into-german-american-spat-over-vaccine-company [https://perma.cc/J39F-333C] ("After days of being identified as the bad guys in the EU coronavirus saga — for banning the export of medical equipment within Europe — German politicians are now queuing up for an opportunity to portray themselves as defenders of the public in Europe and beyond. Economy Minister Peter Altmaier said 'Germany is not for sale,' while Health Minister Jens Spahn on Sunday insisted to public broadcaster ZDF that CureVac would develop any potential coronavirus vaccine 'for the whole world' and 'not for individual countries.' Foreign Minister Heiko Maas told the Funke media group on Monday that "we cannot allow others to seek exclusive results.").

79. Gregory, *supra* note 77.

80. Barbara Kollmeyer, *Germany Investing in Coronavirus Vaccine Maker that it Accused the Trump Administration of Trying to Poach*, MARKETWATCH (June 15, 2020), www.marketwatch.com/story/germany-investing-in-coronavirus-vaccine-maker-that-it-accused-the-trump-administration-of-trying-to-poach-2020-06-15 [https://perma.cc/2P3V-SKAN].

81. *Germany gives extra $1.8bln for vaccine rollout in poor countries*, ALARABIYA NEWS (Feb. 19, 2021), https://english.alarabiya.net/coronavirus/2021/02/19/Coronavirus-Germany-gives-extra-1-8-bln-for-vaccine-rollout-in-poor-countries [https://perma.cc/85U4-BY36].

pany Sanofi and foreign governments, after the CEO of Sanofi publicly announced that the U.S. had "the right to the largest pre-order."[82] A day after the announcement, on the heels of mounting criticism, both the French government and Sanofi announced that the deal would not move forward.[83] Meanwhile, India's Serum Institute (SII)—the world's largest vaccine manufacturer—initially announced that it was committed to "equitable" distribution of COVID-19 vaccines globally, but soon thereafter narrowed that commitment by reserving the majority of initial doses of COVID-19 vaccines for its domestic population.[84]

These were not isolated incidents. Over the course of 2020 and 2021, governments exercised extreme forms of 'vaccine nationalism,' refusing to share COVID-19 vaccines or related knowledge with any populations but their own. According to Ana Santos Rutschman:

> As some governments began narrowing down the roster of projects receiving priority status in late spring, the first hints of "vaccine nationalism" appeared.[85] The expression is linked to agreements that reserve the bulk of emerging vaccines for a limited number of countries, traditionally in the developed world.

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82. *French pharma giant Sanofi to give US preference on future Covid-19 vaccine*, FRANCE24 (May 13, 2020), https://www.france24.com/en/20200513-french-pharma-giant-sanofi-to-give-us-preference-on-future-covid-19-vaccine [https://perma.cc/C4LJ-527F]; US likely to get first access to Sanofi's Covid-19 vaccine candidate, May 14, 2020, https://www.pharmaceutical-technology.com/news/sanofi-vaccine-us-access/ [https://perma.cc/9WKC-XYG2].

83. *Covid-19: Sanofi backpedals on US vaccine priority after French outrage*, FRANCE24 (May 14, 2020), www.france24.com/en/20200514-france-says-unacceptable-for-sanofi-to-give-coronavirus-vaccine-to-us-first [https://perma.cc/EP9K-E7LL].

84. *See* Zeba Siddiqui, *India's Serum Institute to Make Millions of Potential Coronavirus Vaccine Doses*, REUTERS (Apr. 28, 2020), www.reuters.com/article/us-health-coronavirus-india-vaccine/indias-serum-institute-to-make-millions-of-potential-coronavirus-vaccine-doses-idUSKCN22A2YY [https://perma.cc/RC64-XDQR] (quoting Serum Institute owner, Cyrus Poonawalla, as follows: "A majority of the vaccine, at least initially, would have to go to our countrymen before it goes abroad").

85. Paul Karp, *Former WHO board member warns world against coronavirus 'vaccine nationalism'*, THE GUARDIAN (May 18, 2020), https://www.theguardian.com/world/2020/may/18/former-who-board-member-warns-world-against-coronavirus-vaccine-nationalism [https://perma.cc/8793-BTG9] (quoting former WHO board member Jane Halton).

> While these strategies are not new, they have become a recent hallmark of negotiations during large-scale outbreaks of vaccine-preventable diseases. If left unaddressed, vaccine nationalism can have serious consequences for equitable access to the first COVID-19 vaccines to come to market.[86]

But while the trend toward nationalistic vaccine hoarding was strong, it was not universal: over the course of the pandemic, two important and related exceptions to this general rule of non-sharing arose. The first was AstraZeneca's licensure of its technology to SII (although the Government of India later intervened in SII's commitments).[87] The second was the establishment of the COVAX Facility, an international partnership that facilitated access to finished vaccine doses for low- and middle-income countries.

Early on, AstraZeneca, which built upon decades of research at the University of Oxford's Jenner Institute, made a commitment to sell its vaccine doses on a non-profit basis, largely at the urging of Oxford,[88] and licensed its manufacturing know-how to SII with an aim of supplying one billion doses globally.[89] Over the same period, a broader interna-

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86. Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEORGETOWN J. INT'L Aff.'s (Jul. 3, 2020), https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/ [https://perma.cc/5H4M-QBD9].

87. *See* Ankur Banerjee and Uday Kumar, *AstraZeneca's India Vaccine Partner Seeking EU Travel Resolution*, REUTERS (Jun. 28, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/astrazenecas-india-vaccine-partner-seeking-eu-travel-resolution-2021-06-28 [https://perma.cc/J9H5-WCV7] ("Last year, AstraZeneca partnered with SII to supply the vaccine to the Indian Government, as well as to a large number of low and middle-income countries. Covishield accounts for about 88% of the 322 million doses so far administered in India, the country's CoWIN vaccination registration platform shows.").

88. Samuel Cross, et al., *Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine?*, BMJ GLOBAL HEALTH, 6, 1, 2 (explaining that the vaccine technology which supported the Oxford-AstraZeneca COVID-19 vaccine, ChAdOx, relied on two decades of research and development by the Oxford Vaccine Group, and that while the UK government helped fund commercialization of the Oxford-AstraZeneca vaccine, it is unknown who funded the early development of ChAdOx technology).

89. Divya Rajagopal, *AstraZeneca & Serum Institute of India Sign Licensing Deal for 1 Billion Doses of Oxford Vaccine*, ECON. TIMES (Jun. 4, 2020), https://m.economictimes.com/industry/healthcare/biotech/pharmaceuticals/as-

tional collaboration known as the ACT (Access to COVID-19 Tools) Accelerator,[90] began vaccine-specific work on the COVAX Facility.[91] The ACT Accelerator, launched in April 2020, includes four pillars, each with support from key global health organizations: on diagnostics, therapeutics, health systems, and vaccines.[92]

COVAX initially envisioned supplying two billion doses of COVID-19 vaccines, largely through its relationship with SII.[93] The AstraZeneca vaccine was to be supplied by SII at an affordable price so that COVAX could provide shipments to countries that had made adequate financial and other commitments and shown that they could effectively deploy the vaccine.[94]

But as the delta variant of COVID-19 devastated India over the early months of 2021, the government imposed export controls and the supply of vaccines to COVAX was tempo-

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trazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/articleshow/76202016.cms.

90. Seth Berkley, *COVAX* Explained, Gavi (Sept. 3, 2020), www.gavi.org/vaccineswork/covax-explained [https://perma.cc/482G-QJJL].

91. J. Stephen Morrison, Senior Vice President and Director, Center for Strategic and International Studies, opening remarks, The Scramble for Vaccines and the COVAX Facility, 11 August 2020, (CSIS online event) (transcript available at https://csis-website-prod.s3.amazonaws.com/s3fs-public/publication/200811_Scramble_Vaccines.pdf [https://perma.cc/C7PC-EDTR]; Donor profiles, GAVI (Sept. 1, 2022), www.gavi.org/investing-gavi/funding/donor-profiles [https://perma.cc/P4WT-M9V2].

92. *ACT-Accelerator update: Publication of investment cases*, *supra* note 19; *see, e.g.*, Carlson, *supra* note 19, at 4 (noting associated work of the World Bank).

93. Adam Taylor, *Covax promised 2 billion vaccine doses to help the world's neediest in 2021. It won't deliver even half that*, WASH. POST, (Dec. 10, 2021), https://www.washingtonpost.com/world/2021/12/10/covax-doses-delivered/ [https://perma.cc/KVX4-WGHK].

94. Krishna Das, *India's SII promises 40 mln more AstraZeneca doses to COVAX this year*, REUTERS (Dec. 1, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/indias-sii-promises-40-mln-more-astrazeneca-doses-covax-this-year-2021-12-01/ [https://perma.cc/N7SL-LGQ9] ("SII last week sent some 1.4 million doses in total to Nepal and Tajikistan through COVAX. Before the Indian government stopped all vaccine exports in April to inoculate its own population, SII had shipped only around 30 million doses to COVAX. The company has a deal to supply up to 550 million doses of the shot to COVAX, which mainly provides the vaccines to low-income countries.").

rarily curtailed.[95] Meanwhile, Pfizer-BioNTech never committed more than a limited number of doses to COVAX, while manufacturing problems for Johnson & Johnson's vaccine meant that COVAX delivered only around half what it had aimed for by the end of 2021.[96]

This combination of intellectual property protections, rich nation hoarding, and manufacturing limitations left much of the world without access to a single vaccine dose well after the technology was developed.[97] The COVAX Facility, reliant by design on international solidarity and aimed at ensuring widespread distribution of doses manufactured in a handful of countries, was never focused on sharing technology or expanding local manufacturing capability, at least not directly.[98] But this reliance on concentrated controllers of vaccine technologies and production was ultimately fatal to COVAX's success.

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95. Jeffrey Gettleman et al., *India Cuts Back on Vaccine Exports as Infections Surge at Homes*, N.Y. Times (Apr. 22, 2021), https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html [https://perma.cc/S8VA-9EF8] ("The government of India is now holding back nearly all of the 2.4 million doses that the Serum Institute of India, the private company that is one of the world's largest producers of the AstraZeneca vaccine, makes each day. India is desperate for all the doses it can get. Infections are soaring, topping 50,000 per day, more than double the number less than two weeks ago. And the Indian vaccine drive has been sluggish, with less than 4 percent of India's nearly 1.4 billion people getting a jab, far behind the rates of the United States, Britain and most European countries.").

96. Sharon LaFraniere, Noah Weiland and Sheryl Gay Stolberg, *The F.D.A. tells Johnson & Johnson that about 60 million doses made at a troubled plant cannot be used*, N.Y. Times (June 11, 2021), https://www.nytimes.com/2021/06/11/us/politics/johnson-covid-vaccine-emergent.html [https://perma.cc/DY7M-BM7U] ("Federal regulators have told Johnson & Johnson that about 60 million doses of its coronavirus vaccine produced at a troubled Baltimore factory cannot be used because of possible contamination, according to people familiar with the situation. The Food and Drug Administration plans to allow about 10 million doses to be distributed in the United States or sent to other countries, but with a warning that regulators cannot guarantee that Emergent BioSolutions, the company that operates the plant, followed good manufacturing practices.").

97. Lisa Forman et al., *Decolonising Human Rights: How Intellectual Property Laws Result in Unequal Access to the COVID-19 Vaccine*, 6 BMJ Global Health 1, 4 (2021) (noting that "cumbersome rules, political and economic pressures and a lack of transparency conspire to enable the Intellectual Property Regime (IPR) system to sustain and deepen global health inequities").

98. Sam Halabi, *Solving the Pandemic Vaccine Product Liability Problem*, 12 U.C. Irvine L. Rev. 110, 138 (2022).

Some other partnerships have also developed, but they have resulted in few actual vaccine doses. The aforementioned partnership between AstraZeneca and SII has been the most productive.[99] The Pan-American Health Organization has identified the Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation (FIOCRUZ) as an mRNA vaccine manufacturing center in Brazil.[100] "Sinergium Biotech, a private sector biopharmaceutical company, was selected as a similar center in Argentina.[101] Sinergium will partner with mAbxience . . . to develop and manufacture active vaccine ingredients.[102] The two companies have extensive experience in the production and development of vaccines and biotechnological medicines."[103] But those two centers only received their first training in manufacturing mRNA vaccines in March 2022.[104] Equipment delays alone will delay progress for nearly a year.[105] WHO has endeavored to establish a similar center in South Africa, but progress has

99. Lauren Freyer, *The World's Largest Vaccine Maker Took A Multimillion Dollar Pandemic Gamble*, NPR, March 18, 2021, https://www.npr.org/sections/goatsandsoda/2021/03/18/978065736/indias-role-in-covid-19-vaccine-production-is-getting-even-bigger [https://perma.cc/7UXQ-65G4].

100. *Brazil to Develop COVID-19 mRNA Vaccines*, PAN AMERICAN HEALTH ORGANIZATION (Sep. 21, 2021), https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines [https://perma.cc/Y28D-VSFW].

101. *Id.*

102. *Id.*

103. *Id.*

104. *Latin American manufacturers complete first training in mRNA technology in bid to improve regional vaccine production*, PAN AM. HEALTH ORG. (Mar. 24, 2022), https://www.paho.org/en/news/24-3-2022-latin-american-manufacturers-complete-first-trainiing-mrna-technology-bid-improve [https://perma.cc/8RH4-M65X].

105. *See, e.g.*, Nurith Aizenman, *These Brazilian besties are inventing an mRNA vaccine as a gift to the world*, NPR, July 13, 2022, https://www.npr.org/sections/goatsandsoda/2022/07/13/1111137152/these-brazilian-besties-are-inventing-an-mrna-vaccine-as-a-gift-to-the-world [https://perma.cc/R8K6-Q852] ("Although Ano Bom bought the machine from an American supplier four months ago, she's still waiting for it to reach her lab. Ano Bom gives an exasperated sigh. "I think bureaucracy is the reason!" she says. Brazil's regulatory agencies aren't really set up to approve imports of equipment and supplies for fast track vaccine invention.").

been slow because of the intellectual property barriers identified above.[106]

Meanwhile CanSinoBio, Sinopharm, and Sinovac, the major Chinese vaccine developers, have licensed vaccine production in Turkey, Indonesia, Brazil, Malaysia, Mexico, Pakistan, Egypt, and the UAE, but production from any and all of these locations is significantly constrained.[107] Similarly, the Russian Sputnik V vaccine was licensed for production in Argentina, but has resulted in only 5 million doses and is unlikely to produce more.[108]

Thus, intellectual property represents one of the foundational barriers to vaccine access, even in public health emergencies. Even if it is accepted that intellectual property protections are necessary for vaccine development, a disputed claim, those protections should yield during times of global crisis. The next part more fully develops the mechanisms by which such adaptation may occur.

III. Securing Intellectual Property Transfers and Local Production of COVID-19 Vaccines

As the examples above demonstrate, the global community has failed to do much more than rise above nationalist politics. While there are exceptions like COVAX and the partnership between AstraZeneca, the University of Oxford, and SII, the hoarding of vaccines and related technologies by wealthy countries continues to add to the vast disparities in access to vaccines.[109]

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106. *Approval of COVID vaccine made in South Africa could take 3 years, WHO says*, Reuters, February 5, 2022, https://www.reuters.com/world/africa/approval-covid-vaccine-made-south-africa-could-take-3-years-who-says-2022-02-04/ [https://perma.cc/PK73-DVU6].

107. Hu Yuwei & Huang Lanlan, *World COVID-19 Vaccine Production Accelerates as China Licenses Own* Doses Overseas, Global Times, (May 14, 2021), https://www.globaltimes.cn/page/202105/1223495.shtml [https://perma.cc/URJ7-5RBK].

108. Rohit Ranjan, *Argentina Manufactures Over 5 Million Doses of Sputnik Vaccine Developed by Russia*, Republic World (last updated Aug. 28, 2021), https://www.republicworld.com/world-news/rest-of-the-world-news/argentina-manufactures-over-5-million-doses-of-sputnik-v-vaccine-developed-by-russia.html [https://perma.cc/YWK9-JBJ7].

109. Cross et al., *supra* note 88.

A future of more equitable vaccine access can be envisioned, but will require significant changes in international intellectual property law, technology transfer from wealthy to poorer countries to build manufacturing capacity, and the legal tools that governments possess to compel such transfer from the private sector.

The vaccine platform for Pfizer-BioNTech and Moderna's vaccines—mRNA—provides an excellent illustration as to why such commitments are essential. As a platform, mRNA has inherent benefits for manufacturers over other platforms. First, mRNA vaccines are more affordable and simpler to manufacture than traditional vaccines.[110] Second, the same manufacturing capacity used for to produce mRNA vaccines can potentially play a role in the manufacturing of mRNA-based therapeutics.[111] Such therapeutics will likely play a substantial role in the management of non-communicable diseases (NCDs), including cancer, and infectious diseases in the future.[112] Because of this, ensuring local access to mRNA technologies for COVID-19 has the potential to come with significant future benefits in efforts against other diseases.

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110. MSF, SHARE MRNA TECHNOLOGIES, SAVE LIVES (2021) 2, https://msfaccess.org/sites/default/files/2021-08/COVID19_TechnicalBrief_MSF_mRNA%20vaccines_ENG_27.8.2021.pdf [https://perma.cc/4T2C-Z7FH].

111. *See* Mike May, *After COVID-19 successes, researchers push to develop mRNA vaccines for other diseases*, NATURE Med. (May 31, 2021), https://doi.org/10.1038/s41591-021-01393-8 [https://perma.cc/J883-KD84] (noting that, "the manufacturing process stays mostly the same regardless of the sequence of the mRNA").

112. *See* Patrick Boyle, *mRNA technology promises to revolutionize future vaccines and treatments for cancer, infectious diseases*, AAMC (Mar. 29, 2021), https://www.aamc.org/news-insights/mrna-technology-promises-revolutionize-future-vaccines-and-treatments-cancer-infectious-diseases [https://perma.cc/VLJ4-3TMX] ("Messenger RNA (mRNA) — the basis of the first two vaccines cleared for public use by the Food and Drug Administration (FDA) — induces cells to set off an immune response against the coronavirus that causes COVID-19. Vaccine researchers believe the success of these inoculations will usher in the most radical change to vaccine development since Jenner tapped a cow virus two centuries ago. "This is just the beginning," says John Cooke, MD, PhD, medical director of the RNA Therapeutics Program at the Houston Methodist Research Institute. Researchers say mRNA can be used to create a variety of vaccines and treatments in less time and at lower costs than traditional methods. The vaccines' use against COVID-19 will produce more evidence about the effectiveness and safety of this approach.").

Though some of its benefits may come further down the line, expanding capacity for local production of mRNA vaccines needs to be an urgent and immediate priority. mRNA vaccines have among the highest efficacy rates against COVID-19 and have so far proven more easily able than other vaccines to adapt to COVID-19 variants.[113]

Further, existing manufacturing facilities, including those producing injectable medicines, could be repurposed to make mRNA vaccines.[114] In some cases, such facilities have in fact been adapted in as little as 6 months.[115]

Of the two mRNA COVID-19 vaccines commercially available and approved by the U.S. FDA, the Moderna vaccine is more successful than the Pfizer-BioNTech vaccine in generating long-term antibodies,[116] which can positively impact resulting protection and operational conditions, given that it does not require ultra-cold conditions in the supply chain.[117] It is

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113. Kathy Katella, *Comparing the COVID-19 Vaccines: How Are They Different?*, Yale Medicine (Aug. 31, 2022), https://www.yalemedicine.org/news/covid-19-vaccine-comparison [https://perma.cc/GF55-FSLN].

114. *See* James Krellenstein, *Playing Fiddle While the World Burns: The $16 Billion Dollars the Biden Administration Hasn't Used to End the Pandemic*, PrEP4ALL, 6 (Aug. 25, 2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/6126e625c4a13221528dc454/1629939239851/Final+PDF+25+Aug.2.pdf [https://perma.cc/FZ4G-NBJL].

115. Kathryn Ardizzone, *Texas A&M Vaccine Manufacturing Contract Shows that cGMP Manufacturing of COVID*-19 Vaccines Can Start in Five Months, Knowledge Ecology International (May 11, 2021), https://www.keionline.org/36168 [https://perma.cc/FNF7-BMDQ] (noting that a specific manufacturing facility was retrofitted in five months under a contract between the Department of Health and Human Services and Texas A&M University).

116. See Deborah Steensels et al., Comparison of SARS-CoV-2 Antibody Response Following Vaccination With BNT162b2 and mRNA-1273, 326 JAMA 15, 1534 (2021).

117. Jocelyn Kaiser, Temperature concerns could slow the rollout of the new coronavirus vaccines, Science, November 16, 2020, https://www.science.org/content/article/temperature-concerns-could-slow-rollout-new-coronavirus-vaccines [https://perma.cc/47S8-Z4NF] ("That's where the Moderna vaccine may have an edge: Unlike Pfizer's and BioNTech's offering, it does not have to be stored at −70°C, but can tolerate a much warmer −20°C, which is standard for most hospital and pharmacy freezers. That difference means Moderna's vaccine should be easier to distribute and store, particularly in the rural United States and developing countries that lack ultracold freezers.").

also slightly easier to produce.[118] Analysis from the Graduate Institute's Global Health Centre shows that the companies which developed these mRNA vaccines have been based in high-income countries and generally tended to partner with other companies based in high-income countries in manufacturing and technology transfer.[119]

As described above, intellectual property protections comprise the fundamental and enduring barrier to expanded access to COVID-19 vaccines. These protections were internationalized through TRIPS—specifically Article 27, applicable to patents, and Article 31, applicable to trade secrets and other undisclosed information—and may be correspondingly addressed through an international agreement.[120] Article 31 of TRIPS provides for the possibility of compulsory licensing to a producer other than the right-holder.[121] But because many low- and middle-income countries' laws require manufacturing sites to be overseen and staffed by scientific experts, to say nothing of supporting regulatory frameworks, requiring licensure does little, just as it did little in the early, sensational episodes with HIV/AIDS and some cancer drugs.[122]

Governments, state-owned entities, and/or private sector manufacturers must seek licenses for the manufacturing and marketing of COVID-19 vaccines or, alternatively, issue public use or compulsory licenses or other safeguards as part of the TRIPS flexibilities—those parts of the agreement, like Article 31, that allow governments to circumvent IP protections dur-

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118. Harvard School of Public Health, Moderna vaccine slightly more effective than Pfizer vaccine in preventing COVID-19 infection, hospitalization, and death, HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH (Dec. 1, 2021) https://www.hsph.harvard.edu/news/press-releases/moderna-vaccine-slightly-more-effective-than-pfizer-vaccine/ [https://perma.cc/9NJE-5SJE] (detailing the results of a recently-completed study).

119. *New Resources on Covid-19 Manufacturing*, GENEVA GRADUATE INST., https://www.graduateinstitute.ch/Vaccine-Manufacturing (May 22, 2021).

120. *See* Sam F. Halabi, *The Origins and Future of Global Health Law: Regulation, Security, and Pluralism*, 108 GEO. L.J. 1607, 1644–45 (2020) (explaining the effect of Doha Agreement and Article 31, i.e., "that treatments for diseases affecting low- and middle-income countries required that normal rules of trade defer to global health interests").

121. *Id.*

122. *Id.*

ing public health emergencies.[123] Conditions of licenses can include limited geographical scope for marketing and distribution, royalty terms, conditions for further sharing of technology or out-licenses for COVID-19, and use of related technology for non-COVID-19 use.[124] Given that a robust and diverse supply is needed to meet the global COVID-19 vaccine needs, licenses should not be made exclusive to any manufacturer or small set of producers, or small in geographic scope. As World Health Organization Director-General Tedros Adhanom Ghebreyesus implored, "We are calling for the original manufacturers of mRNA #COVID19 vaccines to contribute their technology and know-how to a central hub, and for manufacturers in low- and middle-income countries to express interest in receiving that technology".[125]

The WHO's COVID-19 mRNA Vaccine Technology Transfer Hub, outlined above, has endeavored to reach a deal with Moderna about securing these licenses and then to facilitate the exchange of know-how, quality control, and licenses from technology holders to governments and manufacturers.[126]

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123. Obi Peter Adigwe and Davidson Oturu, *The role of patent waivers and compulsory licensing in facilitating access to COVID-19 vaccines: Findings from a survey among healthcare practitioners in Nigeria*, 2 PLOS GLOB. PUB. HEALTH (2022).

124. OTAs are designations allowed under U.S. federal law to circumvent the normal rights that the U.S. Government enjoys to exploit inventions that result from taxpayer support, as Moderna's vaccine was. *See* Kathryn Ardizzone & James Love, *Other Transaction Agreements: Government Contracts that Eliminate Protections for the Public on Pricing, Access and Competition, Including in Connection with COVID-19 Vaccines and Treatments*, KNOWLEDGE ECOLOGY INT'L, 36–42 (KEI Online "Briefing Note," 2020:3, Jun. 29, 2020), https://www.keionline.org/wp-content/uploads/KEI-Briefing-OTA-29june2020.pdf [https://perma.cc/RST7-7S5N] (detailing pertinent terms of OTA agreements); Other Transaction for Advanced Research (OTAR) Template, Biomedical Advanced Rsch. & Dev. Auth., https://www.phe.gov/about/otar/Documents/otar-consortium.pdf [https://perma.cc/79U2-QH4G] (last visited May 31, 2020), at 16–21 (Article VII: Patent Rights) [hereinafter BARDA OTA Template]; see also Other Transaction Agreements, Biomedical Advanced Rsch. & Dev. Auth., https://www.phe.gov/about/otar/Pages/default.aspx [https://perma.cc/4DKC-JM2Y] (last visited May 31, 2020) (explaining how OTAs and OTARs provide flexibility).

125. World Health Organization (@WHO), Twitter (Apr. 28, 2021, 11:15 AM) https://twitter.com/WHO/status/1384163781098369027 [https://perma.cc/W3FT-NYNS] .

126. *Call for expression of interest to: Contribute to the establishment of a COVID-19 mRNA vaccine technology transfer hub*, WORLD HEALTH ORGANIZATION (Apr.

The WHO Hub, operated by Afrigen in South Africa, has successfully produced its own mRNA vaccines based on Moderna's COVID-19 vaccine, but using only publicly available information, for example, that disclosed in patent applications.[127] As part of supporting the Hub, the United States National Institutes of Health licensed eleven research tools and early stage diagnostic and vaccine technologies to the Medicines Patent Pool through the C-TAP program described in more detail below.[128]

The Hub will use these tools and others to conduct high-quality technology transfers to mRNA vaccine production "spokes" across eleven low- and middle-income countries.[129] The Hub's technology transfer mission is complemented by a WHO Global Biomanufacturing Training Hub, recently established in South Korea, which will, in coordination with the WHO Academy in France and any future training hubs, assist by training key personnel.[130] In addition, two regional vaccine production and manufacturing hubs have been established in Argentina and Brazil by PAHO to create the inputs (vaccine excipients) needed for mRNA vaccine production.[131]

These coordinated efforts require concerted global support. Most importantly, vaccine-producing states must share manufacturing and regulatory know-how. This would hasten the speed with which the Hub and its spokes can attain regula-

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16, 2021), https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-to-contribute-to-the-establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub [https://perma.cc/S2ZQ-Z9K4].

127. *See* Meyer, *supra* note 68 (discussing the process by which the WHO developed its own mRNA vaccine based on Moderna's publicly released information).

128. *WHO and MPP announce agreement with NIH for COVID-19 health technologies*, RELIEFWEB (May 12, 2022), https://reliefweb.int/report/world/who-and-mpp-announce-agreement-nih-covid-19-health-technologies [https://perma.cc/CP3W-PD8P].

129. *Moving forward on goal to boost local pharmaceutical production, WHO establishes global biomanufacturing training hub in Republic of Korea*, WORLD HEALTH ORGANIZATION (Apr. 16, 2021), https://www.who.int/news/item/23-02-2022-moving-forward-on-goal-to-boost-local-pharmaceutical-production-who-establishes-global-biomanufacturing-training-hub-in-republic-of-korea [https://perma.cc/2BXZ-GN5N].

130. *Id.*

131. PAN AMERICAN HEALTH ORGANIZATION, *supra* note 100.

tory approval and leap to the large-scale and commercially sustainable production volumes that will be needed.[132]

But instead, originator vaccine companies are currently refusing to support the proposed WHO technology transfer initiative, including its designated facilities, or comparable national initiatives.[133] For example, though South Korea has the capacity and will rapidly produce up to a billion doses, the mRNA vaccine companies have so far refused to enter into an agreement for technology transfer.[134] Similarly, the consortium operating the South African hub, led by Afrigen, has faced deadlocks so far in its talks with vaccine companies.[135]

Although they often cite concerns about quality control and capacity, the genuine reason behind the originator companies' refusal to engage in technology transfer is likely twofold: their unwillingness to divide market share for COVID-19 vaccines with competitors and, more importantly, their fear of losing market share and profits for future medical innovations based on the same mRNA technology.[136] Without a public sector intervention, these private sector priorities will likely continue to dictate outcomes. As WHO vaccine coordinator Dr. Martin Friede lamented "[w]e would love to get a discussion with Moderna, about a license to their intellectual property —

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132. Sara Jerving, *Without shared tech, South Africa's mRNA COVID-19 jab faces 2-year lag*, DEVEX (Feb. 4, 2022), https://www.devex.com/news/without-shared-tech-south-africa-s-mrna-covid-19-jab-faces-2-year-lag-102603 [https://perma.cc/6X84-U4Y6] ("Without the participation of outside companies, the hub will need to conduct new clinical trials for its vaccine candidate to gain approval.").

133. *See* Meyer, *supra* note 68 (stating that pharmaceutical companies are resistant to sharing technology).

134. Zain Rizvi et al., *Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The* Pandemic Worldwide, Health Aff.'s Blog (Aug. 6, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210804.101816/ [https://perma.cc/T8XE-33YY].

135. Roelf, *supra* note 67.

136. *See* Stephanie Baker and Vernon Silver, *Pfizer Fights to Control Secret of $36 Billion Covid Vaccine Recipe*, BLOOMBERG (Nov. 14, 2021), https://www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid-vaccine/?leadSource=Uverify%20wall [https://perma.cc/2VB2-8XH2] (detailing the major vaccine manufacturers' market share in rich countries as well as the complex global supply chain involved in, and possible downstream consequences for medical innovation of, vaccine research and development).

this would make life so much simpler, but for the moment all attempts have resulted in no reply . . ."[137]

Both the problem and its prospective solutions stem from public policy. In places like the United States, Germany, and the broader European Union, decision-makers at the national and supranational levels can and should employ legal tools to compel companies to engage in technology transfers with entities like those outlined by the World Health Organization. National regulatory mechanisms may be used to compel technology transfer; it is unlikely that vaccine companies will shift to cooperative methods without at least a credible threat of regulatory intervention.[138]

The following sections sketch out a series of mutually supportive yet independent actions that various actors for global health governance at both the national and international level could take to expand access to vaccines for both COVID-19 and future pandemics.

A. *Exempting World Health Organization Blueprint List of Priority Diseases from International Intellectual Property Protection*

One obvious way to address intellectual property barriers to COVID-19 vaccine access is to, temporarily or permanently, dispense with intellectual property protections at the international level for the technologies used to produce them.[139] TRIPS, the international agreement establishing high floors for intellectual property protection, is one of the most important of these barriers.[140] While TRIPS is the focus of this analy-

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137. Stephanie Nolen and Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Sept. 22, 2021, Updated Nov. 9, 2021).

138. *See* Rizvi et al., *supra* note 134 (detailing how the U.S. could use the Defense Production Act to mandate technology transfer).

139. *See* Tedros Adhanom Ghebreyesus (@DrTedros), Twitter (Aug. 21, 2021), https://twitter.com/DrTedros/status/1428979808495624199 [https://perma.cc/J6RX-YMNX] (listing "[w]aiv[ing] intellectual property" protections as what "we need [for] #VaccinEquity").

140. Sam Halabi, *Multipolarity, Intellectual Property and the Internationalization of Public Health Law*, 35 MICH. J. INT'L. L. 715, 744 (2014) ("Unlike the general theory of *reducing* barriers to trade that justified GATT, TRIPS was theoretically justified by the need to *increase* legal protections for intellectual property rights holders in order to facilitate the expansion of products,

sis, it is important to note that many bilateral and regional agreements offer protections that exceed TRIPS, although those protections may also be addressed through the recommendations outlined below.[141]

From its inception, TRIPS has raised significant concerns regarding access to medicines, in part because pharmaceutical patents apply whether or not a given medicine is needed by a small number of patients with the ability to pay for it, or by millions of prospective recipients who live in poverty.[142] This issue was highly pertinent during the early 2000s, when HIV/AIDS exploded in Africa but early retroviral medications were priced well out of the reach of those who needed it.[143] The activism of the HIV/AIDS community and their supporters were critical to this change in international law, leading to the

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processes, accompanying trademarks, and creative works into new markets.").

141. *Id.* at 750 ("More common than broad, multilateral trade instruments like TRIPS . . . bilateral and regional investment and trade agreements contain some of the strongest protections for intellectual property. Bilateral investment treaties ("BITs"), for example, take a number of forms and include provisions authorizing IP rights-holders to vindicate claims in national or international courts or dispute resolution fora. Generally, BITs are negotiated between developed and developing states."); Sam Halabi, *International Intellectual Property Shelters*, 90(4) TUL. L. REV. 903, 906 (2016) ("Thousands of bilateral investment treaties, largely forged between developed states and developing states, include strong protections for intellectual property rights that frequently exceed those in existing international agreements, even TRIPS, and certainly those typically found in national legislative frameworks. 6 This network of agreements has generated a wide range of enforcement mechanisms that reach beyond the slow and relatively impotent diplomatic methods that characterized the earlier generation of international intellectual property protections.").

142. *See* Kojo Yelpaala, *Quo Vadis WTO? The Threat of TRIPS and the Biodiversity Convention to Human Health and Food Security*, 30 B.U. INT'L L.J. 55, 85–86 (2012) ("Trade and investment liberalization have produced certain negative externalities in health in developing countries. Trade liberalization has enabled greater availability of highly processed, calorie-rich and nutrient-deprived food in developing countries. Trade liberalization has also opened up the markets of developing countries to other high health-risk products such as tobacco.").

143. William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, THE LAW AND BUSINESS OF PATENTS, 4-5 (last updated Feb. 10, 2005), http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf [https://perma.cc/PUZ2-2LT6].

Doha Declaration on the TRIPS Agreement and Public Health.[144]

In light of that experience, the World Trade Organization, driven by dispute resolution between the governments of Brazil and the United States, adopted the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health.[145] Developed to expand access to medicines for HIV/AIDS, tuberculosis, malaria and "other epidemics," the Doha Declaration asserted that treatments for diseases affecting low- and middle-income countries required that normal rules of trade defer to global health interests.[146]

On October 2, 2020, the governments of India and South Africa submitted a TRIPS waiver proposal to the WHO, akin to that adopted for HIV/AIDS, tuberculosis, and malaria.[147] It covered "patents, industrial designs, copyright and protection of undisclosed information" applicable to "medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need."[148] Following consideration of the proposal, a draft WTO ministerial decision, issued on July 6, 2022, ruled that

144. *See* Halabi, *supra* note 140, at 755-56 (discussing the events that led to the Doha Declaration).

145. R. Elliott, *US filed WTO complaints against Brazil over requirement for "local working" of patents*, 5 CAN. HIV AIDS POL. L. REV. 28 (2000).

146. Declarations and Decisions adopted by WTO Members at the Doha Ministerial (compiled without reference to a WTO document number, available here: https://www.wto.org/english/res_e/booksp_e/ddec_e.pdf [https://perma.cc/4ZBJ-KYD3]) at 24; Ellen F.M. 'T Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 CHI. J. INT'L L. 27, 32 (2002); *see also*, Susan Okie, *Fighting HIV—Lessons from Brazil*, 354 NEW ENG. J. MED. 1977, 1981 (2006) (indicating that "Brazil's economic clout helped to push through a landmark agreement between the governments of 11 Latin American countries and 26 drug companies to lower the cost of . . . drugs").

147. Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, ¶ 1, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W669R1.pdf&Open=True [https://perma.cc/S5D7-C7LZ].

148. Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreements for the Prevention, Containment and Treatment of COVID-19*, ¶¶ 3, 5, WTO Doc. IP/C/W/669 (Oct. 2,

the waiver covered only patents and did not apply to all of the intellectual property necessary for COVID-19 vaccine production.[149]

Even if it were written with wider reach, it is not clear how much a TRIPS waiver alone would accomplish toward vaccine access. As described above, passively not enforcing an intellectual property right and actively sharing relevant information are two different things.[150] A government may not allow a company to enforce a patent infringement claim, but those seeking to use the patented technology may nevertheless need disclosure of other relevant information.[151]

Rather than adopting piecemeal approaches through the WTO, with accompanying bureaucratic and diplomatic delays, the international community should adopt a single, universal exemption from bilateral, regional, and multilateral trade and investment agreements for diagnostics, therapeutics, and vaccines applicable to the World Health Organization's Blueprint List of Priority Diseases. "Worldwide, the number of potential pathogens is very large, while the resources for disease research and development (R&D) is limited."[152] So-called

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2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W669.pdf&Open=True [https://perma.cc/63TJ-JKKD].

149. Draft Texts on WTO Response to Pandemic, IP Response Sent to Ministers for Decision, World Trade Organization (Jun. 10, 2022), https://www.wto.org/english/news_e/news22_e/covid_10jun22_e.htm [https://perma.cc/Q6U8-LJC4]; see also, Ministerial Conference Twelfth Session Geneva, 12-15 June 2022, *Draft Ministerial Decision on the TRIPS Agreement*, WTO Doc. WT/MIN(22)/W/15/Rev.2 (Jun. 17, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/MIN22/W15R2.pdf&Open=true [https://perma.cc/4X97-HBLG] (detailing how "an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement . . . by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic"); MSF Statement, *Lack of a real IP waiver on COVID-19 tools is a* disappointing failure for people, June 17, 2022, https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people [https://perma.cc/2U6H-RHWG].

150. Draft Texts, *supra* note 149.

151. *MSF Calls on Moderna to Transfer mRNA Vaccine Technology without Further Delay*, Médecins Sans Frontières (Apr. 27, 2022), https://reliefweb.int/report/world/msf-calls-moderna-transfer-mrna-vaccine-technology-without-further-delay [https://perma.cc/68C6-BBW2].

152. *Prioritizing Diseases for Research and Development in Emergency Contexts*, World Health Org., https://www.who.int/activities/prioritizing-diseases-

"blueprint diseases" are those prioritized for research and development based on which diseases pose the greatest public health risk due to their epidemic potential and/or whether there are no or insufficient countermeasures.[153] The priority diseases are: COVID-19; Crimean-Congo haemorrhagic fever; Ebola virus disease and Marburg virus disease; Lassa fever; Middle East respiratory syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS); Nipah and henipaviral diseases; Rift Valley fever; and Zika.[154]

Adopting a broad, multilateral exception for blueprint diseases would facilitate the legally sanctioned development of broad coalitions of governments, charitable organizations, and researchers.[155] But a broad exception to international intellectual property protections alone is insufficient; more is needed.

B. *Making the World Health Organization's Pandemic Influenza Preparedness Framework an All-Pathogens Technology Transfer Entity*

Though imperfect, the impressive results of the global commitment to increasing vaccine manufacturing capacity for influenza presents a path forward for other pathogens, including SARS-CoV-2.[156] That commitment was born out of a struggle, which became prominent around 2005, by nations in the Global South against two, related injustices: (1) the inequali-

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for-research-and-development-in-emergency-contexts#:~:text=worldwide%2C%20the%20number%20of%20potential,in%20public%20health%20emergency%20contexts [https://perma.cc/74SP-G64K].

153. *Id.*

154. *Prioritizing diseases for research and development in emergency contexts,* WORLD HEALTH ORG., https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts [https://perma.cc/EN8S-6PXD] (last visited Sep.17, 2022).

155. Cf. IAN F. Fergusson, Cong. Rsch. Serv., IF11858, Potential WTO TRIPS Waiver and Covid-19 (Sept. 13, 2021), https://crsreports.congress.gov/product/pdf/IF/IF11858 [https://perma.cc/SGX2-6DUP] (noting that "the Biden administration announced its support for the concept of [a TRIPS waiver]" and highlighting the popularity of such a broad, multilateral exemption).

156. *See* Rep. of the Dept. of Immunization, Vaccines and Biologicals and the Dept. of Epidemic and Pandemic Alert and Response, at 4, WHO Doc. WHO/IVB/06.13 and WHO/CDS/EPR/GIP/2006.1 (2006) (prognosticating that "the full production capacity for the monovalent pandemic influenza vaccine [will] be several billion doses short of the expected demand if there were to be a pandemic").

ties in influenza vaccine manufacturing capacity meant they would have to beg for access to vaccines in a pandemic, and (2) countries that shared crucial samples of emergent influenza strains did not receive any direct benefits in return for their contribution to influenza surveillance and vaccine development.[157]

Pursuant to a 2005 resolution of its Member States and following a year of consultation, the WHO launched the Global Action Plan for Influenza Vaccines (GAP) in September 2006.[158] The GAP presented a ten-year strategy to increase equitable access to pandemic influenza vaccines, including by boosting global capacity high enough to produce enough vaccines to immunize 70% of the world's population in a compressed timeframe.[159] At the launch of the GAP, the global production capacity for influenza vaccines was approximately 500 million doses of seasonal vaccine and 1.5 billion doses of pandemic vaccine, with the vast majority of production concentrated in high-income countries.[160] Ten years later, at the close of the GAP, annual production capacity was estimated to have almost tripled, including key expansions of production capacity in low- and middle-income countries.[161] These

157. *See* World Health Assembly Res. 58.5, U.N. Doc. A58/13 (May 23, 2005) (wherein the 58th World Health Assembly, "[a]ware of the need to expand the availability of the influenza vaccine so that protection in a pandemic can be extended to populations in more countries, with particular attention to requirements in developing countries," urged Member States "to ensure prompt and transparent reporting of outbreaks" and "to take all necessary measures during a global pandemic, to provide timely and adequate supplies of vaccines . . . using to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights").

158. Rep. of the Dept. of Immunization, Vaccines and Biologicals and the Dept. of Epidemic and Pandemic Alert and Response, *supra* note 156; *see also*, Sparrow, *infra* note 159.

159. Erin Sparrow et al., *Global production capacity of seasonal and pandemic influenza vaccines in 2019*, 39 VACCINE 512 (2021) ("In 2006, WHO launched the Global Action Plan for Influenza Vaccines (GAP) to serve as a ten-year strategy with the overarching goal to increase equitable access to pandemic influenza vaccines, including through increasing global production capacity to be able to produce enough vaccine to immunize 70% of the world's population with two doses of a pandemic vaccine within six months from the availability of the vaccine virus strain to manufacturers.").

160. K.A. McLean et al., *The 2015 global production capacity of seasonal and pandemic influenza vaccine* 34 VACCINE, 5410 (2016).

161. *Id.*

achievements were due in significant part to a technology transfer project under the GAP in which WHO, supported by partners including U.S. BARDA and PATH, provided seed funding and technical support to vaccine manufacturers located in low- and middle-income countries.[162]

Although the GAP guaranteed graduate progress on global vaccine supplies, it did not include any guarantees of near-term access to vaccines during an influenza pandemic.[163] In December 2006, after a company used viral samples taken from WHO's sharing system to patent an influenza vaccine, and in the context of broader concerns about access to vaccines,[164] Indonesia announced its unilateral refusal to share influenza virus samples without reciprocal guarantees of access to vaccines developed using them.[165] Indonesia was joined by other members of the Global South in a 2007 Jakarta Declaration demanding that the sharing of pandemic influenza virus samples and viral information be accompanied by greater access to resulting vaccines.[166] This sparked negotiations for what eventually became the Pandemic Influenza Preparedness (PIP) Framework.[167] The PIP Framework was founded upon an "equal footing" principle: all countries would be placed on an equal footing in the sense that, provided all countries

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162. *Id.* ("This pandemic capacity increase despite seasonal capacity decrease is due primarily to multiple manufacturers shifting from trivalent to tetravalent technology. This technology allows more monovalent vaccine doses to be produced within the existing seasonal vaccine production infrastructure.").

163. *Id.* ("The overall goal of the GAP is to have enough production capacity to immunize the global population *within six months* of the transfer of the candidate vaccine virus to manufacturers.") (emphasis added).

164. Endang R. Sedyaningsih, et. al, *Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia*, 37 ANNALS ACAD. OF MED. 482, 482 (2008).

165. *See* Michelle F. Rourke, *Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World*, 82 INFECTIOUS DISEASES IN THE NEW MILLENNIUM. INTERNATIONAL LIBRARY OF ETHICS, LAW, AND THE NEW MEDICINE 167, 173 (2020) (describing how Indonesia revoked access to its virus samples and the basis on which it did so).

166. David P. Fidler, *Influenza Virus Samples, International Law, and Global Health Diplomacy*, 14 EMERGING INFECTIOUS DISEASE 88, 88–89 (2008).

167. Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Human Pathogens for Infectious Disease Research*, 28 ANNALS OF HEALTH LAW 101, 123-24 (2019).

would share samples and relevant information globally, benefits derived from these networks would accrue to nations based on need, rather than on a preferential basis.[168] Although it was adopted by WHO's Member States, the Framework is not a nationally binding treaty: instead, all legal relationships are between WHO and those influenza labs and manufacturers that receive influenza virus samples from WHO.[169]

There are two key components to the PIP Framework: (1) the sharing of influenza viral samples with members of the WHO Global Influenza Surveillance and Response System (GISRS); and (2) GISRS's sharing of viral samples with vaccine manufacturers, in return for their agreement to share benefits with the WHO and its members.[170] All vaccine manufacturers and some other related industrial players who access GISRS pay "partnership contributions" to support the system.[171] This model ameliorated the previous reliance on ad hoc influenza vaccine donations and created a system in which influenza vaccines would be contractually guaranteed to low-income countries, in exchange for biological material through a negotiated Standard Material Transfer Agreement (SMTA), aligned with a model provided in the PIP Framework's annex.[172]

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168. *See* Halabi, *supra* note 141, at 946 ("Under the Framework, major pharmaceutical manufacturers retain their ability to access samples shared through the WHO's Global Influenza Surveillance and Response System, but now firms using the system must contribute towards half the cost of its maintenance (approximately $30 million annually) and must promise to share either intellectual property, products developed through use of the system, or other medical countermeasures critical to pandemic response.").

169. *PIP Framework Partnership Contribution*, WORLD HEALTH ORGANIZATION, https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/partnership-contribution [https://perma.cc/7VZG-DJK4].

170. Sam F. Halabi, *supra* note 167, at 124 ("The PIP was explicitly committed to 'increas[ing] the access of developing countries to vaccines and other pandemic related supplies.' Under the Framework, major pharmaceutical manufacturers retain their ability to access samples shared through GISRS, however firms using the system must contribute towards half the cost of its maintenance (approximately $30 million annually). Firms must promise to share either intellectual property, products developed through use of the system, or other medical countermeasures critical to pandemic response.").

171. *Id.*

172. Michelle Rourke et al., *Access and Benefit-Sharing: Implications for Accessing Biological Samples for United Nations Secretary-General Mechanism Investigations*, [2019] GEO. UNIV. MED. CTR., CTR. GLOB. HEALTH & SEC. 1, 17.

The PIP Framework is not perfect. As of August 2020, none of the companies with which WHO has concluded SMTAs had actually agreed to technology transfers, opting instead to donate vaccines, retrovirals, and related final product medicines.[173] The Framework has, moreover, not yet been tested by a public health emergency involving pandemic potential influenza. In such an event, it is possible that the governments which host influenza manufacturing capacity would simply expropriate all available vaccines, regardless of any PIP commitments.[174] Since the Framework is not a multinational treaty, governments would not formally breach any legal obligation in doing so. The manufacturers themselves would likely be protected from liability for failing to deliver, due to clauses on exceptional intervening events provided for in their SMTAs.[175] But despite PIP's imperfections and its limited scope, the Framework was the first international agreement to address inequalities of vaccine access and has been described as a "milestone for global health."[176]

Since 2015, several expert groups and governments have argued the PIP Framework should include all pathogens that may threaten global health security.[177] The GISRS has already

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173. WHO, SMTA2 WITH VACCINE & ANTIVIRAL MANUFACTURERS (Aug. 2020), https://cdn.who.int/media/docs/default-source/pip-framework/smta2/smta2-cata-25aug2020.pdf?sfvrsn=D004e66_2 [https://perma.cc/H7R4-7YSV].

174. *Id.*

175. Michelle F. Rourke, *Restricting Access to Pathogen Samples and Epidemiological Data: A Not-So-Brief History of "Viral Sovereignty" and the Mark It Left on the World*, 82 INFECTIOUS DISEASES IN THE NEW MILLENNIUM. INTERNATIONAL LIBRARY OF ETHICS, LAW, AND THE NEW MEDICINE 167, 183 (2020).

176. Mark Eccleston-Turner, *The Pandemic Influenza Preparedness Framework: A Viable Procurement Option for Developing States?*, (17)4 MED. L. INT'L 227, 232 n.5 (2017), *citing* D. Fidler and L. Gostin, *The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health*, JAMA 306(2) (2011).

177. Rep. of the High-level Panel on the Global Response to Health Crises, at 66, U.N. Doc. A/70/723 (Feb. 9, 2016) ("The Panel recommends that WHO invite its member States to negotiate a broadening of the coverage of the PIP Framework beyond influenza viruses, while taking into account the principles of the Nagoya Protocol."); WHO Director-General, *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, 31, WHO Doc. A69/21 (May 13, 2016) ("The possible expansion of the PIP Framework to include infectious agents other than influenza warrants exploration."); WHO Director-General, *Review of the Pandemic Influenza*

been adapted to provide surveillance of COVID-19 variants.[178] This expansion could be a precursor to coverage of other pathogens under the PIP Framework.[179] Such an arrangement would create an all-pathogen surveillance and response system designed to facilitate the sharing of pathogen samples and related genetic sequencing data (GSD), and make recommendations about the composition of new COVID-19 vaccines.[180] Manufacturers of vaccines, therapeutics and diagnostics would be granted access to novel samples and GSD in exchange for providing partnership contributions and entering into SMTAs. To further strengthen this approach, the model SMTA provided for in an annex to the PIP Framework should be reconfigured, requiring commitments to technology transfer unless manufacturers commit to providing 100% of relevant pandemic pathogen vaccine production to WHO, COVAX, or equivalent future coalitions for equitable distribution. Prospective SMTAs under this system would include provisions to ensure that the transfer of technology from companies in Europe, North America, and East Asia to producers in low- and middle-income countries would include sharing the know-how fundamental to next-generation platforms such as mRNA.

C. *Building a Global Scientific Technical Corps*

As the above analysis emphasizes, the ability to manufacture vaccines begins with research and technical expertise,

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Preparedness Framework, 34, WHO Doc. EB 140/16 (Dec. 29, 2016), https://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf [https://perma.cc/TLA5-KK7Y] (proceeding from the "Discussion on expanding the PIP Framework to seasonal influenza").

178. WHO, Maintaining surveillance of influenza and monitoring SARS-CoV-2 – adapting Global Influenza surveillance and Response System (GISRS) and sentinel systems during the COVID-19 pandemic https://www.who.int/publications/i/item/maintaining-surveillance-of-influenza-and-monitoring-sars-cov-2-adapting-global-influenza-surveillance-and-response-system-(gisrs)-and-sentinel-systems-during-the-covid-19-pandemic [https://perma.cc/ACP9-8AEQ] at 3 (incorporating "additional considerations for assessing and addressing disruptions in influenza sentinel surveillance systems and for extending influenza sentinel surveillance to COVID-19").

179. *Id.*

180. *Cf.* Klaus Stöhr & Nancy Cox, *COVID-19 Vaccines: Call for Global Push to Maintain Efficacy*, 590 NATURE 36, 36 (2021) (expressing the need for establishing a framework with these characteristics).

coupled with access to advanced facilities. Each of these crucial predicates to manufacturing can be hindered by intellectual property protections and related technical barriers.[181] Even so, eliminating those protections alone may not do enough to foster technology transfer and the expansion of technical capacity.

Under WHO and UNESCO leadership, a global scientific corps should be developed to respond and assist countries to build vaccine manufacturing capacity. Because middle-income countries not only lack access to know-how but also to scientists themselves,[182] governments should agree to adequately support an international capacity building service.

Just as the World Health Organization and key governments committed to expanding local production of influenza vaccines through dedicated experts, a similar system could be established for mRNA or other vaccine platforms. This corps already exists in nascent form in South Korea and could be built upon with support from technical experts worldwide.[183]

In the United States, a similar model was used to expand research capacity in the agricultural context over the course of the nineteenth century. In the 1862 Morrill Act, the U.S. government funded the establishment of universities that would specialize in agricultural and mechanical research and development.[184] These so-called "land-grant" universities became the backbone of national research efforts in sciences of the highest importance. The Smith Lever Act formalized these arrangements in 1914, establishing federal agencies' partnership with land-grant universities to apply research and provide education in agriculture.[185]

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181. As discussed, *supra*, in Part II and accompanying footnotes.

182. Constance S. Shumba and Adelaide M. Lusambili, Not enough traction: Barriers that aspiring researchers from low- and middle-income countries face in global health research, J. OF GLOB. HEALTH ECON. AND POL. 1 (2021) (emphasizing the lack of scientists to engage in mentoring and collaboration).

183. Kim Han-joo, *S. Korea aims to develop at least 1 mRNA vaccine by 2023*, YONHAP NEWS AGENCY, Sept. 30, 2021, https://en.yna.co.kr/view/AEN20210930006200320 [https://perma.cc/AZW3-DLY4].

184. The First Morrill Act, 12 Stat. 503, as amended by P.L. 111-122 (effective, Dec. 22, 2009).

185. Smith-Lever Act, 38 Stat. 372, as amended by P.L. 115-334 (enacted, Dec. 20, 2018).

A similar corps, funded through voluntary training and educational contributions by medical schools and biomedical companies, could fuel a similar technical corps for international assistance. The Consultative Group for International Research or CGIAR provides a template for how such a corps might be formed.[186] The CGIAR, established as part of the Green Revolution, are all located in low- or middle-income countries and advance research and training about agricultural and livestock techniques oriented toward tackling food security.[187] This model could be replicated under a partnership between WHO and UNESCO.

D. *G7 and Financial Institutions: Funding Local Production*

In addition to technical know-how and licenses, funding is needed to support the development of local vaccine manufacturing and development capacity. According to an Imperial College of London analysis commissioned by Médecins Sans Frontières (MSF), the estimated cost of starting up mRNA vaccine manufacturing with a production target of 100 million doses at an existing manufacturing site "could be as little as US$127 million for Pfizer-BioNTech's vaccine and $270 million for Moderna's vaccine."[188]

For example, while it "has yet to develop a comprehensive plan to ensure global vaccination," existing U.S. legislation allows the government to fund the development of vaccine manufacturing abroad.[189] At least $10 billion of the $16.05 billion of funding in the American Rescue Plan Act (ARPA) for the procurement or manufacturing of COVID-19 vaccines, drugs, diagnostics, and personal protective equipment, remains un-

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186. *Cf.* R. E. Evenson & D. Gollin, *Assessing the Impact of the Green Revolution, 1960 to 2000*, 300 SCI. 758,758 (2003) (assessing the impact of CGIAR's development of modern crop varieties).

187. *See* Derek Byerlee & H.L. Dubin, *Crop improvement in the CGIAR as a Global Success Story of Open Access and International Collaboration*, 4 INT'L J. COMMONS 451, 476 (2010) (noting that the emergence of the CGIAR during the Green Revolution set off a chain of significant scientific achievements).

188. MSF, *supra* note 110.

189. James Krellenstein, *Playing Fiddle While the World Burns: The $16 Billion Dollars the Biden Administration Hasn't Used to End the Pandemic*, PREP4ALL, 2 (Aug. 25, 2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/6126e625c4a13221528dc454/1629939239851/Final+PDF+25+Aug.2.pdf [https://perma.cc/NV2Q-GHZF].

spent.[190] Crucially, these unspent funds could be used to support building new vaccine manufacturing capacity, including "building new publicly owned or privately-owned manufacturing capacity,"[191] instead of the current plan to purchase hundreds of millions of doses to donate to low- and middle-income countries.[192] Similarly, under the Team Europe initiative, the European Union has been channeling one billion Euros into supporting technical transfers to and developing manufacturing capacity in African countries.[193] Scaling up this funding is imperative.

Meanwhile, the World Bank's constituent organization focused on the private sector, the International Finance Corporation (IFC), leads a consortium of development banks and agencies in providing financing for vaccine production hubs in Africa, including in South Africa, Senegal, and Rwanda.[194]

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190. JOSEPH R. BERGER, JESSICA V. HAIRE, TOM MASON, FRANCIS E. (CHIP) PURCELL, JR. & MONA ADABI, THOMPSON HINE, THE AMERICAN RESCUE PLAN ACT COVID-19 UPDATE (2021) (law firm client notice), https://www.thompsonhine.com/publications/the-american-rescue-plan-act-funding-provisions-for-government-pandemic-response-health-care-infrastructure-transportation-science-and-technology-and-oversight [https://perma.cc/4JJH-QQZF] ("In order to combat COVID-19 and address shortfalls in the medical supply chain, ARPA provides $10 billion to expand domestic production of personal protective equipment (PPE), vaccines and other medical supplies through the Defense Production Act (DPA).").

191. James Krellenstein, *Playing Fiddle While the World Burns: The $16 Billion Dollars the Biden Administration Hasn't Used to End the Pandemic*, PREP4ALL, 6 (Aug. 25, 2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/6126e625c4a13221528dc454/1629939239851/Final+PDF+25+Aug.2.pdf [https://perma.cc/VNV7-6U5V].

192. *See, e.g.*, Tyler Page, Laurie McGinley & Dan Diamond, *U.S. to buy hundreds of millions more doses of Pfizer vaccine to* donate to the world, Wash. Post (Sept. 17, 2021), https://www.washingtonpost.com/health/2021/09/17/biden-pfizer-vaccine-global/ [https://perma.cc/BX9E-WW3Q] (referencing the U.S. partnership with Covax for the first major purchase of vaccines in June 2021, which targeted low- and middle-income countries).

193. *See, e.g.*, European Commission Press Release IP/21/2594, _1 billion Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (May 21, 2021), https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594 [https://perma.cc/8QHU-33JQ] ("The Team Europe initiative will support technology transfer and develop a number of regional manufacturing hubs in alignment with the African Union and the Africa Centres for Disease Control and Prevention.").

194. World Bank Press Release 2021/181/HD, World Bank and African Union Team Up to Support Rapid Vaccination for Up to 400 million People in Africa (June 21, 2021), https://www.worldbank.org/en/news/press-re-

The goal is to support vaccine production first for COVID-19 and then for other potentially pandemic vaccines.[195]

E. *Coordination with and Compulsion of the Private Sector*

The solutions above are based entirely on voluntary arrangements and support mapped over existing bureaucratic infrastructure at WHO. But voluntary measures may not be enough. Coercive measures may be justified in certain circumstances and are in fact provided for in existing legal instruments. For example, the TRIPS agreement permits coercive government measures under Article 31 on compulsory licenses.[196] It is important to identify and catalogue other public law measures that may be used to address intellectual property and related technical barriers to pandemic vaccine access. These public law measures are distinct from private law mechanisms, which entail the use of provisions within contracts between governments and companies, or restrictions arising from the government itself being the patent holder. Notably, domestic enforcement power varies, and the most significant leverage rests with the handful of high-income countries in which the vaccine companies are headquartered or already have sizable manufacturing operations.

i. *Public Law Mechanisms*

Most powers that governments use to expropriate or nationalize services like vaccine manufacturing require that fair

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lease/2021/06/21/world-bank-and-african-union-team-up-to-support-rapid-vaccination-for-up-to-400-million-people-in-africa [https://perma.cc/FH9T-PGRQ].

195. Press Release, Int'l Fin. Corp., IFC and Partners Support New COVID-19 Vaccine Manufacturing Facility of Institute Pasteur de Dakar in Senegal (July 9, 2021), https://pressroom.ifc.org/all/pages/PressDetail.aspx?ID=26493 [https://perma.cc/6R5T-GWZY] (describing the plan to "significantly upgrade the capacity of [Institute Paseur de Dakar]'s vaccine manufacturing facility" for COVID-19 production first, following by additional vaccines).

196. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] (in particular, note that "other use" includes "compulsory licenses," and Article 31 implicitly permits government's coercive measures regarding compulsory licenses if the enumerated provisions are not met).

compensation be provided to those affected.[197] These requirements tend to be mirrored in international obligations like TRIPS.[198] Compensation costs can be substantial, but they are small compared to the cost of the ongoing pandemic.[199] For example, the estimated total US$200 billion market value of Moderna today is still only a small fraction of the estimated US$9.2 trillion cost of vaccine inaccessibility, with at least half of that loss incurred in wealthy countries.[200] In addition, direct expropriation of otherwise protected vaccine technologies could be targeted in practice, which would limit the necessary compensation costs to those targeted losses a company faces, rather than the entire value of the company.[201]

Because legal protections for mRNA vaccines are strongest in the United States, it is also worth noting that the U.S. Defense Production Act (DPA) could be used to compel U.S.-based pharmaceutical corporations to transfer mRNA technology to mRNA technology hubs and manufacturers, including those outside of the United States.[202] As authors Zain Rizvi, Jishan Ravinthiran, and Amy Kapczynski point out, the scope of the DPA has expanded since its World War II origins to include "military or critical infrastructure assistance to any foreign nation. . . infrastructure assistance and protection. . .

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197. *See, e.g.*, Ministerial Agreement on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141, June 22, 2022 (outlining a series of "clarifications and waiver[s]" to TRIPS).

198. WTO, TRIPS and Health: Frequently Asked Questions, *Compulsory licensing of pharmaceuticals* and TRIPS, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/B8AX-96DV] (stating in the case of compulsory licensing that: "[t]he patent owner still has rights over the patent, including a right to be paid compensation for copies of the products made under the compulsory licen[s]e").

199. *Study Shows Vaccine Nationalism could Cost Rich Countries US$4.5 Trillion*, ICCWBO (Jan. 25, 2021), https://iccwbo.org/media-wall/news-speeches/study-shows-vaccine-nationalism-could-cost-rich-countries-us4-5-trillion/ [https://perma.cc/XE3F-GTNV] (noting that "a . . . $27.2 billion investment on the part of advanced economies . . . is capable of generating as high as 166x the investment").

200. *Id.* (noting that studies estimate the total cost to the world without equitable vaccination for developing economies to be between US $1.5 – 9.2 trillion, while $27.2 billion investment by advanced economies to fully capitalize the ACT Accelerator and its vaccine pillar COVAX could generate as high as 166 times the investment).

201. *Id.*

202. 50 U.S.C. § 4552 (2022).

[and] emergency preparedness activities."[203], The use of the DPA would likely trigger claims for compensation from vaccine companies, but the extent of that compensation could likely be reduced by the narrow scope of the power's use.[204] If the U.S. government only directed vaccines to populations outside of the most lucrative high-income markets, this would lessen the profit lost by these companies.[205] Similarly the reliance of affected companies, particularly Moderna, on U.S. government investment and inventions in developing their vaccines can be used to offset some of any claimed losses.[206] The specter of DPA use helped to bring about the collaboration between J&J and Merck in which J&J, did share tech know how and provide a manufacturing license to Merck.[207]

The contract which structured the U.S. government's investment in Moderna's mRNA vaccine reserved options for facilitating technology transfer was one of only two companies with which the strongest form of funding agreement was agreed.[208] Under the agreement, the government maintains (1) the right to produce the Moderna vaccine itself, (2) the right to force Moderna to license the vaccine's productions to others, and (3) rights to access Moderna's data relating to the vaccine.[209] Similar private law rights arise from the U.S. government's ownership, via the U.S. National Institutes of

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203. Rizvi et al., *supra* note 134.

204. *Id.* (stating that the claims are unlikely to succeed if the government provides "just compensation").

205. *Id.*

206. *Id.* (detailing how the government can demand more than a billion dollars in compensation from Modera for their use of key patented government technology).

207. Amy Kapczynski, *How to Vaccinate the World, Part 1*, LAW & POLITICAL ECONOMY (Mar. 30, 2021), https://lpeproject.org/blog/how-to-vaccinate-the-world-part-1/?fbclid=IWAR3NWXjgOEdt-eKMGg9fm-8D1lapHEU8EfQjdkAN0oZPmjkxa2tdi1DWiyM [https://perma.cc/RF2B-4LPL].

208. *See* James Love, *KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five using "Other Transactions Authority" that weaken or eliminate Bayh-Dole and FAR Safeguards*, KNOWLEDGE Ecology Int'l (July 1, 2020), https://www.keionline.org/covid19-ota-contracts [https://perma.cc/E3YC-ZFXH] (listing Moderna and Sanofi as the two BARDA, non OTA contract recipients); *accord* Contract No. 75A501220C00034 Development of an mRNA Vaccine for SARS-CoV-2 (Apr. 16, 2020) (on file with author) (detailing the contractual relationship between the U.S. and Moderna).

209. 35 U.S.C. §§ 203, 210(c).

Health, of a patent on prefusion coronavirus spike proteins essential for the vaccine mechanism of action of the Pfizer-BioNTech vaccines and required for Moderna's manufacture of its own vaccines.[210] Exercising these rights to expand vaccine production and access outside of the United States would certainly raise controversy and attract legal challenges.[211] But it undoubtedly would create leverage with which to compel compliance.[212]

In a similar vein, Germany's federal constitution, the Basic Law, permits expropriation, provided it is in the public interest.[213] Any such expropriation must be legislatively authorized and accompanied by fair compensation.[214] Fortunately, relevant legislative authorization already exists in the Patentgesetz (Patent Act) and the Infektionsschutzgesetz (Infection Prevention Act).[215] The Patent Act permits the state to use an invention or licens the invention to other parties when doing so is in the public interest.[216] Under the Infection Prevention Act, the Ministry of Health can, by decree, take

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210. Sheryl Gay Stolberg and Rebecca Robins, *Moderna and U.S. at Odds over Vaccine Patent Rights*, N.Y. Times, Nov. 9, 2021, https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html [https://perma.cc/45HB-59FE].

211. Kapczynski, *supra* note 207.

212. *Id.*; Kapczynski, *supra* note 207; *But see* Rachel Silverman, *Waiving Vaccine Patents Won't Help Inoculate Poorer* Nations, Wash. Post: Outlook (Mar. 15, 2021), https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/ [https://perma.cc/H7LX-GKH9] (suggesting that compulsory licensing is controversial but may facilitate partnerships).

213. Grundgesetz [GG] [Basic Law], Art. 14-15, translation at http://www.gesetze-im-internet.de/englisch_gg/index.html [https://perma.cc/WTY4-N2YX] (in particular, Art. 14(3), "[e]xpropriation shall only be permissible for the public good").

214. *Id.*

215. Patentgesetz [PatG] [Patent Act], Dec. 16, 1980, BGBl. I 1981, p. 1, revised Oct. 8 2017, BGBl. I p. 3546 (Ger.) (in particular, section 13(1), "[t]he patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare").

216. Heike Anger, *Suche nach Medikamet gegen Covid-19: Gesundhetsministerium kann Nutzung von Patenten anorden [Search for a drug against Covid-19: Ministry of Health can order the use of patents]*, HANDELSBLATT (Ger.) (Mar. 31, 2020), https://www.handelsblatt.com/politik/deutschland/coronavirus-suche-nach-medikament-gegen-covid-19-gesundheitsministerium-kann-nutzung-von-patenten-anordnen/25695508.html [https://perma.cc/CVL8-FMUY].

"Maβnahmen zur Sicherstellung der Versorgung" (measures to ensure the supply) of needed products, such as vaccines, when doing so is in the "öffentlichen Wohlfahrt" (public interest).[217]

Under these statutes, the German government may order the licensing of vaccines to other manufacturers without going through the usual compulsory licensing procedure.[218] Moreover, the government can also require their transfer of technological know-how, that would otherwise be covered by trade secrets protections.[219] Such a move would be subject to approval by German courts, which in turn would necessitate accepting that supplying vaccines internationally is within the statute's scope.[220] The courts would need to conclude that there is (1) a public interest in global vaccination that outweighs private interests in retaining control of property, and (2) that transfer of licenses and know-how is necessary for advancing the world's vaccination.[221]

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217. *Id.*; Gabriella Muscolo & Amalia Luzzati, *Pharma & COVID-19: An Overview of EU and National Case Law*, CONCURRENCES, (11 March 2021), n.31 and associated text, https://www.concurrences.com/en/bulletin/special-issues/pharma-covid-19/pharma-covid-19-an-overview-of-eu-and-national-case-law-99409-en [https://perma.cc/QW5Q-5LH6] (highlighting the Epidemic Protection Act of March 2020, "which amends the German Act on the Prevention and Control of Infectious Diseases in Humans" to give patents "no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare").

218. Gabriella Muscolo & Amalia Luzzati, *Pharma & COVID-19: An Overview of EU and National Case Law*, CONCURRENCES, (11 March 2021), n.31 and associated text, https://www.concurrences.com/en/bulletin/special-issues/pharma-covid-19/pharma-covid-19-an-overview-of-eu-and-national-case-law-99409-en [https://perma.cc/84XZ-UW3B].

219. *Id.*

220. *Id.* (examining the *Raltegravir* case (2017), in which the German Federal Supreme Court provided exactly this type of approval).

221. *See* MARIE-STELLA BIATEL, DIE ENTEIGNUNG NACH ART. 14 ABS. 3 GC UND DIE VERGESELLSCHAFTUNG NACH ART. 15 GG, Deutscher Bundestag Nr. 05/19 (May 6, 2019), https://www.bundestag.de/resource/blob/640256/7039208bc770dc873cecee22b17e06d3/Enteignung-nach-Art-14-data.pdf [https://perma.cc/4GAA-CTYJ] (reported for Deutscher Bundestag) (explaining that public interests need to be weighed more than those of an individual for any issues of eminent domain); See Code de la Santé Publique [C. San. Pub] [Public Health Code] Art. L3131-15, for France's similar but more narrow provision, which provides that the measures taken must be confined to particular territorial districts in which a state of health emergency is declared.

Germany has potential rights and real public opinion leverage over the technology developed by the company CureVac.[222] As part of a 300 million euro investment into vaccine development, Germany took a 23% ownership stake in the company.[223] CureVac also received loans from the European Investment Bank and an additional no-strings-attached grant of 252 million Euros from the German government.[224] Unfortunately the CureVac vaccine faltered in Stage III trials and its development and production has since been downsized.[225] It is unclear just how much Germany's ownership share provides it with leverage over the disposition of the real and intangible assets assembled by CureVac.[226] Regardless, CureVac should not be permitted to sit on the intellectual property and production capacity it has established so far while it waits for a more lucrative moment to return to COVID-19 vaccine production. Instead, all legal powers derived from Germany's shareholding capacity and under German public law should be used to compel and encourage wholesale intellectual property and technology transfer to the WHO mRNA hubs and manufacturers of the Global South willing to pick up from where CureVac left off.[227]

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222. *Bundesregierung beteiligt sich an Impfstoffherstellar CureVac [Federal Government takes a stake in vaccine manufacturer CureVac]*, ZEIT ONLINE (Ger.) (June 15, 2020), https://www.zeit.de/wirtschaft/unternehmen/2020-06/corona-impfstoff-curevac-bundeswirtschaftsministerium [https://perma.cc/5WMK-YVVH].

223. *Corona Impfstoff: Bundesregierung beteiligt sich an Impfstoffhersteller CureVac*, ZEIT ONLINE (June 15, 2020), https://www.zeit.de/wirtschaft/unternehmen/2020-06/corona-impfstoff-curevac-bundeswirtschaftsministerium [https://perma.cc/E7A5-NYCJ].

224. Chad P. Bown, *Don't Let CureVac's COVID-19 Supply Chain Go to Waste,* PIIE (August 9, 2021), https://www.piie.com/blogs/realtime-economic-issues-watch/dont-let-curevacs-covid-19-vaccine-supply-chain-go-waste [https://perma.cc/4CHQ-RQ6P]; Zeit Online*, supra* note 222.

225. Ludwig Burger and Patricia Weiss, *CureVac Slashes COVID-19 Vaccine Production Plans*, REUTERS (Sept. 14, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/curevac-slashes-covid-19-vaccine-production-plans-2021-09-14/.

226. ZEIT ONLINE*, supra* note 222.

227. *Cf.* Chad P. Bown, *supra* note 224 ("Repurposing the CureVac supply chain would align with [concerned governments'] approach[, and i]n exchange for their help, policymakers should obtain commitments from companies in the revamped CureVac network to allocate a hefty share of the 1 billion doses to [COVAX].").

Similar considerations apply to Sanofi's mRNA vaccine, which received positive results in trials but was abandoned by the company in September 2021 due to concerns about the commercial viability of production given the growing dominance of the Pfizer-BioNTech and Moderna vaccines.[228] This decision came after this vaccine's development was subsidized by France and other governments via $31 million in direct public funding and $4.9 billion in advance purchase agreements that minimized the risk of research.[229] Médecins Sans Frontières (MSF) has asked Sanofi to voluntarily transfer its technology, and to provide access to its logistics and already-developed supply chain to the South African WHO mRNA hub.[230] Instead of allowing the time and resources expended on developing the Sanofi vaccine to go to waste, governments should use all the legal leverage at their power to force technology transfer. As Alain Alsalhani, Vaccines and Special Projects Pharmacist at MSF's Access Campaign, has asserted,

> Considering the public funding that Sanofi received for its COVID-19 vaccine portfolio, the corporation has a responsibility to ensure that its mRNA vaccine eventually reaches people. MSF also calls on the French government, as well as other governments that funded Sanofi's research, to put pressure on the corporation to take a rational decision of sharing this technology instead of abandoning it.[231]

While the European Union does not possess an equivalent authorization statute to that of the U.S. DPA or Germany's Infection Prevention Act, the European Council does have broad powers to use "appropriate" measures when

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228. *MSF urges Sanofi to hand over abandoned mRNA vaccine candidate to WHO mRNA vaccine tech transfer hub in South Africa*, MÉDECINS SANS FRONTIÈRES (Sept. 30, 2021), https://reliefweb.int/report/world/msf-urges-sanofi-hand-over-abandoned-mrna-vaccine-candidate-who-mrna-vaccine-tech [https://perma.cc/ZM9A-VPQ].

229. Global Health Center, *COVID-19 Vaccine R&D Investments*, GENEVA GRADUATE INSTITUTE (Jul. 8, 2021), https://www.knowledgeportalia.org/covid-19-vaccine-r-d-funding [https://perma.cc/L3TJ-8GB7].

230. *MSF urges Sanofi to hand over abandoned mRNA vaccine candidate to WHO mRNA vaccine tech transfer hub in South Africa*, MÉDECINS SANS FRONTIÈRES (Sept. 30, 2021), https://reliefweb.int/report/world/msf-urges-sanofi-hand-over-abandoned-mrna-vaccine-candidate-who-mrna-vaccine-tech [https://perma.cc/V86B-Q8TX].

231. *Id.*

"severe difficulties arise in the supply of certain products."[232] The Council's Legal Service has interpreted this provision as a viable legal mechanism to compel vaccine manufacturers to share intellectual property.[233]

Several other countries could rapidly become hosts for the manufacturing of mRNA vaccines. This would likely expand the number of national governments with the ability to impose conditions. For example, Moderna is establishing prospective manufacturing sites in Australia, where the government has broad existing powers under its Biosecurity Act to issue appropriate and minimally restrictive directions needed to control the spread of COVID-19 to other countries, prevent its spread to Australia, and give effect to WHO recommendations on COVID-19.[234] Moderna's planned expansion of proprietary manufacturing facilities to Rwanda and Senegal may offer those countries similar opportunities.[235] The image below shows promising sites where these host locations may develop.

232. Consolidated Version of the Treaty of the Functioning for the European Union art. 122, Oct. 10, 2012, 2012 O.J. (C 326) 98.

233. *See* Ashleigh Furlong and Sarah Anne Aarup, Europe hints at patent grab from Big Pharma, Politico (Feb. 3, 2021), https://www.politico.eu/article/europe-patent-grab-big-pharma/ [https://perma.cc/VD8B-7VXX] ("Ever so softly, European politicians are beginning to voice a once unthinkable threat by suggesting they could snatch patents from drug companies to make up for massive shortfalls in the supply of coronavirus vaccines."); ARNOLD & PORTER, LLP, MAJOR Market Comparison of Key COVID-19 Legislation 7 (2021), https://www.arnoldporter.com/-/media/files/perspectives/publications/2021/03/major-market-comparison-of-key-covid19-legislation.pdf [https://perma.cc/U9EH-9MD8].

234. *Biosecurity Act 2015* (Cth) ss 475, 478.

235. Giselda Vagnoni and Emily Roe, *Moderna's search for African site set to intensify – chairman*, REUTERS, Oct. 12, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/modernas-search-african-site-set-intensify-chairman-2021-10-12/ [https://perma.cc/ZCE5-H7F2].

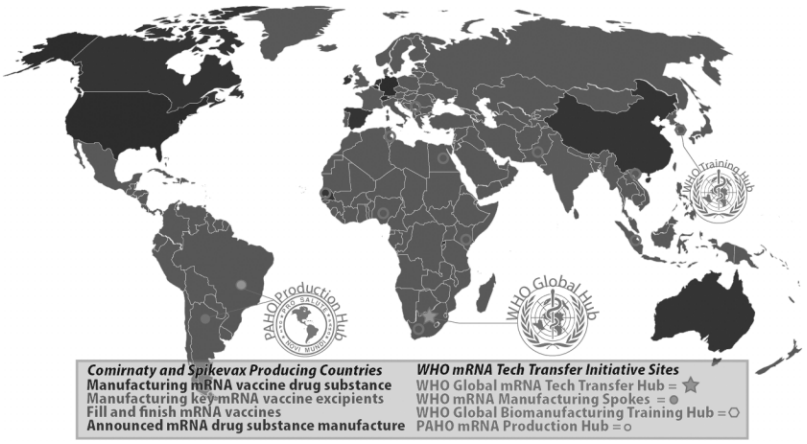

Figure 2 As of March 3, 2022: Countries with current and prospective manufacturing or fill and finish capacity for the vaccines developed by Pfizer-BioNTech and Moderna as well as the countries hosting WHO's mRNA tech transfer hub, its mRNA production spokes, its mRNA training hub, and PAHO's production hubs.[236] **Note that when a country hosts manufactures involved in multiple stages of mRNA vaccine production only the most technically advanced level is shown (drug substance > announced drug substance > vaccine excipients > fill and finish)*

Other countries with vaccine manufacturing capacity but without existing mRNA manufacturing operations that go beyond the fill-and-finish stage, such as Argentina and Indonesia, also possess powers equivalent to those of the U.S. DPA.[237]

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236. UNICEF, COVID Market Dashboard, https://www.unicef.org/supply/covid-19-vaccine-market-dashboard [https://perma.cc/AB7K-4WZF] (last visited Sept. 25, 2022) (select "Vaccines" on first top filter; then select "Capacity" on second top filter; and then select "Production Locations" under "View Options" on bottom left); Alexandra Stevenson, *These Vaccines Have Been Embraced by the World. Why Not in China?,* N.Y TIMES (Feb. 18, 2022), https://www.nytimes.com/2022/02/18/business/china-coronavirus-vaccines.html [https://perma.cc/2GPB-PMLN]; Angus Liu, *Moderna Swings Into Expansion Mode, adding 6 European Countries To Its Commercial Empire*, FIERCE PHARMA (Feb. 17, 2022), https://www.fiercepharma.com/pharma/moderna-swings-to-expansion-mode-adding-6-european-countries-to-its-mrna-vaccine-commercial [https://perma.cc/XAY6-XYS8]; Donna Lu, *Australia's mRNA vaccine deal: what does it mean, and why haven't we done it already?,* THE GUARDIAN (Dec. 14, 2021), https://www.theguardian.com/society/2021/dec/14/australias-mrna-vaccine-deal-what-does-it-mean-and-why-havent-we-done-it-already [https://perma.cc/AU2A-WQ73].

237. Nurul Barizah, *Indonesian Patent Policy on Compulsory License and Access to Affordable Medicines*, 7 EUROPEAN J. OF MOLECULAR & CLINICAL MED. 467 (2020).

In addition to the twelve announced WHO production hubs and two PAHO production hubs, trials of internally developed mRNA COVID-19 vaccines are already underway in India, China, and Thailand.[238] MSF and Access IBSA, a tricontinental project aimed at expanding access to medicines, have determined that there are at least seventeen low- and middle-income countries that can host the estimated 120 manufacturers with existing capacity sufficient for producing mRNA vaccines should suitable support and technology transfer be provided.[239] An example of efforts to provide this support include a Brazilian bill—passed by its Senate but then vetoed by the President—that allows an emergency declaration to trigger the suspension patent protection for COVID-19 vaccines and medicines, as well as permit authorities to require patent holders to transfer all needed technology for their production.[240] Granted, it is unlikely that Brazil or any other country without existing mRNA capacity could easily enforce requirements that vaccine originating companies share intellectual property, enter into licensing agreements or facilitate technology transfers.[241] They could, however, use public powers of emergency direction and expropriation provided for their under constitu-

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238. Stephanie Nolen, *Here's Why Developing Countries Can Make mRNA Covid Vaccines*, N.Y. TIMES, Oct. 22, 2021, https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html [https://perma.cc/7SM3-7XCD].

239. *See* Achal Prabhala & Alain Alsalhani, *Pharmaceutical Manufacturers Across Asia, Africa and Latin America with the Technical Requirements and Quality Standards to Manufacture mRNA Vaccines*, THE ACCESSIBSA PROJECT 2, 6–9 (Dec. 10, 2021), https://accessibsa.org/mrna/ [https://perma.cc/TZ2U-HFR7] (listing 120 manufacturers in seventeen countries that can meet "the technical requirements and quality standards to manufacture mRNA vaccines").

240. Adam Houldsworth, *Bolsonaro Vetoes Brazil's First-of-a-Kind Compulsory Tech Transfer Law*, IAM MEDIA, Sept. 03, 2021, https://www.iam-media.com/article/bolsonaro-vetoes-brazils-first-of-kind-compulsory-tech-transfer-law [https://perma.cc/V3YN-7X9Z].

241. *Cf.* Ricardo Brito, *Brazil Senate Votes to Suspend Patent Protection on COVID-19 Vaccines*, REUTERS, Apr. 29, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/brazil-senate-votes-suspend-patent-protection-covid-19-vaccines-2021-04-30 [https://perma.cc/SE5T-GRR2] (noting that it "remains unclear if lower house lawmakers will pass [a] bill" obliging patent holders "to provide authorities with all the information needed to produce COVID-19 vaccines and medicines"). In any case, Brazil law allows vaccine and medication patents to be broken in a public emergency, even if Bolsonaro vetoed some of the broader provisions.

tions and statutes to marshal resources and direct national capacity domestically and in coordination with other states. When these powers are not available in a usable form, countries should consider alternatives. A bill submitted to Congress in Argentina aims to classify vaccine production facilities as public utilities.[242] These actions could be taken even the absence of support from vaccine companies and action from their host countries.

Such powers could be used to support the WHO mRNA tech transfer initiative and its partner facilities, to ensure production, distribution, and sustainable markets for the reverse engineered Moderna COVID-19 vaccine, as well as to help establish similar initiatives elsewhere. By using these broad legal powers to marshal existing capacity and resources behind trailblazing initiatives to work around the intransigence and moral failure of global north companies and countries, a real opportunity to accelerate local production capacities could emerge. At the same time, funding and coordinating these initiatives will present vaccine companies with a credible threat that, by refusing to transfer technology in a structured way now, they will lose wholesale control over their technology. This would likely serve to further incentivize those companies to enter into voluntary licensing and supportive technology transfers, which in turn will benefit global health.

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242. *Proponen expropiar el laboratorio de Garín donde se fabrica la vacuna de AstraZeneca* [*They Propose to Expropriate the Laboratory Where the Astra Zeneca Vaccine is Manufactured*], El Litoral (Santa Fe, Argentina) (Mar. 28, 2021), https://www.ellitoral.com/nacionales/proponen-expropiar-laboratorio-garin-fabrica-vacuna-astrazeneca_0_1aDJuLFsUb.html [https://perma.cc/2LEQ-GRZ4] (reporting that a bill would be presented the following Monday that would immediately declare to be a public utility a laboratory in Argentina where the active ingredient of COVID-19 vaccines is produced, subjecting the laboratory to expropriation); ¿Y las vacunas que se iban a envasar en México? Argentina enfurece contra AstraZeneca [And the Vaccines that Were Going to be Bottled in Mexico? Argentina Becomes Infuriated with Astra Zeneca], El Financiero (Mexico City) (May 3, 2021), https://www.elfinanciero.com.mx/mundo/2021/05/03/y-las-vacunas-que-se-iban-a-envasar-en-mexico-argentina-enfurece-contra-astrazeneca/ [https://perma.cc/JKH7-SJCL] (reporting that left-wing parties had presented to Congress a bill that would declare an Argentinean laboratory that produces the active ingredient of the AstraZeneca vaccine in Buenos Aires ("mAbxience") to be a public utility).

ii. *Private Law Mechanisms*

Beyond public expropriation and related public law mechanisms, contractual approaches and private law mechanisms may also help address intellectual property barriers to greater and more widespread production of COVID-19 vaccines. Nearly all biomedical products brought to market rely on publicly funded research, even if through both direct and indirect means, and, in the specific context of COVID-19, many of the producers were beneficiaries of public-sector funding.[243] The originator vaccine companies built their mRNA vaccines for COVID-19 using generous public grants provided in 2020 to reduce the risk of their investments, and on coattails of technological developments achieved over previous decades by publicly funded researchers.[244] This not only creates an argument in favor of employing extraordinary powers of expropriation, but also means funder governments should and often do have private law rights.[245] For example, governments can assert their rights via the contractual arrangements they entered into with vaccine manufacturers and utilize their intellectual property rights they gained by developing research fundamental to today's most successful vaccines.

Pursuant to the U.S. Bayh-Dole Act of 1980, for example, inventions that receive federal funding belong to the U.S. government unless the recipients commit to commercialize the invention and agree to the government's reservation of certain

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243. NATIONAL INSTITUTES OF HEALTH, MEASURING THE IMPACTS OF FEDERAL INVESTMENT IN RESEARCH (2011) ("First, there is consistent evidence across on the importance of public sector biomedical R and D for the efficiency of private sector R and D. The evidence is compelling since it is based on a range of studies using different techniques and samples, including surveys, case studies, and econometric analyses.").

244. *See, e.g.*, Allie Clouse, *Fact Check: Moderna Vaccine Funded by Government Spending, with Notable Private Donation*, USA TODAY (Nov. 25, 2020), https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/ [https://perma.cc/TH8N-3632](discussing government support and funding for Moderna's mRNA vaccine development).

245. *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-742, INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 5 (Jul. 2009), https://www.gao.gov/products/gao-09-742 [https://perma.cc/L36K-ZFLM] (discussing the U.S. government's licensing rights and march-in authority).

rights.[246] These include rights to protect the public against non-use or unreasonable use of publicly funded inventions.[247] Making credible threats to use these powers in the absence of voluntary licensing and full-fledged technology transfers could provide leverage with respect to certain mRNA vaccine producers.[248] One point of prospective leverage lies in the government's non-transferable right to royalty free use of publicly funded inventions for or on behalf of the United States.[249] Another is a march-in right to compel patent holders to license their inventions to third parties under reasonable terms.[250]

Under the Bayh-Dole Act, march-in rights are only permissible when (1) the contractor fails to take effective steps to achieve practical application of the invention or (2) they are necessary to alleviate health or safety needs which are "not reasonably satisfied."[251] No administration or executive agency has ever used these march-in rights, and there has never been a successful petition for their use in the four decades the Act has been in existence, though their use was arguably needed and legally justified in the past.[252] Even so, present circumstances are distinguished by the serious threat inadequate vac-

246. *See* Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., 563 U.S. 776, 782-83 (2011) (highlighting that the Bayh-Dole Act seeks to foster collaboration between commercial interests and nonprofit organizations and ensure that the Government has rights in the inventions they support); *see also* Jordan Paradise, *COVID-IP: Staring Down the Bayh–Dole Act with 2020 Vision*, 7 J. L. & Biosciences 1, 6 (2020) (discussing the government's retained license and march-in rights if the contractor has not commercialized the invention in time).

247. *Id.*

248. Stephanie Nolen and Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. Times (Sept. 22, 2021, Updated Nov. 9, 2021).

249. *See, e.g.*, *Several March-in and Royalty Free Rights Cases, Under the Bayh-Dole Act*, Knowledge Ecology Int'l (last visited Sept. 23, 2022), https://www.keionline.org/cl/march-in-royalty-free [https://perma.cc/4Y7U-QNLH] (showing a 1999 NIH letter that rejected transfer of rights and clarified the U.S. government's royalty-free license for publicly funded inventions).

250. William O'Brien, Comment, *March-in Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?*, 43 Seton Hall L. Rev. 1403, 1404, 1408, 1411 (2013).

251. *Id.* at 1404.

252. *Id.* at 1404-05.

cination poses to the health and safety of people worldwide, further justifying their current use.[253]

Their use has, moreover, been recommended as a possible solution to drug pricing issues by the U.S. Department of Health and Human Services.[254] The political salience of these rights is also visible in the Biden administration's swift reversal of an executive order issued by the prior Administration which sought to forbid the use of march-in-rights in response to pricing issues.[255] The most compelling COVID-19-related case for enactment of march-in rights lies in the Moderna COVID-19 vaccine, for which clinical development was significantly funded by the U.S. government, in an effort to offset the risk of scaling up production of vaccines before their efficacy was clear.[256]

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253. *Cf.* Roger Kuan et al., *Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19,* 33(1) INTELL. PROP. & TECH. L. J. 11, 13 (2021) (noting the "robust debate around the federal government exercising march-in-rights" in the context of Covid-19 and discussing how the COVID-19 health crisis has raised the prospect of march-in rights being invoked).

254. *See* U.S. DEP'T OF HEALTH AND HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES 22 (2021), https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf [https://perma.cc/9XWM-D6RF] (noting that "HHS, NIH, and other agencies have been petitioned to take action under these provisions" in the Bayh-Doyle Act relating to march-in rights).

255. *Id.* at 22 (further noting the "Competition Executive Order, which directs the Director of the National Institute for Standards and Technology to consider not finalizing any provisions on march-in rights and product pricing in the proposed rule, 'Rights to Federally Funded Inventions and Licensing of Government Owned Inventions'").

256. Simi V. Siddalingaiah, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS (2021); Arthur Allen and Kaiser Health News, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, SCIENTIFIC AMERICAN (Nov. 18, 2020), https://www.scientificamerican.com/article/for-billion-dollar-COVID-vaccines-basic-government-funded-science-laid-the-groundwork/# [https://perma.cc/4H2E-CLSW] (highlighting the $4.94 billion spend on doses and $954 million spent in development); see also, Trump Administration Announces Framework and Leadership for 'Operation Warp Speed,' U.S. Dep't of Health & Hum. Servs. (May 15, 2020), https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html [https://perma.cc/4FDQ-ZRGF] (explaining that OWS allows for the manufacturing capacity for selected candidates to be "advanced while they are still in devel-

However, despite the careful statutory preservation of public rights in research funded by U.S. taxpayers, by structuring many of its funding contracts with original vaccine companies as "Other Transaction Agreements" (OTAs), Operation Warp Speed (OWS) exempted them from the mandatory Bayh-Dole Act terms and the Federal Acquisition Regulation (FAR). The use of OTAs—authorized under the CARES Act of 2020—is common in defense procurement, and their use in public health procurement reflects the militarized OWS process provided.[257] It is unclear what benefits the government received as a result of the use of OTAs in these circumstances.[258]

As a result, although most Bayh-Dole provisions are found in the OTAs vaccine contracts, they are subject to carve-outs, including for third-party licensing for commercial purposes, intellectual property, and data rights.[259] In addition to the substantive impact of the carve outs, the use of atypical terms rather than their well-understood FAR counterparts also gives rise to interpretative uncertainty as to the legal effect of the

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opment, rather than scaled up after approval or authorization, as is the case with traditional development timelines").

257. *See* Love, *supra* note 208 (demonstrating that the CARES Act authorized BARDA and the Department of Defense to enter into OTAs); *See also*, MOSHE SCHWARTZ & HEIDI M. PETERS, CONG. RSCH. SERV., R45521, DEPARTMENT OF DEFENSE USE OF OTHER TRANSACTION AUTHORITY: BACKGROUND, ANALYSIS, AND ISSUES FOR CONGRESS 11 (2019) (stating that the use of such agreements in defense procurement is "growing quickly and expected to continue to grow at a rapid pace"); Sidney Lupkin, *How Operation Warp* Speed's Big Vaccine Contracts Could Stay Secret, NPR (Sept. 29, 2020), https://www.npr.org/sections/health-shots/2020/09/29/917899357/how-operation-warp-speeds-big-vaccine-contracts-could-stay-secret [https://perma.cc/H274-HZZG] (explaining how the Trump administration used defense-type contracting for its vaccine program); Scott Amey, Other Transactions: Do the Rewards Outweigh the Risks?, POGO (Mar. 15 2019), https://www.pogo.org/report/2019/03/other-transactions-do-the-rewards-outweigh-the-risks [https://perma.cc/FK9X-QNM] (noting that "72 percent of the research OTA funding and 97 percent of the prototype OTA funding went to traditional DoD contractors in the late 1990s").

258. *Cf.* Schwartz and Peters, *supra* note 257, at 6-8, 15-16 (highlighting both "Potential Benefits" and uncertainty of OTAs).

259. James Love, *KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five using "Other Transactions Authority" that weaken or eliminate Bayh-Dole and FAR Safeguards*, KEI ONLINE (Jul. 1, 2020), https://www.keionline.org/covid19-ota-contracts [https://perma.cc/H29L-2SSD].

agreements.[260] The OTA contracts with Genetech, Regeneron, and Johnson & Johnson all limit march-in rights while that with BioNTech and Pfizer excludes them entirely—although in the latter case this reflects the commercial reality that development had occurred without U.S. government funding.[261]

Moderna was one of only two companies with which FAR contracts were agreed.[262] Because of this, Bayh-Dole applies to the Moderna agreement and legal options for facilitated technology transfer are reserved to the U.S. government.[263] Most specifically, FAR clauses 52.227-11 and 14 are preserved.[264][265] These preserve the U.S. government's right to use, its march-in rights, and its rights over data for one of two most effective mRNA vaccines.[266]

Under the terms of the Bayh-Dole Act, a company that licenses an invention from the federal government is required to make the resultant product, in this case a COVID-19 vaccine, 'available to the public on reasonable terms,' an obligation that includes, but is not limited to, reasonable pricing."[267] Even when a product is licensed, the government has the right to "terminate the license if the licensee fails to achieve practi-

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260. Kapczynski, *supra* note 207.

261. *See* Love, *supra* note 208 (noting that: "the Regeneron contract is redacted in such a way that the grounds for a march-in are actually a secret, which is absurd, since it is normally a right the public can use [and] [i]n the cases of the OTAs involving Genentech . . . , Johnson & Johnson, AstraZeneca . . . and the Medicines Company, the march-in rights were modified to eliminate two of the four grounds in the Bayh-Dole Act") ; *see also*, James Love, *KEI receives seven new contracts for COVID 19 research from BARDA and DOD, including five* using "Other Transactions Authority" that weaken or eliminate Bayh-Dole and FAR Safeguards, KEI Online (Jul. 1, 2020), https://www.keionline.org/covid19-ota-contracts [https://perma.cc/QTX9-9S97] (compiling COVID contracts and government use licenses showing limited or excluded march-in rights).

262. Love, *supra* note 208.

263. Contract No. 75A501220C00034 Development of an mRNA Vaccine for SARS-CoV-2 (Apr. 16, 2020) (on file with author).

264. FAR 52.227-11 (2014).

265. FAR 52.227-14 (2014).

266. 35 U.S.C. §§ 203, 210(c).

267. Kathryn Ardizzone, *License to NiH Spike Protein Needed in COVID-19 Vaccine Demonstrates "Available to the Public on Reasonable Terms" Requirement*, Knowledge Ecology Int'l (Mar. 30, 2021) https://www.keionline.org/35746 [https://perma.cc/LTJ8-2MX3].

cal application of the licensed invention" where "[p]ractical application is defined as manufacturing, operating, or practicing an invention in such a manner as 'to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[268]

These statutory and contractual mechanisms represent important tools for the government to use during public health emergencies. Rather than draft contracts that circumvent these important protections for the use of public money during emergencies, governments should prepare for their enhanced use as part of pandemic planning.

IV. Conclusion

In May 2023, the World Health Assembly will convene to consider a new international agreement that will focus on global pandemic prevention and preparedness.[269] That agreement, and all related national efforts, must address the management of intellectual property barriers erected over the course of this and the past several pandemics including conditions for open science, access, affordability, and transparency.[270] The initiatives include the U.S. governments proposed $65 billion 'Apollo' -style pandemic preparedness program,[271] Germany's pandemic preparedness,[272] and the EU

268. *Id.*

269. *World Health Assembly*, WHO, https://www.who.int/about/governance/world-health-assembly [https://perma.cc/8W2L-UHGH].

270. Gostin, Halabi & Klock, *supra* note 1.

271. Lev Facher, *The White House wants $65 billion for an 'Apollo'-style pandemic preparedness program*, STAT NEWS (Sept. 3, 2021), https://www.statnews.com/2021/09/03/biden-wants-65-billion-for-apollo-style-pandemic-preparedness-program/ [https://perma.cc/Z2JP-YX4Q]; American Pandemic Preparedness: Transforming Our Capabilities, White House, 7 (Sept. 2021), https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf [https://perma.cc/U364-UCRT](describing the goal of "Managing the Mission, with the seriousness of purpose, commitment, and accountability of the Apollo Program").

272. Caroline Copley, *Germany to build up reserve vaccine capacity to fight future pandemics*, REUTERS (Jun. 2, 2021) https://www.reuters.com/world/europe/germany-build-up-reserve-vaccine-capacity-fight-future-pandemics-2021-06-02/ [https://perma.cc/H5SA-YCVA].

Health Emergency Preparedness and Response Authority (HERA), among others.

Intellectual property, of course, is not the only issue relevant to the current response nor the only international agreement to be formed. Other work must also be done to address the most glaring examples and drivers of inequitable access to COVID-19 vaccines, including the capacity for production at the local level in Africa, South America, and Asia.[273] With such a yawning gap in access to vaccines, a situation in which excess supplies sit unused should not be permitted.[274] But even in these cases, intellectual property remains the foundation of the higher prices companies receive for boosters in the United States rather than for initial doses in poorer countries and the associated export limitations.

Intellectual property protections have imposed meaningful and material barriers to a coordinated, equitable, and rational global response. For public health emergencies, the fundamental bargains at the heart of patent and trade secret protections must give way to approaches that prioritize global public health. Adopting a broad, multilateral TRIPS waiver for WHO Blueprint Diseases, creating international infrastructure for global vaccine manufacturing capacity, replete with financial support, and leveraging the tremendous value transmitted through public funding of research are basic and straightforward tools that must be incorporated into any framework that claims global equity as part of effective pandemic preparedness.

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273. BOOSTER COVID-19 SHOTS SHOULD BE DELAYED -WHO DIRECTOR-GENERAL, REUTERS (Aug. 23, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/booster-covid-19-shots-should-be-delayed-who-director-general-2021-08-23/#:~:text=BUDAPEST%2C%20Aug%2023%20(Reuters),the%20population%20has%20been%20inoculated [https://perma.cc/XDY6-WUT7] (WHO Director-General declaring that COVID-19 booster shots should be delayed, "as priority should be given to raising vaccination rates in countries where only 1% or 2% of the population has been inoculated").

274. *See* Jane Feinmann, *How the world is (not) handling surplus doses and expiring vaccines*, 374 BMJ 2062 (2021) (detailing this exact situation).