

GIVING THE WORLD A SHOT: INCREASING  
ACCESS TO COVID-19 VACCINES BY  
EXPANDING LOCAL PRODUCTION

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*How can governments improve vaccine manufacturing for future pandemics? I argue that the COVID-19 pandemic has shown that a strong public health response requires an adequate vaccine supply in developing countries, which neither market-based allocation nor a donation-based allocation mechanism can provide. This paper analyzes various obstacles to an adequate vaccine supply in developing countries: lack of investment in research and manufacturing, coordination problems in vaccine allocation, sustainability problems with a donation-based system, the lack of local production, the need for local autonomy, and efficiency issues. I focus most on the latter dilemma, analyzing proposed solutions including a waiver of intellectual property protections, reverse engineering of existing vaccines, and the expansion of manufacturing to developing countries by current industry leaders. I argue that in order to respond effectively to future pandemics, the global community must commit to a binding allocation mechanism for vaccines, invest in and support local research and manufacturing, and ensure that technology transfer to developing country manufacturers is a condition of future advance market commitments by wealthy countries.*

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## I. INTRODUCTION

The first COVID-19 outbreak began in December 2019, with the World Health Organization (WHO) declaring COVID-19 a pandemic on March 11, 2020.<sup>1</sup> Initially compared to outbreaks of related coronaviruses like SARS and MERS, the novel coronavirus had spread much more quickly, with international cases identified within a month of the initial outbreak.<sup>2</sup> As cases rose and the world went into lockdown, so began the race to develop a vaccine.<sup>3</sup> Only six days after the pandemic was declared, the first human trial for a coronavirus vaccine began in Seattle, Washington.<sup>4</sup> By the time an American health care worker received the first dose of a coronavirus vaccine given outside a clinical trial—on December 14, 2020<sup>5</sup>—over 1.82 million people had died of the disease glob-

1. *CDC Museum COVID-19 Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 5, 2022), <https://www.cdc.gov/museum/timeline/covid19.html> [<https://perma.cc/5BMY-BCZC>].

2. Noah C. Peeri et al., *The SARS, MERS and Novel Coronavirus (COVID-19) Epidemics, the Newest and Biggest Global Health Threats: What Lessons Have We Learned?*, 49 INT'L J. EPIDEMIOLOGY 717, 717–718 (2020).

3. For an overview of six of the vaccine designs which had emerged by mid-2020, see Ewen Callaway, *The Race for Coronavirus Vaccines: A Graphical Guide*, NATURE (Apr. 28, 2020), <https://www.nature.com/articles/d41586-020-01221-y> [<https://perma.cc/N6HP-MJZV>].

4. Victoria Forster, *First Person Injected with Trial Coronavirus Vaccine in Seattle*, FORBES (Mar. 17, 2020), <https://www.forbes.com/sites/victoriaforster/2020/03/17/first-person-injected-with-trial-coronavirus-vaccine-in-seattle/?sh=2bac95722583> [<https://perma.cc/EW2M-L9WN>].

5. Luis Ferré-Sadurní & Joseph Goldstein, *Ist Vaccination in U.S. is Given in New York, Hard Hit in Outbreak's First Days*, N.Y. TIMES (Dec. 14, 2020), <https://www.nytimes.com/2020/12/14/nyregion/coronavirus-vaccine-new-york.html> [<https://perma.cc/4R5Q-843Z>].

ally,<sup>6</sup> and the highly contagious Delta variant had emerged in India.<sup>7</sup> The pandemic had also shocked the global economy; gross domestic product (GDP) declined worldwide in the worst economic downturn since the Great Depression.<sup>8</sup> The world was desperate for vaccines, but the question remained: who would get them?<sup>9</sup>

The WHO established COVAX, a global initiative to ensure that once vaccines were available, they could be distributed equitably, alongside the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance.<sup>9</sup> The initial design of COVAX invited all countries to participate in pooled advance purchases of vaccine doses, which COVAX would then allocate fairly, with wealthier countries helping to subsidize the cost of doses for poorer countries.<sup>10</sup> COVAX was only one of several mechanisms, proposed or actual, which emerged during the pandemic to address issues of disparate access to COVID-19 vaccines and expand access in developing countries.<sup>11</sup> This paper develops a taxonomy of market failures that emerged during the pandemic and discusses the various interventions to address them, in order to identify their advantages and disadvantages. Each section of

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6. WHO *Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG. (May 11, 2022), <https://covid19.who.int/> [<https://perma.cc/XHU9-MXCX>] (tracking cumulative deaths over time among other statistics).

7. Kathy Katella, *5 Things To Know About the Delta Variant*, YALE MED. (Mar. 1, 2022), <https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid> [<https://perma.cc/GUF9-BLL6>] (summarizing up-to-date information about the then-new variant).

8. Gita Gopinath, *The Great Lockdown: Worst Economic Downturn Since the Great Depression*, IMF BLOG (Apr. 14, 2020), <https://blogs.imf.org/2020/04/14/the-great-lockdown-worst-economic-downturn-since-the-great-depression>.

9. Felix Stein, *Risky Business: COVAX and the Financialization of Global Vaccine Equity*, GLOBALIZATION & HEALTH, Sept. 2021, 2.

10. MEDECINS SANS FRONTIERES ACCESS CAMPAIGN, COVID-19 VACCINE GLOBAL ACCESS (COVAX) FACILITY: KEY CONSIDERATIONS FOR GAVI'S NEW GLOBAL FINANCING MECHANISM 3 (2020), [https://msfaccess.org/sites/default/files/2020-06/MSF-AC\\_COVID-19\\_Gavi-COVAXFacility\\_briefing-document.pdf](https://msfaccess.org/sites/default/files/2020-06/MSF-AC_COVID-19_Gavi-COVAXFacility_briefing-document.pdf) [<https://perma.cc/B6B7-P6RY>].

11. See, e.g., WHO *Covid-19 Technology Access Pool*, WORLD HEALTH ORG., <https://www.who.int/initiatives/covid-19-technology-access-pool> [<https://perma.cc/42DR-BJJD>] (last visited May 22, 2023) (describing the COVID-19 Technology Access Pool, a mechanism for increasing access through voluntary IP sharing); Shayerah I. Akhtar, CONG. RSCH. SERV., R47231, WORLD TRADE ORGANIZATION: "TRIPS" WAIVER FOR COVID-19 VACCINES, 4 (2022) (describing and evaluating the TRIPS waiver adopted in June 2022).

the paper addresses a different problem that the interventions must solve to increase access to COVID-19 vaccines in the Global South.

Part II of this paper describes the need to incentivize investment in vaccine manufacturing to overcome the risk aversion of the industry. In Part III, it discusses the tendency toward vaccine hoarding and the need for coordinated vaccine procurement and distribution. Part IV then turns to the problem of inconsistent and inequitable distribution, perpetuated by a system characterized by reliance on donated vaccines. Part V evaluates proposals for increasing access in low-income countries by addressing the need for expanded local supply, concluding that the COVAX vaccine manufacturing initiative represents the best means to increase access. Part VI discusses how the need for local autonomy and recognition in scientific research influences the impact of these proposals. Part VII addresses how efficiency and timeline concerns interface with the various proposals described in this paper. Finally, Part VIII concludes with lessons for the future and remaining questions which must be answered for the world to build an equitable pandemic response.

## II. THE NEED FOR INVESTMENT IN VACCINE MANUFACTURING

The first anticipated market failure to emerge in the context of COVID-19 vaccines was the problem of underinvestment in COVID-19 research.<sup>12</sup> Years before the pandemic began, scientists had failed to find clinical trial funding for a coronavirus vaccine they had developed in response to SARS because the vaccine was completed only after the outbreak had ended.<sup>13</sup> Although the COVID-19 pandemic was ongoing and the need for vaccines was acute, competition, potential failure, and unsecured demand made pharmaceutical compa-

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12. See Elizabeth Webster et al., *The Take of Innovation Economists on the COVID-19 Crisis*, CTR. FOR ECON. & POL'Y RSCH. (May 6, 2020), <https://cepr.org/voxeu/columns/take-innovation-economists-covid-19-crisis> [<https://perma.cc/77DK-DUKS>] (explaining that the significant underinvestment in vaccine research derives from the gap between social and private rates of return on R&D and the under-consumed nature of vaccines as an economic good).

13. Arthur Allen, *How the Feds Missed Their Chance at a Coronavirus Vaccine*, POLITICO (Jan. 31, 2020), <https://www.politico.com/news/2020/01/31/coronavirus-vaccine-missed-chance-109709> [<https://perma.cc/FG3R-277V>].

nies perceive investment in coronavirus research as a risk.<sup>14</sup> Several interventions sought to address this problem, including direct funding for manufacturing, regulatory interventions, and advance market commitments.

By directly investing in manufacturing, both state and non-state actors could subsidize against failure, paying for the costs of research and capacity building. Through COVAX, the Gates Foundation invested \$150 million<sup>15</sup> in the Serum Institute of India, which makes the Covovax and Covishield vaccines.<sup>16</sup> Through Operation Warp Speed, the United States Biomedical Advanced Research and Development Authority (BARDA) invested billions in funding research and development, and increased manufacturing capacity for Moderna, Sanofi/GSK, Janssen, and Merck/IAVI's vaccine candidates.<sup>17</sup> Ninety-seven percent of funding for the Oxford/AstraZeneca ChAdOx vaccine came from the U.K. government.<sup>18</sup>

In cases where funding is less dramatically skewed than it was for the Oxford/AstraZeneca vaccine, it is more difficult to determine what role such grant funding played in incentivizing research and manufacturing. By 2021, the U.S. government had invested \$6 billion in the Moderna vaccine, including both research grants and advance purchases.<sup>19</sup> However, between 2020 and 2022 alone, Moderna's own R&D spending

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14. Stein, *supra* note 9, at 6.

15. *Gates Foundation Invests \$150 Million in COVID-19 Vaccine Production*, PHILANTHROPY NEWS DIG. (Aug. 10, 2020), <https://philanthropynewsdigest.org/news/gates-foundation-invests-150-million-in-covid-19-vaccine-production> [<https://perma.cc/JJM8-6KAB>].

16. *Covid-19: Covovax Will be Approved as Booster Dose in Next 15 days, Says Adar Poonawalla*, SCROLL (Jan. 9, 2023), <https://scroll.in/latest/1041483/covid-19-covovax-will-be-approved-as-booster-dose-in-next-15-days-says-adar-poonawalla> [<https://perma.cc/V68K-Y8FR>].

17. SIMI SIDDALINGALAH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 2 (2021).

18. Michael Safi, *Oxford/AstraZeneca Covid Vaccine Research 'Was 97% Publicly Funded'*, THE GUARDIAN (Apr. 15, 2021), <https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded> [<https://perma.cc/JS59-WEM4>].

19. Jonathan Saltzman, *The US Government Has Now Paid Moderna \$6b for Vaccine Effort*, BOSTON GLOBE (Apr. 29, 2021), <https://www.boston.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/> [<https://perma.cc/3LEY-RXAL>].

totaled over \$6 billion.<sup>20</sup> BioNTech received \$445 million from the German government as the company developed its mRNA vaccine.<sup>21</sup> Over the course of 2019 and 2020, the company spent less than a billion on all research efforts, including development of the COVID-19 vaccine.<sup>22</sup>

In addition to facilitating direct investments in manufacturing to counter the risk of failure, COVAX also provided regulatory assistance to low-income countries to ensure that they would be able to obtain approval for vaccines and prepare the necessary infrastructure for vaccine delivery, in addition to assisting with programs to combat anti-vaccine sentiment.<sup>23</sup> This intervention primarily addressed the problem of securing economic demand in developing countries, where need might be high, but regulatory problems and low ability to pay may create an uncertain market.<sup>24</sup> However, neither of these interventions addressed the problem of competition between various vaccine manufacturers, which could lead to a much smaller market share for any manufacturer. This problem, as well as the problem of uncertain demand, would be addressed by advance market commitments.

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20. MODERNA, 2022 ANNUAL REPORT 102 (2023), [https://s29.q4cdn.com/435878511/files/doc\\_financials/2022/ar/Moderna-2022-Annual-ReportvF.pdf](https://s29.q4cdn.com/435878511/files/doc_financials/2022/ar/Moderna-2022-Annual-ReportvF.pdf) [<https://perma.cc/T6SW-976J>].

21. *BioNTech Wins \$445 Million German Grant for COVID-19 Vaccine*, REUTERS (Sept. 15, 2020), <https://www.reuters.com/article/health-coronavirus-germany-vaccine/biontech-wins-445-million-german-grant-for-covid-19-vaccine-idUSKBN2661KP> [<https://perma.cc/74j5-XX8N>].

22. *BioNTech Announces Full Year 2020 Financial Results and Corporate Update*, GLOBENEWSWIRE (Mar. 30, 2021), <https://www.globenewswire.com/news-release/2021/03/30/2201363/0/en/BioNTech-Announces-Full-Year-2020-Financial-Results-and-Corporate-Update.html> [<https://www.globenewswire.com/news-release/2021/03/30/2201363/0/en/BioNTech-Announces-Full-Year-2020-Financial-Results-and-Corporate-Update.html>, archived at <https://perma.cc/SQ7U-G4KK>].

23. Anna Rouw et al., *COVAX and the United States*, KAISER FAM. FOUND. (Feb. 18, 2021), <https://www.kff.org/coronavirus-covid-19/issue-brief/covax-and-the-united-states/> [<https://perma.cc/H49M-LKTT>].

24. See RUTH LEVINE ET AL., CTR. FOR GLOB. DEV., *MAKING MARKETS FOR VACCINES: IDEAS TO ACTION* 14 (2020), <https://www.cgdev.org/sites/default/files/archive/doc/books/vaccine/MakingMarkets-complete.pdf> [<https://perma.cc/6WPY-7NV3>] (discussing economic conditions and procurement policies in developing countries which result in low revenues for pharmaceutical producers).

By securing a specific volume of doses in advance at a decided price, advance market commitments guaranteed that regardless of competition or demand problems, manufacturers could expect a certain amount of revenue.<sup>25</sup> Advance market commitments took the form of both multilateral agreements through COVAX and bilateral agreements between specific governments and manufacturers.<sup>26</sup> In each case, advance market commitments further lowered the risk of investment in vaccine manufacturing by addressing both competition and failure. For example, given the costs Moderna faced in its vaccine development, any losses would have been difficult to recover with grant funding alone if their vaccine candidate had failed.<sup>27</sup> Advance market commitments may therefore have served as an additional incentive—perhaps a necessary one—to induce pharmaceutical companies to risk their own funds in the pursuit of a vaccine. That said, it is difficult to parse which risks pharmaceutical companies might have taken if advance market commitments or public funding had been attached to other equity-based conditions.

### III. COORDINATION PROBLEMS IN PROCUREMENT AND DISTRIBUTION

Given the precedent of the 2009 influenza pandemic, in which vaccine hoarding by wealthy countries led to inequities in the global burden of disease, the organizations comprising the COVAX partnership were eager to facilitate a system of equitable procurement and distribution with sustainable financing and allocation driven by health needs.<sup>28</sup> The COVAX Advance Market Commitment theoretically allowed participat-

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25. See *The Gavi COVAX AMC Explained*, GAVI, THE VACCINE ALL. (Feb. 15, 2021), <https://www.gavi.org/vaccineswork/gavi-covax-amc-explained> [<https://perma.cc/6RBT-D843>] (discussing the goal of COVAX to create volume guarantees for manufacturers).

26. *Id.*; Nicholson Price et al., *COVID-19 Vaccine Advance Purchases Explained*, BILL OF HEALTH (Aug. 11, 2020), <https://blog.petrieflom.law.harvard.edu/2020/08/11/covid19-vaccine-advance-purchases-explained/> [<https://perma.cc/CNX8-KHB3>].

27. See *supra* notes 19–20 and accompanying text (discussing Moderna’s financing of R&D relative to state grants).

28. See Thomas J. Bollyky, Lawrence O. Gostin & Margaret A. Hamburg, *The Equitable Distribution of COVID-19 Therapeutics and Vaccines*, 323 J. AM. MED. ASS’N 2462, 2462 (2020) (explaining the problem of vaccine hoarding during the 2009 influenza pandemic).

ing countries to engage in pooled procurement of vaccine doses through a tiered pricing model, under which wealthier countries could subsidize the cost of vaccines for poorer countries.<sup>29</sup> By teaming up with higher-income countries, low-income countries which would typically be less competitive purchasers could acquire greater leverage with manufacturers. In addition, by purchasing together, countries could collectively drive prices down for all parties.<sup>30</sup>

However, each of these advantages—subsidizing low-income countries, lowering prices, and incentivizing investment—depended on adequate participation from wealthy countries. Low-income countries were likely to participate in an agreement which would allow them to purchase more doses than they could otherwise afford. Although wealthy countries had the resources to pursue bilateral deals, the COVAX partners hoped they would participate to insure against failure if the bilateral deals they made with pharmaceutical companies did not produce effective vaccines.<sup>31</sup>

In practice, however, several flaws in this model emerged. One was the need for coordination among many actors; countries which were desperate to secure doses and which could negotiate their own agreements were unlikely to engage in pooled procurement through COVAX.<sup>32</sup> Another problem was the lack of significant incentives for wealthy countries and pharmaceutical manufacturers to participate in a system that depended on their buy-in. In part due to COVAX's policy cap-

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29. See Stein, *supra* note 9, at 4–5; see also Kenneth Shadlen, *12 Days of Global Health: Power and the reproduction of global inequalities*, GLOB. HEALTH LSE (Dec. 14, 2020) (discussing the planned functioning of COVAX and its contrast with the reality of vaccine procurement, and later acknowledging weaknesses in practice), <https://blogs.lse.ac.uk/globalhealth/2020/12/14/12-days-of-global-health-power-and-the-reproduction-of-global-inequalities/> [<https://perma.cc/8JZ4-SCS2>].

30. Stein, *supra* note 9, at 5.

31. David McAdams et al., *Incentivising wealthy nations to participate in the COVID-19 Vaccine Global Access Facility (COVAX): a game theory perspective*, BMJ GLOBAL HEALTH, Nov. 2020, at 3, <https://gh.bmj.com/content/5/11/e003627> [<https://perma.cc/5Q9F-XRME>] (arguing that COVAX could be valuable to wealthy countries “as an insurance policy”).

32. Shadlen, *supra* note 29 (highlighting countries which negotiated bilateral agreements in order to acquire more doses and choose from a variety of vaccines, and arguing that this weakened COVAX as a pooled procurement mechanism).



ping vaccine purchases at twenty percent of the population per country—which was later increased to fifty percent—wealthy countries purchased large supplies of vaccines for themselves, depleting the supplies available for COVAX.<sup>33</sup> Countries like the United States and the United Kingdom, which could afford to make bilateral agreements directly with pharmaceutical companies, secured hundreds of millions of doses via advance market commitments by mid-August 2020.<sup>34</sup> Negotiating bilateral agreements allowed these countries to ensure coverage for a greater percentage of their populations, and to do so quickly—an important advantage given the speed of the pandemic’s spread. Wealthy country governments had strong political incentives to choose self-interest, with leaders seeking the favor of their constituents at a time of crisis.<sup>35</sup> Relative to a system in which individual members of a country acquired doses based on their personal ability to pay, a bilateral advance market commitment still ensured that vaccines could be more equitably distributed within a country’s population.<sup>36</sup> Pharmaceutical companies also had no incentives to sell to COVAX specifically, and were willing to sell to the highest bidder.<sup>37</sup> COVAX lacked the power and resources to compete

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33. SIDDALINGALAH, *supra* note 17, at 2 (noting that through Operation Warp Speed the US contracted to purchase 300 million doses of the Moderna vaccine and 300 million doses of the Pfizer/BioNTech vaccine, numbers far exceeding twenty or even fifty percent of the U.S. population).

34. See Ewen Callaway, *The unequal scramble for coronavirus vaccines — by the numbers*, NATURE (Aug. 24, 2020), <https://www.nature.com/articles/d41586-020-02450-x> [<https://perma.cc/R6XE-RV7M>] (explaining that the United States secured 800 million and the United Kingdom 340 million doses of various vaccines by mid-August).

35. See Sigal Samuel, *The US should give away its vaccine doses. Now.*, VOX (May 15, 2021), <https://www.vox.com/future-perfect/22432536/biden-donate-vaccine-doses-india-brazil> [<https://perma.cc/T4E3-LP38>] (explaining that the United States engaged in vaccine nationalism and prioritized its interests).

36. See generally ALAN HO & JAKE TAYLOR, USING ADVANCE MARKET COMMITMENTS FOR PUBLIC PURPOSE TECHNOLOGY DEVELOPMENT (2021), <https://www.belfercenter.org/publication/using-advance-market-commitments-public-purpose-technology-development> [<https://perma.cc/Y99T-EH5P>] (explaining the concept of advance market commitment).

37. See Stephanie Nolen & Rebecca Robbins, *Vaccine Makers Kept \$1.4 Billion in Prepayments for Canceled Covid Shots for the World’s Poor*, N.Y. TIMES (Feb. 1, 2023), <https://www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html> [<https://perma.cc/VFT9-UY9E>] (explaining

with wealthy country purchasers in the marketplace, forcing developing countries to make do with leftover doses.<sup>38</sup>

However, compared to payers in multilateral agreements, bilateral purchasers were more likely to pay more. For example, while COVAX paid \$10 per dose of the Moderna vaccine, the United States paid \$15.<sup>39</sup> Some may argue that for the wealthiest countries, higher prices are an acceptable trade-off that more accurately reflects the value of vaccines to society and rewards manufacturers accordingly, maintaining strong incentives for socially beneficial innovation.<sup>40</sup> However, this argument is less applicable to less wealthy countries; for example, the price of the Moderna vaccine for Colombia was \$30 per dose, despite a lesser ability to pay.<sup>41</sup> Bilateral agreements may therefore decrease the leverage poor countries have to demand doses at better prices.

#### IV. EQUITY AND CONSISTENCY IN VACCINE DISTRIBUTION

As COVAX struggled with procurement, another component of its model grew in importance: vaccine donations, which, by 2021, comprised sixty percent of the doses distributed by COVAX.<sup>42</sup> Given the need for multiple doses of vaccines, the potential for doses to expire, and the need for doses

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that pharmaceutical companies prioritized selling doses to high-income countries and initially shut COVAX out of the market).

38. *Id.* (noting that through Gavi, COVAX eventually contracted with nine manufacturers, though low-income countries did not receive a significant number of doses until 2021).

39. See Darcy Jimenez, *Covid-19: vaccine pricing varies wildly by country and company*, PHARM. TECH. (Oct. 26, 2021), <https://www.pharmaceutical-technology.com/features/covid-19-vaccine-pricing-varies-country-company/> [<https://perma.cc/GPJ7-PZW2>] (supporting that the United States paid \$15 for Moderna vaccine).

40. See Lisa Ouellette et al., *What role should governments play in setting rewards for medical innovation?*, 11 N.Y.U. J. INTELL. PROP. & ENT. L.J. 1, 3 (2021) (presenting an argument for greater financial rewards for socially beneficial innovation).

41. See Jimenez, *supra* note 39 (highlighting Colombia as an example of a less wealthy country that paid high prices for vaccines).

42. See Antoine de Bengy Puyvallée & Katerini Tagmatarchi Storeng, *COVAX, vaccine donations and the politics of global vaccine inequity*, GLOBALIZATION & HEALTH, Mar. 2022, 4, <https://globalizationandhealth.biomedcentral.com/counter/pdf/10.1186/s12992-022-00801-z.pdf> [<https://perma.cc/4RFJ-WSND>] (explains the impact of vaccine donations in COVAX's global vaccine procurement mechanism).

to be kept under cold-chain conditions, ensuring a consistent supply proportional to need was crucial for distribution of donated vaccines. In order to address this problem, COVAX created an allocation mechanism to manage competing demands among participating countries and decide which countries should receive particular doses at what times.<sup>43</sup> In theory, a global allocation mechanism could contribute to equity, allocating doses according to need rather than ability to pay. However, COVAX's inherent reliance on donated doses reduced the effectiveness of its allocation system, as only a small fraction of doses arrived on time.<sup>44</sup> At times, recipient countries were forced to allocate initial doses without knowing when a second dose would arrive.<sup>45</sup> Delayed donations also led to waste, as vaccines arrived on the verge of expiration and low-income countries were forced to reject millions of doses.<sup>46</sup> In some countries, where under twenty percent of the population was fully vaccinated after waiting for over a year for vaccine doses, governments received such a rapid influx of doses that the local distribution system was overwhelmed and had to pause accepting donations.<sup>47</sup>

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43. See Allocation logic and algorithm to support allocation of vaccines secured through the COVAX Facility, WORLD HEALTH ORG. (2021), <https://www.who.int/publications/m/item/allocation-logic-and-algorithm-to-support-allocation-of-vaccines-secured-through-the-covax-facility> [https://perma.cc/L5RZ-M92A], at 3–4 (describing the steps and algorithm of COVAX's allocation mechanism).

44. See Sigal Samuel, *Why Covax, the fund to vaccinate the world, is struggling*, Vox (May 20, 2021), <https://www.vox.com/future-perfect/22440986/covax-challenges-covid-19-vaccines-global-inequity> [https://perma.cc/LUU9-V84P] (discussing problems stemming from donation of excess doses, and pointing out that five months into 2021, COVAX was only 3.4% of the way to its allocation goal for the year).

45. See Press Release, Economic and Social Council, Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting, U.N. Press Release ECOSOC/7039 (Apr. 16, 2021) (recounting Director-General Tedros's reference to countries not receiving and being able to allocate second doses on time).

46. Francesco Guarascio, *Poorer Nations Reject Over 100 Mln COVID-19 Vaccine Doses as Many Near Expiry*, REUTERS (Jan. 14, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/more-than-100-million-covid-19-vaccines-rejected-by-poorer-nations-dec-unicef-2022-01-13/> [https://perma.cc/Z78X-5BG7].

47. Dave Lawler, *44 Countries Have COVID Vaccination Rates Under 20% Despite Supply Increase*, AXIOS WORLD (Mar. 31, 2022), <https://www.axios.com>.

As an allocation mechanism, COVAX failed to meet its targets. By the end of 2021, COVAX had only distributed half of the two billion doses it had hoped to deliver.<sup>48</sup> While the United States has promised 900 million doses to COVAX, as of April 2022 only twenty-six percent of those doses have arrived.<sup>49</sup> As of 2023, only thirty-six percent of the population in the African region has been even partially vaccinated, compared to eighty-one percent in the region of United States and Canada.<sup>50</sup>

Under COVAX's vaccine distribution model, most doses pledged and shipped have come from the United States and European Union.<sup>51</sup> For low-income countries, particularly those with a colonial history, relationships with wealthy countries are already defined by a dynamic of donor-and-recipient.<sup>52</sup> Although the donated doses are needed, this relationship of reliance can entrench existing inequalities of power and resources, even as one country seems to aid the other.<sup>53</sup> The difference between countries which can afford massive advance purchases, like the United States, and those relying on donated doses is stark; in the former, presence in the country

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com/countries-vaccination-rates-under-20-percent-46966a29-e459-43b9-a3fe-942855263652.html [https://perma.cc/259H-SJAE].

48. See Gavi, the Vaccine Alliance, *COVAX – 1 Billion Doses Delivered*, YOUTUBE (Jan. 15, 2022), <https://www.youtube.com/watch?v=87D676W6XOU> [https://perma.cc/JNE6-7NPX] (noting COVAX delivered one billion vaccine doses by January of 2022); Gavi, the Vaccine Alliance, *First COVAX Deliveries and Campaigns Begin*, YOUTUBE (Mar. 9, 2021), <https://www.youtube.com/watch?v=0mFnQEY8MeQ> [https://perma.cc/NJT2-GJA7] (detailing that COVAX secured over two billion vaccine doses at the start of 2021).

49. *COVID-19 Vaccine Doses Donated to COVAX*, OUR WORLD IN DATA (Mar. 23, 2022), <https://ourworldindata.org/grapher/covax-donations?country=FRA~ESP~SWE~USA~CAN~NOR~NZL~GBR~DNK~CHE~ITA~DEU~PRT~ARE~BEL~European+Union~JPN~NLD~FIN~HKG~IRL> [https://perma.cc/XJB9-5MU3].

50. Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES, <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> [https://perma.cc/44W7-KH68] (last updated Mar. 13, 2023).

51. OUR WORLD IN DATA, *supra* note 49.

52. See Johanna T. Crane, *Scrambling for Africa* 111 (2013).

53. *Id.* at 112 (arguing that “the entanglement of research with development makes it especially difficult for U.S. and Ugandan physicians and researchers to forge the kind of equitable scientific collaborations to which they all aspire”).

confers early access to vaccinations, while in the latter, the population must rely on what anthropologist Vinh-Kim Nguyen has termed “therapeutic citizenship,” or the benefits and responsibilities conferred by treatment programs and other authorities (such as COVAX or foreign governments) in the place of the state.<sup>54</sup> For legal citizens of a state, this means that rather than acquiring access to vaccines through their rights as citizens, they must depend on the will of donor countries.<sup>55</sup> The result is an injury to national sovereignty and to the strength of the relationship between citizens and the state.

The imbalance in power between donor and recipient countries also creates risks of abuse, especially when donor countries can sidestep COVAX’s allocation system altogether. In December 2021, meetings between U.S. officials and the governments of Myanmar and Taiwan suggested that the United States might be circumventing COVAX to earmark doses for specific countries as a tool of diplomatic leverage.<sup>56</sup> European countries have also chosen to earmark doses for particular countries themselves rather than rely on COVAX’s allocation mechanism, creating logistical hurdles for COVAX and delaying donations.<sup>57</sup> In at least one case, a politically-canny

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54. See Vinh-Kim Nguyen et al., *Adherence as therapeutic citizenship: impact of the history of access to antiretroviral drugs on adherence to treatment*, 21 AIDS S31, S34 (2007) (coining and defining the term “therapeutic citizenship,” while detailing that individuals living with HIV in countries with inadequate public health infrastructure often rely on donor programs for essential antiretroviral drugs); see also Carrie Kahn, *Some Mexicans Travel to U.S. for COVID Vaccines as Their Country’s Rollout Stumbles*, NPR (Mar. 26, 2021), <https://www.npr.org/2021/03/26/981548822/some-mexicans-travel-to-u-s-for-covid-vaccines-as-their-countrys-rollout-stumble> [<https://perma.cc/65CP-YGU8>] (clarifying that often presence in a country, not mere citizenship, could confer access to vaccines, as undocumented immigrants and tourists could be vaccinated in the U.S.).

55. See Miriam Ticktin, *Medical Humanitarianism in and Beyond France: Breaking Down or Patrolling Borders?*, in *MEDICINE AT THE BORDER* 116, 116 (Alison Bashford ed., 2007) (describing France’s humanitarian “illness clause” which permitted unauthorized immigrants with critical maladies to remain in the country if receiving sufficient medical care their country of citizenship was unattainable).

56. Erin Banco, *‘It’s a sore spot’: Why officials are raising questions about Biden’s vaccine donations*, POLITICO (Dec. 8, 2021), <https://www.politico.com/news/2021/12/08/biden-administration-officials-questions-vaccine-donations-523922> [<https://perma.cc/Z6WQ-GSC4>].

57. Puyvallée & Storeng, *supra* note 42.

announcement of vaccine donation doses to Taiwan by U.S. senators bypassed the U.S. State Department and USAID donation task force entirely.<sup>58</sup> If used as a diplomatic tool to maintain control over developing nations, national vaccine donation programs would be obviously neocolonialist, using an inequity in resources to deepen inequities in political power.

## V. THE NEED FOR INCREASED LOCAL SUPPLY

A lack of local production has left the supply of vaccines in developing countries insecure, leading to a reliance on inconsistent donations. Developing countries, along with the WHO, have suggested that empowering nations in the Global South to make their own vaccines would solve problems with inconsistent local supply, in addition to addressing unequal power dynamics.<sup>59</sup> However, local production requires a significant investment in resources, and remains controversial as a solution.<sup>60</sup> Furthermore, both the leading manufacturers in wealthy countries and local manufacturers in developing coun-

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58. See *U.S. Senators Promise COVID-19 Vaccines For Taiwan Amid China Row*, NPR (June 6, 2021), <https://www.npr.org/2021/06/06/1003725907/us-senators-promise-vaccines-for-taiwan-amid-china-row> [<https://perma.cc/A7Y9-XPUJ>] (reporting that three U.S. Senators promised 750,000 doses to Taiwan during a congressional delegation visit).

59. See S. Ctr., *Proposal by India and South Africa to Waive Certain Provisions of the WTO TRIPS Agreement to Support the Global COVID-19 Pandemic Response (2020)*, <https://www.southcentre.int/wp-content/uploads/2020/11/Note-on-India-SA-proposal-waiver-TRIPS.pdf> [<https://perma.cc/Z6J4-YGEC>] (stating support for a proposal to allow local manufacturing on behalf of 54 developing countries); see also Sarah Boseley, *WHO chief: waive Covid vaccine patents to put world on war footing*, *The Guardian* (Mar. 5, 2021), <https://www.theguardian.com/world/2021/mar/05/covid-vaccines-who-chief-backs-patent-waiver-to-boost-production> [<https://perma.cc/PD6R-2JAA>] (describing Director-General Tedros's support for local manufacturing).

60. See Ludwig Burger, *BioNTech to ship mRNA vaccine factory kits to Africa*, *REUTERS* (Feb. 16, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/biontech-ship-mrna-vaccine-factory-kits-africa-2022-02-16/> [<https://perma.cc/C4US-4S3A>] (describing the manufacturing process as complex and requiring 50,000 steps); see also *COVID vaccine donations matter more than waivers, EU leaders say*, *AL JAZEERA* (May 7, 2021), <https://www.aljazeera.com/economy/2021/5/7/covid-vaccine-donations-matter-more-than-waivers-eu-leaders-say> [<https://perma.cc/LK6M-VX46>] (discussing arguments by several government leaders favoring donations over local production).

tries believe they should be the ones to lead production of vaccines in the region.<sup>61</sup>

#### A. *History of Local Production*

Long before the WHO declared the COVID-19 outbreak a global pandemic on March 11, 2020, WHO member states had been exploring ways to increase local production of pharmaceuticals around the world.<sup>62</sup> Following WHO's designation in 1977 of 186 drugs as "essential medicines" under the leadership of Director-General Mahler, member states endorsed local production at the International Conference on Primary Health Care in 1978, in addition to adopting the Declaration of Alma-Ata, which labeled health a human right.<sup>63</sup> Over the next few decades, developing countries continued to push for policies that could expand regional production of medicines, both inside and outside WHO.<sup>64</sup> In 1982, member states adopted the WHO Action Programme on Essential Drugs, which included local production as one component.<sup>65</sup> At the World Trade Organization (WTO), developing countries secured the Doha Declaration on TRIPS and Public

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61. See Sara Jerving, Moderna's patents stand in way of mRNA vaccine hub's grand vision, DEVEX (Apr. 21, 2022), <https://www.devex.com/news/moderna-s-patents-stand-in-way-of-mrna-vaccine-hub-s-grand-vision-103055> [<https://perma.cc/5XJF-L35N>] (describing Moderna CEO's Bancel's claim that working with African manufacturers was not a good use of the company's time); see also Andrew Meldrum & Carley Petesch, *South African firm to make Pfizer vaccine, first in Africa*, AP NEWS (July 21, 2021), <https://apnews.com/article/africa-business-health-government-and-politics-coronavirus-pandemic-3367836b55c4dd0fa86d1c6c4cc321cc/> [<https://perma.cc/VQL4-K227>] (describing criticism of Pfizer's manufacturing expansion to Africa as insufficient because it does not enable independent manufacturing on the continent).

62. See *infra* notes 63–67 (describing WHO member states' efforts to increase local production prior to the pandemic).

63. See Jeremy A. Greene, *When did medicines become essential?*, 88 Bulletin World Health Org. 483, 483 (2010) (recounting the international discussions which resulted in the emergence of essential medicines as a global health priority); World Health Organization & United Nations Children's Fund International Conference on Primary Health Care, *Declaration of Alma-Ata*, art. 2 (September 1978).

64. See *infra* notes 65–67 (describing these policies).

65. WORLD HEALTH ORG., THE USE OF ESSENTIAL DRUGS 13 (1983), <https://www.who.int/publications/i/item/9241206853> [<https://perma.cc/4KZ5-TFBG>].

Health in 2001, reaffirming the ability of signatories to the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights to issue “compulsory licenses” on patented pharmaceuticals when required by the public interest.<sup>66</sup> In 2008, member states adopted the Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property, which highlighted the need for local production under its third element, “building and improving innovation capacity.”<sup>67</sup>

Despite being driven by a commonsense logic, the assumption that local production is critical for improving access to medicines and empowering developing countries is far from a truism. The choice of local production may depend on whether it is the best means to increase access to medicines, whether it is feasible for an adequate number of countries in the Global South, and whether it could have inadvertent negative effects on innovation.<sup>68</sup> Local production may have varying impacts on different components of access, including affordability, geographic availability, actual use, and quality of medicines and vaccines.<sup>69</sup> Notably, local production can have

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66. Dianne Nicor & Olasupo Owoeye, *Using TRIPS flexibilities to facilitate access to medicines*, 91 BULLETIN WORLD HEALTH ORG. 533 (2013).

67. WORLD HEALTH ORGANIZATION, OVERALL PROGRAMME REVIEW OF GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY 10–11 (2011), <https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/review-gspa> [<https://perma.cc/LGX4-59G7>].

68. *See, e.g.*, WARREN KAPLAN & RICHARD LAING, LOCAL PRODUCTION OF PHARMACEUTICALS: INDUSTRIAL POLICY AND ACCESS TO MEDICINES 25 (2005), <https://medeor.de/images/themen/konferenz/KaplanLocalProductionFinal5b15d.pdf> [<https://perma.cc/6PAU-NB9M>] (arguing that “only a few developing and transitional economy countries” have sufficient industrial capacity to make local production feasible, and questioning whether it is possible to produce medicines locally “that will be competitive on the open market”).

69. *See* M. Ewen et al., *Prices and availability of locally produced and imported medicines in Ethiopia and Tanzania*, J. PHARM. POL. & PRAC., 2017, 6–7, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5242052/pdf/40545\\_2016\\_Article\\_95.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5242052/pdf/40545_2016_Article_95.pdf) [<https://perma.cc/58Q7-JX8G>] (reviewing mixed findings in empirical research on the relationship between local production and price or availability of medicines); *see also* Warren A. Kaplan et al., *Local production of medical technologies and its effect on access in low and middle income countries: a systematic review of the literature*, 4 S. MED. REV. 51, 55–56 (2011) (summarizing theoretical and empirical work on local production and access to medical products).



mixed results with respect to price, and importing generic drugs can sometimes be more affordable than producing them domestically.<sup>70</sup> The little empirical evidence available indicates that local production may have some positive effects on supply, yet typically a negative effect on quality; in other cases local production reduced doctor and patient acceptance, and the relationship between local production and expanding innovation capacity is unclear.<sup>71</sup> However, if there were high standards for quality control established through oversight, a reliable supply (implicating the factors of availability and accessibility) could become more useful. As a result, regional manufacturing may still be the best means of improving access during a pandemic in which the consistent global supply has fallen far short of need.<sup>72</sup>

### B. *TRIPS Waiver*

One intervention to increase local production was proposed in October 2020, when India and South Africa introduced a proposal to the WTO for a waiver of certain intellectual property provisions under the TRIPS Agreement.<sup>73</sup> Under the proposal, which quickly garnered the support of developing countries, these provisions would be waived where necessary to “contain, prevent, and treat” COVID-19.<sup>74</sup>

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70. M. Ewen et al., *supra* note 69 at 6–8 (reviewing survey results showing imported generics to be cheaper than local products for patients in Ethiopia and Tanzania, due in the former case to government procurement costs and in the latter case to government mark-ups).

71. Kaplan et al., *supra* note 69 at 54–56.

72. See Amy Maxmen, *The fight to manufacture COVID vaccines in lower-income countries*, 597 NATURE 455, 455 (2021), <https://www.nature.com/articles/d41586-021-02383-z> [<https://perma.cc/2V7R-FZCT>] (noting extremely low levels of full vaccination in low-income and lower-middle-income countries relative to wealthy countries).

73. Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter TRIPS Waiver Proposal].

74. *Id.*; see also Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Jordan, Kenya, the LDC Group, Malaysia, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe WTO Doc. IP/C/

WTO member states have battled over the scope of a potential waiver.<sup>75</sup> Initially, the proposed waiver was: to include a wide range of intellectual property, including trade secrets and other proprietary information; to cover vaccines, treatments, and diagnostics; and to apply to all low and middle income countries (LMICs).<sup>76</sup> A leaked draft of text representing a compromise between the sponsoring countries, the United States, and the European Union proved controversial for limiting the waiver to patents on vaccines for developing countries only.<sup>77</sup> Such a waiver would exclude much of the intellectual property most relevant for making mRNA vaccines, for which trade secrecy and know-how represent a more significant barrier than patents, and would also exclude many countries which have low vaccination rates but the capacity to make their own vaccines.<sup>78</sup>

A waiver with wider scope could have several advantages. First, the threat of implementing the waiver could give national governments increased leverage in negotiations with vaccine manufacturers, encouraging them to share informa-

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W/684 (Sept. 30, 2021) (summary of TRIPS Waiver Proposal co-sponsors' interventions).

75. See Peter Ungphakorn, *8 reasons why countries disagree over a WTO intellectual property waiver*, TRADE BETA BLOG (Feb. 22, 2022), <https://tradebetablog.wordpress.com/2022/02/22/8-reasons-waiver/> [<https://perma.cc/YMS8-R7C3>] (discussing the positions of various countries and points of disagreement).

76. See MEDECINS SANS FRONTIERES ACCESS CAMPAIGN, WTO COVID-19 TRIPS WAIVER PROPOSAL: MYTHS, REALITIES AND AN OPPORTUNITY FOR GOVERNMENTS TO PROTECT ACCESS TO LIFESAVING MEDICAL TOOLS IN A PANDEMIC I (2020), [https://msfaccess.org/sites/default/files/2020-12/MSF-AC\\_COVID\\_IP\\_TRIPSWaiverMythsRealities\\_Dec2020.pdf](https://msfaccess.org/sites/default/files/2020-12/MSF-AC_COVID_IP_TRIPSWaiverMythsRealities_Dec2020.pdf) [<https://perma.cc/NL2M-324H>] (stating that proposed waiver included four categories of IP rights: copyright, industrial designs, patents and undisclosed information).

77. See *WTO Text Would Undermine Global Access to Medicines*, PUB. CITIZEN (May 20, 2022), <https://www.citizen.org/article/leaked-wto-proposal-is-not-the-covid-19-medicines-waiver-we-need/> [<https://perma.cc/4PL7-NSTF>] (criticizing the limitations of the leaked draft).

78. See SEAN FLYNN ET AL., NON-PATENT INTELLECTUAL PROPERTY BARRIERS TO COVID-19 VACCINES, TREATMENT AND CONTAINMENT, 12–13 (2021) (highlighting the importance of trade secrecy as an intellectual property barrier to accessing COVID-19 vaccines); see also David Gindler & Jasper L. Tran, *COVID-19, Patents, and Trade Secrets*, BILL OF HEALTH (June 22, 2022), <https://blog.petrieflom.law.harvard.edu/2022/06/22/covid-19-patents-and-trade-secrets/> [<https://perma.cc/VQ9J-ZEYR>] (criticizing a perceived focus on patents as opposed to trade secrecy in the waiver debate).

tion voluntarily.<sup>79</sup> Second, the waiver could grant local manufacturers broad freedom to operate by clarifying areas of legal ambiguity and disrupting intellectual property barriers along the supply chain.<sup>80</sup> A waiver could also grant broader freedom to policymakers who would like to take other measures to compel technology transfer without falling afoul of international law. Finally, a waiver could represent global political recognition of the role governments have already played in subsidizing and funding vaccine development, and an assertion that, under the right circumstances, global health priorities surpass concerns about industry intellectual property protections.<sup>81</sup>

To those who understand COVID-19 vaccine development as an intellectual property success story, however, this policy would make little sense. Assuming vaccine development was driven by intellectual property incentives, a waiver could punish companies for their success, disincentivizing companies from investing during future emergencies.<sup>82</sup> Many high-income countries see strong intellectual property protection as critical to a strong science sector and a precondition for industry success, despite also providing significant funding to the industry. For example, Germany—a strident opponent of a broad waiver, and home to BioNTech—provided the company with \$445 million USD in funding for COVID-19 vaccine research.<sup>83</sup> According to this perspective, however, the promise

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79. See Siva Thambisetty et al., *Addressing Vaccine Inequity During the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond*, 81 *CAMBRIDGE L.J.* 384, 406 (2022) (noting that proposals for a TRIPS waiver have led to positive impacts including increased transparency about manufacturing and pricing as well as cooperation in voluntary deals).

80. *Id.* at 385 (“If adopted [the waiver] would provide companies the freedom to operate and to produce COVID-19 vaccines . . . without the fear of infringing another party’s IP rights and attendant threat of litigation”).

81. See *id.* at 415–16 (suggesting that the waiver debate alone may result in long-lasting “material developments . . . such as expanding the number of Medicines Patent Pool licenses, encouraging the nascent work of Afrigen and the mRNA hub in South Africa, and ensuring the negotiations over the WHO Pandemic Treaty include equity provisions”).

82. See generally Lisa Ouellette et al., *supra* note 40 (discussing the incentives driving the development of patents).

83. Priti Patnaik, *Understanding Germany’s Trenchant Opposition to the TRIPS Waiver*, GENEVA HEALTH FILES (Aug. 13, 2021), <https://genevahealthfiles.substack.com/p/understanding-germanys-trenchant> [<https://perma.cc/Y75J-MAXH>].

of intellectual property protection also drove research, with trade secret protection enabling BioNTech and Pfizer to begin working together prior to formalization of their contract. In that case, without the guarantee of trade secret protection, companies might be reluctant to collaborate earlier, and may wait for the formalization of an agreement to protect proprietary information.

Regardless of one's perspective on the effectiveness of intellectual property incentives more generally, there may be reason to be skeptical of a waiver's effectiveness on its own. A waiver may increase openness and competition but could cause inefficiencies if new entrants to the market struggle to reverse-engineer existing vaccines and instead require assistance from the originators. In those cases, licensing and partnership might be preferable to openness and competition.<sup>84</sup>

### C. *mRNA Vaccine Manufacturing Hubs*

In addition to the earlier interventions aimed at generating and regulating demand, COVAX has also developed a proposal to directly increase supply. In April 2021, the WHO and its partners announced the formation of a COVAX Supply Chain & Manufacturing Taskforce, which would invest in building sustainable domestic manufacturing capacity and strengthening the health systems of developing countries.<sup>85</sup> The WHO emphasized that while the taskforce intended to focus on the short-term problem of access to COVID-19 vaccines, it also intended to establish a long-term platform for sustainable local vaccine manufacturing in underserved regions.<sup>86</sup> In particular, the taskforce focused on the sharing of trade

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84. See Kenneth Shadlen, *To Speed New COVID Vaccines, Look to Patenting*, ISSUES SCI. AND TECH. (Aug. 11, 2020), <https://issues.org/covid-vaccines-development-distribution-patenting-shadlen/> [<https://perma.cc/KU2Z-VDAB>] (arguing in favor of licensing and partnership in “exceptional circumstances” where openness and competition are insufficient).

85. Priti Patnaik, *Make way for the COVAX Manufacturing Taskforce*, GENEVA HEALTH FILES (Apr. 13, 2021), <https://genevahealthfiles.substack.com/p/make-way-for-the-covax-manufacturing> [<https://perma.cc/8NZD-F4NY>].

86. *Id.*; see also *COVAX Manufacturing Task Force to Tackle Vaccine Supply Challenges*, COAL. FOR EPIDEMIC PREPAREDNESS INITIATIVES (May 14, 2021), [https://cepi.net/news\\_cepi/covax-manufacturing-task-force/](https://cepi.net/news_cepi/covax-manufacturing-task-force/) [<https://perma.cc/3SFP-6MP7>] (listing medium-term to long-term objectives of the taskforce, including supporting the establishment or upgrading of vaccine manufacturing facilities particularly in LMICs).

secrets and know-how, and hoped to provide a mechanism to support and facilitate the transfer of knowledge.<sup>87</sup> The WHO announced that they had chosen to focus on mRNA vaccines due to their demonstrated effectiveness, their adaptability to new variants, and the broader range of facilities that can be used to produce them.<sup>88</sup>

The taskforce settled on a multilateral technology transfer hub model which could address manufacturing gaps during and beyond the COVID-19 pandemic.<sup>89</sup> COVAX's approach to the hubs was modeled on previous efforts spurred by the spread of H5N1, including a successful ten-year collaboration between the WHO, BARDA, and the nonprofit Program for Appropriate Technology in Health (PATH), to develop influenza vaccine manufacturing in Brazil, China, India, Serbia, Thailand, and Vietnam.<sup>90</sup> The WHO had also engaged in a prior survey of various technology transfer models, identifying a growing trend of public sector-driven models featuring a centralized hub with multiple recipients.<sup>91</sup> A hub model could involve a pilot plant which would provide manufacturers with standard operating procedures and training, while helping regulatory authorities to accelerate registration. As the WHO observed, the benefits of a hub model included the resource-

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87. COAL. FOR EPIDEMIC PREPAREDNESS INITIATIVES, *supra* note 86.

88. *Establishment of a COVID-19 mRNA Vaccine Technology Transfer Hub to Scale Up Global Manufacturing*, WORLD HEALTH ORG. (Apr. 16, 2021), <https://www.who.int/news-room/articles-detail/establishment-of-a-covid-19-mrna-vaccine-technology-transfer-hub-to-scale-up-global-manufacturing> [<https://perma.cc/B6UT-78HP>].

89. *Supply Chain & Manufacturing Taskforce*, COVAX (May 12, 2021), [https://cepi.net/wp-content/uploads/2021/05/20210512\\_COVAX-Supply-Chain-Manufacturing-Taskforce-ACT-A-Introduction.pdf](https://cepi.net/wp-content/uploads/2021/05/20210512_COVAX-Supply-Chain-Manufacturing-Taskforce-ACT-A-Introduction.pdf) [<https://perma.cc/22WS-QEKL>].

90. *Enhancing Influenza Vaccine Development in Low-Resource Countries*, PATH (Sept. 2018) <https://www.path.org/resources/enhancing-influenza-vaccine-development-low-resource-countries-pandemic-preparedness-through-seasonal-sustainability/> [<https://perma.cc/E7BF-C7VE>] (describing increased vaccine manufacturing in response to the spread of H5N1, also known as bird flu or avian flu).

91. WORLD HEALTH ORG., *INCREASING ACCESS TO VACCINES THROUGH TECHNOLOGY TRANSFER AND LOCAL PRODUCTION 15–16* (2011) (discussing “technology transfer hubs” as one among the models of technology transfer emerging globally).

effectiveness of bringing multiple experts and recipients together, rather than requiring travel to each recipient site.<sup>92</sup>

Among the advantages of the hub model was the ability to leverage WHO expertise to counter concerns about capacity and labor requirements in developing countries.<sup>93</sup> The taskforce created detailed due diligence criteria in order to evaluate potential hub sites and technology donors.<sup>94</sup> Hubs were evaluated for vaccine know-how (previous experience with mRNA vaccines and other vaccines currently in development); infrastructure (including existing facilities, cost per year of allocating a plant for mRNA training, and suitability for industrial scale production); experience with technology transfer; suitability of workforce (the size and expertise of staff, and the possibility of allocating staff for the creation of a hub); regulatory qualifications (including recent regulatory approval); ability to close the equity gap (access to regional populations and potential for export to other markets); and financing (including access to funds, sustainability of funding, and partnerships with relevant public or private sector actors).<sup>95</sup>

In selecting technology for transfer, the taskforce chose to consider safety and efficacy data, IP protections on upstream inputs that could lead to bottlenecks, the manufacturing process (including scalability, cost, and facility size for creating the drug substance), manufacturing inputs (including any non-IP constraints), deliverability (including the thermostability of the technology), access and incentives (including willingness to accept pro-access provisions in contracts), and experi-

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92. *Id.* at 17.

93. *See id.* at 7 (discussing how global capacity is severely limited and that technology transfer to developing countries increases global capacity); *see also* Martin Friede, *Manufacturing Task Force – Workstream 3: Increasing Manufacturing Capacity in LMICs*, MED. PATENT POOL (Dec. 9, 2021), <https://medicinespatentpool.org/uploads/2021/12/WHO-Martin-Friede-TTHUB-Dec9.pdf/> (slides discussing how the COVAX manufacturing taskforce structured its workstream to address the need for capacity in LMICs, specifically by establishing sustainable biomanufacturing capacity in regions with no significant capacity, as well as building human capital for regulation and biomanufacturing in LMICs).

94. *See COVAX Manufacturing Taskforce – Workstream 3*, WORLD HEALTH ORG. (May 12, 2021), <https://www.who.int/publications/m/item/covax-manufacturing-taskforce> [<https://perma.cc/3DUM-BWEN>] (slides discussing the progress of the due diligence process and the criteria used).

95. *Id.*

ence with technology transfer.<sup>96</sup> By vetting hubs and donors according to these criteria, WHO and its partners could compile evidence that vaccines developed through the hub model would be safe and effective.

At the end of July, the WHO signed a letter of intent along with the Medicines Patent Pool (MPP), manufacturers Afrigen Biologics and Biovac, the South African Medical Research Council (SAMRC), and the Africa Centre for Disease Control and Prevention (CDC) to establish the first mRNA technology transfer hub in South Africa.<sup>97</sup> The WHO agreed to lead as the “directing and coordinating authority” in conjunction with its regional office in Africa; the MPP, a nonprofit organization that facilitates access-oriented licensing, would analyze and manage intellectual property issues; Afrigen would function as the initial hub site and establish a training program for technology transfer; Biovac would be the first recipient of technology transfer and would produce vaccine doses; SAMRC would oversee clinical trial design and implementation; and the Africa CDC would provide expertise as necessary.<sup>98</sup> The letter of intent further stated that parties would be responsible for maintaining the confidentiality of one another’s confidential information (defining the term as extending beyond trade secrets or even just intellectual property), and clarified that all parties would maintain ownership of their own intellectual property, while rights to jointly-developed intellectual property would be assigned via future agreements.<sup>99</sup> While groups promoting greater access to medicines responded to the announcement of the first hub with excitement, some also criticized COVAX for insufficient trans-

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96. *Id.*

97. *New consortium working to boost vaccine production in South Africa*, WORLD HEALTH ORG. (July 30, 2021), <https://www.who.int/news/item/30-07-2021-new-consortium-working-to-boost-vaccine-production-in-south-africa> [<https://perma.cc/69XU-8H89>].

98. Letter of intent between the World Health Organization, the Medicines Patent Pool Foundation, Afrigen Biologics (Pty) Limited, the Biologicals and Vaccines Institute of South Africa, the South African Medical Research Council, and the African Centres for Disease Control and Prevention (July 29, 2021), [https://cdn.who.int/media/docs/default-source/2021-dha-docs/press-release-letter-of-intent-30-july-2021.pdf?sfvrsn=7906619c\\_5](https://cdn.who.int/media/docs/default-source/2021-dha-docs/press-release-letter-of-intent-30-july-2021.pdf?sfvrsn=7906619c_5) [<https://perma.cc/NZD7-CJ7V>].

99. *Id.*

parency around the hub's creation, specifically its planned intellectual property strategy.<sup>100</sup>

### 1. *COVAX's Success in Reverse Engineering*

At first, COVAX attempted to convince Moderna, Pfizer, and BioNTech to contribute their know-how to the hubs, but the companies refused.<sup>101</sup> In October 2021, Afrigen shared that the company had decided to reverse engineer their own version of the Moderna vaccine.<sup>102</sup> Afrigen scientists first determined the equipment and specialized ingredients needed; the biggest challenges after that were determining exact concentrations, mixing times and conditions, and the technique required to create lipid nanoparticles (as opposed to other kinds of encapsulations).<sup>103</sup> On February 3, 2022, Afrigen announced that its team of scientists in Cape Town—working in collaboration with scientists at the University of Witwatersrand in Johannesburg—had successfully reverse engineered the Moderna vaccine, although only in very small quantities, and

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100. Priti Patnaik, *South Africa bags first mRNA tech transfer hub; The EU's push for a declaration at the WTO*, GENEVA HEALTH FILES (June 22, 2021), <https://genevahealthfiles.substack.com/p/south-africa-bags-first-mrna-tech> [<https://perma.cc/7PBJ-468F>].

101. See David Meyer, *Moderna wouldn't share its vaccine technology, so South Africa and the WHO made a COVID jab based on it anyway*, L.A. TIMES (Feb. 4, 2022), <https://fortune.com/2022/02/04/south-africa-afrigen-moderna-covid-vaccine-mrna-who-hotez-corbevax/> [<https://perma.cc/JF2J-4WVF>] (reporting that “Moderna wouldn't share its vaccine technology, so South Africa and the [World Health Organization] made a COVID jab based on it”); see also Fraiser Kansteiner, *BioNTech advocate accused of undermining WHO's African mRNA production campaign: report*, FIERCE PHARMA (Feb. 9, 2022), <https://www.fiercepharma.com/manufacturing/biontech-rep-kenup-foundation-accused-undermining-who-s-african-mrna-production> [<https://perma.cc/6NBN-49MF>] (showing that a foundation representing BioNTech actively tried to halt the progress of WHO's hub).

102. Lori Hinnant et al., *Africa Tries to End Vaccine Inequity by Replicating Its Own*, U.S. NEWS & WORLD REPORT (Oct. 24, 2021), <https://www.usnews.com/news/world/articles/2021-10-24/african-effort-to-replicate-mrna-vaccine-targets-disparities>.

103. *Id.*; see also Xucheng Hou et al., *Lipid nanoparticles for mRNA delivery*, 6 NATURE REVIEWS MATERIALS 1078, 1078 (2021) (discussing generally issues associated with “the clinical translation of lipid nanoparticle–mRNA formulations, including good manufacturing practice, stability, storage and safety”).



hoped to work towards scaling up production.<sup>104</sup> Early in March 2022, Afrigen provided its first training in mRNA vaccine manufacturing to scientists from Sinergium Biotech in Argentina, and the Bio-Manguinhos Institute of Technology (Fiocruz) in Brazil.<sup>105</sup> Presently, Fiocruz has been working to reverse engineer its own vaccine, and will use Afrigen's vaccine as a control in trials.<sup>106</sup> Following Afrigen's success, the WHO also has established a second mRNA vaccine manufacturing hub in South Korea.<sup>107</sup> Meanwhile, the South African hub will expand to provide training to manufacturers in Bangladesh, Indonesia, Pakistan, Serbia, and Vietnam.<sup>108</sup>

## 2. *Continuing Challenges for the mRNA Hubs*

Despite this initial success, challenges remain for COVAX's mRNA hubs. While reverse engineering the know-how appeared to be the most significant barrier to local manufacturing, Afrigen was also relying on a pledge Moderna had made in the fall of 2020 not to enforce their patents for the duration of the pandemic.<sup>109</sup> There had been signs that

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104. *Africa is bringing vaccine production home*, 602 NATURE 184, 184 (2022), <https://www.nature.com/articles/d41586-022-00335-9> [<https://perma.cc/EZ7W-YLJ6>]; Sarah Lazare, *What Moderna Reveals About the Cruel Absurdity of "Innovation" Under Pharmaceutical Monopolies*, IN THESE TIMES (Feb. 9, 2022), <https://inthesetimes.com/article/south-africa-scientists-moderna-afrigen-biologics-mrna-vaccine-covid> [<https://perma.cc/G5Z8-X7YX>].

105. *Latin American Manufacturers Complete First Training in mRNA Technology in Bid to Improve Regional Vaccine Production*, PAN AMER. HEALTH ORG. (Mar. 24, 2022), <https://www.paho.org/en/news/24-3-2022-latin-american-manufacturers-complete-first-training-mrna-technology-bid-improve> [<https://perma.cc/C5EA-B6DK>].

106. *Id.*

107. *Moving Forward on Goal to Boost Local Pharmaceutical Production, WHO establishes global biomanufacturing training hub in Republic of Korea*, WORLD HEALTH ORG. (Feb. 23, 2022), <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/4566-YGRF>].

108. *Id.*

109. See Nurith Aizenman, *Moderna Won't Share Its Vaccine Recipe. WHO Has Hired an African Startup to Crack It*, NPR (Oct. 19, 2021), <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun> [<https://perma.cc/WR77-4ATF>] (quoting a WHO officer who noted that the decision to reverse-engineer Moderna's vaccine was influenced both by Moderna's commitment not to enforce its IP and by the public availability of ample information about the Moderna vac-

Moderna's pledge might not hold stable. In October 2021, AstraZeneca announced that it would be transitioning to making a profit from their vaccine—declaring the pandemic over from their perspective, as the company had previously pledged to make their vaccine not-for-profit until the end of the pandemic.<sup>110</sup> Moderna, it seemed, could easily do the same as soon as it seemed like their pledge might have consequences.

On March 7, about a month after Afrigen announced its reverse engineering success, Moderna published a revised version of its patent pledge.<sup>111</sup> The new policy continued to pledge non-enforcement in ninety-two low income countries, but enabled Moderna to enforce its patents in middle and high income countries.<sup>112</sup> In addition, Moderna filed eight patent applications related to its vaccine in South Africa, securing four, which raised concerns that the company might seek to deter the COVAX hub's efforts.<sup>113</sup> A Moderna spokesperson stated that they would not interfere with the reverse-engineering by the South African hub; the co-founder of BioNTech echoed that statement, saying that the company would not enforce its intellectual property rights against institutions that successfully reverse-engineer the Pfizer-BioNTech vaccine.<sup>114</sup>

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cine); Ashleigh Furlong, *Copying Moderna's jab: The project to democratize vaccine production*, POLITICO EU (Feb. 2, 2022), <https://www.politico.eu/article/who-copy-moderna-jab-project-democratize-vaccine-production/> [https://perma.cc/LC6F-YA9E] (“Moderna's own assertions about not enforcing patents during the pandemic mean ‘that the hub can produce a Moderna vaccine based on the Moderna technology without worrying about intellectual property issues anywhere on earth.’”).

110. Tom Espiner, *AstraZeneca to Take Profits from Covid Vaccine*, BBC (Nov. 12, 2021), <https://www.bbc.com/news/business-59256223> [https://perma.cc/845Q-FQRA].

111. Rebecca Robbins, *Moderna Pledged to Keep Its Vaccines Patent Free. Now It's Changing Track.*, FORBES INDIA (Mar. 8, 2022), <https://www.forbesindia.com/article/global-news/moderna-pledged-to-keep-its-vaccines-patent-free-now-its-changing-track/74287/1> [https://perma.cc/FV6A-APKJ].

112. *Id.*

113. Catherine Tomlinson, *In-depth: How a Cape Town company made an mRNA vaccine and what happens next*, NEWS24 (Mar. 7, 2022), <https://www.news24.com/health24/medical/infectious-diseases/coronavirus/in-depth-how-a-cape-town-company-made-an-mrna-vaccine-and-what-happens-next-20220307> [https://perma.cc/KUV6-3D5J].

114. Ludwig Burger, *BioNTech Says It Won't Challenge Vaccine Copying in Africa*, REUTERS (Feb. 16, 2022), <https://www.reuters.com/business/health-care-pharmaceuticals/biontech-pledges-african-access-its-future-cancer-drugs-2022-02-16/> [https://perma.cc/GA6P-525Q]; Wendell Roelf & Julie

However, under its new policy, Moderna could enforce its patents against the hub's technology recipients in Argentina and Brazil. Furthermore, Afrigen has argued that it needs a permanent license for the relevant intellectual property from Moderna in order to commercialize its product.<sup>115</sup> Even if Moderna does not enforce its patents on its mRNA COVID-19 vaccine, it has shown no willingness to provide data to Afrigen going forward, which means the company could face an approval timeline of thirty-six months—a timeline which could have been cut down to a year with support from Moderna.<sup>116</sup>

### 3. *Industry Concerns About mRNA Hubs*

The pharmaceutical companies which hold the intellectual property on COVID-19 mRNA vaccines have raised several concerns about the mRNA vaccine manufacturing hubs since COVAX first announced the project. First, they have argued that engaging in technology transfer to the hubs would be a misuse of their resources. Although Pfizer has engaged in some technology transfer to contract manufacturing organizations in Europe and North America, in addition to fill-and-finish contracts with Biovac in South Africa and Eurofarma in Brazil, the company has argued that additional manufacturers outside Pfizer's control would disrupt the limited supply of raw materials needed for Pfizer to manufacture its own doses.<sup>117</sup>

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Steenhuysen, *Charities Say Moderna Patents Could Hit Africa COVID Vaccine Hub*, REUTERS (Feb. 17, 2022), <https://www.reuters.com/business/health-care-pharmaceuticals/charities-say-moderna-patents-could-hit-africa-covid-vaccine-hub-2022-02-17/> [<https://perma.cc/44JW-WSL6>].

115. Vicky Stark, *Africa's First mRNA COVID-19 Vaccine Produced*, VOA NEWS (Feb. 4, 2022), <https://www.voanews.com/a/africa-s-first-mrna-covid-19-vaccine-produced-/6426738.html> [<https://perma.cc/4VU3-YT8L>].

116. Furlong, *supra* note 109.

117. See Zoltán Kis & Zain Rizvi, *How to Make Enough Vaccine for the World in One Year*, PUB. CITIZEN (May 26, 2021), <https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/> [<https://perma.cc/MD7F-F2HZ>] (explaining the production process for mRNA vaccines); Albert Bourla, *An Open Letter From Pfizer Chairman and CEO to Colleagues*, PFIZER (2021), [https://www.pfizer.com/news/hot-topics/why\\_pfizer\\_opposes\\_the\\_trips\\_intellectual\\_property\\_waiver\\_for\\_covid\\_19\\_vaccines](https://www.pfizer.com/news/hot-topics/why_pfizer_opposes_the_trips_intellectual_property_waiver_for_covid_19_vaccines) [<https://perma.cc/L4S8-4J9P>] (arguing that additional manufacturing would “unleash a scramble for critical inputs [Pfizer] require[s] in order to make a safe and effective vaccine”).

Moderna, which has had the largest share of its vaccines go to wealthy nations and was the last manufacturer to supply doses to COVAX, has received significant pressure from the public and the United States government to transfer its technology to manufacturers in LMICs.<sup>118</sup> However, Moderna's CEO has argued that they are a "small company," and that dedicating resources to technology transfer would mean foregoing work on the company's other products, which he believes to be a greater priority for the company.<sup>119</sup>

Some have questioned whether local manufacturers in the Global South have the capacity to sustain the complex process required to make high quality mRNA vaccines.<sup>120</sup> These arguments typically raise at least one of the following issues: scientific expertise;<sup>121</sup> sufficient facilities;<sup>122</sup> cold chain infra-

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118. See Bob Herman, *Biden Admin Warns Moderna to 'Step Up' Global Vaccine Supply*, AXIOS (Oct. 13, 2021), <https://www.axios.com/2021/10/13/covid-vaccine-moderna-biden-global-supply-covax> [https://perma.cc/LK2S-9HQQ] (recounting David Kessler's claims that the government has made Moderna aware of its concerns and that "this has been anything but light touch").

119. Ashleigh Furlong, *Moderna to Share Vaccine Tech, Commits to Never Enforce COVID-19 Jab Patents*, POLITICO (Mar. 8, 2022), <https://www.politico.eu/article/moderna-share-vaccine-tech-never-enforce-covid19-patents/> [https://perma.cc/QM4S-R2V7]; see also *Our Global Commitment to Vaccine Access*, MODERNA (Oct. 8, 2021), <https://investors.modernatx.com/Statements-Perspectives/Statements-Perspectives-Details/2021/Our-Global-Commitment-to-Vaccine-Access/default.aspx> [https://perma.cc/9DPB-H8FX] (stating the company's position to add pillars to their current strategy in order to meet vaccine demand without undermining current company commitments).

120. See The Editorial Board, *A Global Covid Vaccine Heist*, WALL ST. J. (Nov. 19, 2020), <https://www.wsj.com/articles/a-global-covid-vaccine-heist-11605829343> [https://perma.cc/6EZ7-TRH9] (claiming that "[i]t's not clear developing countries even have the ability to manufacture large-scale, complex technologies like Moderna's mRNA vaccine or Eli Lilly's monoclonal antibody cocktail—let alone distribute them").

121. Bill Bostock, *Moderna's CEO said he 'didn't lose a minute of sleep' over the US support for waiving patents for COVID-19 vaccines*, BUS. INSIDER (May 7, 2021), <https://www.businessinsider.com/coronavirus-vaccine-waiver-moderna-ceo-says-didnt-lose-sleep-2021-5> [https://perma.cc/Z99M-TNXW] (quoting Stéphane Bancel's statement that "[y]ou cannot go hire people who know how to make mRNA. . . [t]hose people don't exist [outside Moderna]"); see also Carla Delgado, *Experts Say Patent Waivers Aren't Enough To Increase Global Vaccination*, VERYWELL HEALTH (May 25, 2021) (arguing that lack of manufacturing capacity and lack of technology, skills, and raw materials remain major barriers to manufacturing in low-income countries).

structure;<sup>123</sup> and raw materials.<sup>124</sup> While the WHO attempted to address these concerns with its due diligence process, independent analysts have also evaluated local manufacturing capacity. An analysis by the *New York Times* found ten companies across South America, Africa, and Asia which have the necessary facilities, labor, regulatory system, and political and economic climate to produce mRNA vaccines.<sup>125</sup> Scientists at Biovac, for example, have argued that with technology transfer, they could produce mRNA vaccines within twelve to eighteen months.<sup>126</sup>

Further, Moderna, Pfizer, and BioNTech have not relied solely on mRNA experts to scale production in wealthy countries, but also provided training to personnel with relevant equipment and expertise—for example, partnering with a cancer drug-making facility in Germany, or a contract manufacturer staffed by former food scientists in Switzerland.<sup>127</sup> Research has shown that any pharmaceutical company that manufactures sterile injectables meets the minimum criteria to manufacture mRNA vaccines, with over 100 qualifying labs in Asia, Africa, and Latin America.<sup>128</sup> These findings suggest that

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122. Bostock, *supra* note 121 (quoting Stéphane Bancel’s statement that “[t]here is no idle mRNA manufacturing capacity in the world”).

123. Letter from Thom Tillis, U.S. Sen., to Katherine Tai, U.S. Trade Rep. (Dec. 1, 2021), at 2, <https://ipwatchdog.com/wp-content/uploads/2021/12/12.1.21-Tillis-TRIPS-Waiver-Letter-No.-5-to-USTR-002.pdf> [<https://perma.cc/YR36-NY9X>].

124. Delgado, *supra* note 121.

125. 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/4KYX-68GN>] (noting that those companies include the Serum Institute of India, which currently produces non-mRNA COVID-19 vaccines under contracts with AstraZeneca and Novavax; Biological E (also in India) and Aspen Pharmacare (in South Africa), which have fill-and-finish contracts for Johnson & Johnson’s vaccine; Biovac in South Africa, which has a fill-and-finish contract for Pfizer’s vaccine; Instituto Butantan in Brazil, which produces the Sinovac vaccine; and Biofarma in Indonesia, which has a fill-and-finish contract for Sinovac).

126. *Id.*

127. *Id.*

128. Achal Prabhala & Alain Alsalhani, *Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines*, ACCESSIBSA (Dec. 10, 2021), <https://accessibsa.org/mrna/> [<https://perma.cc/4Y8M-4CF7>].

local production can be expanded far beyond the initial South African hub.

Still, for several reasons, pharmaceutical companies remain unlikely to transfer their technology to the hubs. One obvious incentive for companies to maintain their monopolies is greater profit than they could gain simply by licensing their IP to the hubs; while pharmaceutical companies may point to vaccine donations or tiered pricing as evidence that they do not seek to profit from the pandemic, Pfizer's pre-tax profit margin was over thirty-one percent in 2022,<sup>129</sup> while Moderna's was over forty-three percent,<sup>130</sup> and BioNTech's was over seventy-three percent,<sup>131</sup> compared to a "typical" industry profit margin of twenty percent.<sup>132</sup> AstraZeneca, which produces a viral vector vaccine as opposed to an mRNA one, and initially made its vaccine not-for-profit, has announced its intention to make a profit from the vaccine in 2022 via tiered pricing.<sup>133</sup>

Another key question is why pharmaceutical companies fight to maintain monopolies in developing countries while donating free vaccines to those same countries, as opposed to allowing competition and letting the free market produce an affordable price point. Kaushik Sunder Rajan has suggested two reasons: first, that the industry's aim is not to protect the IP on specific products but to monopolize all future uses of a particular technology; and second, that companies are less concerned about success in Global South markets than they

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129. PFIZER, 2022 ANNUAL REPORT 47 (2023), [https://s28.q4cdn.com/781576035/files/doc\\_financials/2022/ar/PFE-2022-Form-10K-FINAL-\(without-Exhibits\).pdf](https://s28.q4cdn.com/781576035/files/doc_financials/2022/ar/PFE-2022-Form-10K-FINAL-(without-Exhibits).pdf) [<https://perma.cc/R6TF-SAB7>].

130. MODERNA, 2022 ANNUAL REPORT 116 (2023), [https://s29.q4cdn.com/435878511/files/doc\\_financials/2022/ar/Moderna-2022-Annual-ReportvF.pdf](https://s29.q4cdn.com/435878511/files/doc_financials/2022/ar/Moderna-2022-Annual-ReportvF.pdf) [<https://perma.cc/L4AR-6Z8L>].

131. BIONTECH, ANNUAL REPORT 2022 139 (2023), <https://investors.biontech.de/static-files/4e7e11ad-14dd-4b8b-9ad8-5500c6681b4a>.

132. Mark R. Wilson, *Vaccine Manufacturers Are Profiteering. History Shows How to Stop Them.*, POLITICO (Nov. 4, 2021, 5:00 PM), <https://www.politico.com/news/magazine/2021/11/04/vaccine-manufacturers-are-profiteering-history-shows-how-to-stop-them-519504> [<https://perma.cc/BE9L-JP33>].

133. Tom Espiner, *AstraZeneca to take profits from Covid vaccine*, BBC (Nov. 12, 2021), <https://www.bbc.com/news/business-59256223> [<https://perma.cc/9NN9-TA9V>].

are about protecting Western markets.<sup>134</sup> Therefore, rather than charging the highest prices possible for vaccines in all markets, manufacturers seek control over all markets to ensure that they can retain their monopolies in the most profitable ones.<sup>135</sup> Even significant public pressure, then, might fail to convince companies that they should voluntarily give up their monopolies if they believe that ceding control in a less profitable market could endanger their revenues in a highly profitable one. Meanwhile, programs such as Pfizer and BioNTech's donation of U.S. doses to COVAX allow companies to provide an ethical justification for monopoly power (i.e., suggesting that because mRNA vaccine companies are taking steps to expand their manufacturing and supply more doses to the Global South, they need not take any steps to aid in local production).<sup>136</sup>

Perhaps the biggest concern for mRNA vaccine manufacturers arises from the novelty of the technology. Moderna and Pfizer hope to use their mRNA platforms to develop additional therapies, so stringent protection of their trade secrets may grant them some competitive advantage.<sup>137</sup> While the leading Western companies might be less concerned about smaller

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134. KAUSHIK SUNDER RAJAN, *PHARMOCRACY: VALUE, POLITICS, AND KNOWLEDGE IN GLOBAL BIOMEDICINE* 157, 188 (2017) (describing Novartis's philanthropy as a vehicle for monopoly and its prioritization of Western markets over Indian markets).

135. See Zahra Hayat, *Beyond the Market Monopoly: How Patents Act*, *MED. ANTHROPOLOGY Q.* (July 21, 2021), <https://medanthroquarterly.org/rapid-response/2021/07/beyond-the-market-monopoly-how-patents-act/> [<https://perma.cc/QC6Z-YRFH>] (noting that Novartis fought to retain its monopoly over a leukemia drug in India despite no prospect of profit in the Indian market).

136. See *Pfizer and BioNTech to Provide 500 Million Doses of COVID-19 Vaccine to U.S. Government for Donation to Poorest Nations*, *PFIZER* (June 10, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-500-million-doses-covid-19> [<https://perma.cc/4GJC-EN8F>] (illustrating how companies promote their donation efforts as a solution to access problems).

137. See *Moderna's mRNA Platform*, *MODERNA*, <https://www.modernatx.com/power-of-mrna/modernas-mrna-platform> [<https://perma.cc/EN3W-NF6W>] (introducing Moderna's efforts to develop mRNA medicines to help prevent or treat disease); see also *Harnessing the Potential of mRNA*, *PFIZER*, <https://www.pfizer.com/science/innovation/mrna-technology> [<https://perma.cc/L5MU-Q3E4>] (discussing the potential of mRNA to deliver new vaccines and treatments).

companies in the Global South using their mRNA technology in COVID-19 vaccines, they may be concerned about losing control over trade secrets that could determine future profits. However, this does not explain why the successful reverse engineering of the Moderna vaccine has failed to change the company's position on sharing its regulatory data—hardly the most commercially sensitive of its proprietary information.

#### 4. *Industry Expansion in Africa*

Rather than partnering with manufacturers in developing countries, Moderna and Pfizer have both announced plans to expand their own production to the African continent.<sup>138</sup> Moderna faced particular pressure to increase access to its vaccine for the global poor, including from the U.S. government.<sup>139</sup> Against the backdrop of a dispute between the National Institutes of Health (NIH) and Moderna over inventorship credit and ownership of a critical patent on the mRNA vaccine technology, senior officials in the Biden administration spoke to the *New York Times* about the administration's frustration with the company and desire to see them expand their production and transfer their technology to overseas manufacturers.<sup>140</sup> A week later, Dr. David Kessler, Chief Science Officer of the White House COVID-19 Response Team, echoed those criticisms of Moderna, telling a panel of access

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138. Joseph Keenan, *Moderna to pour \$500M into Africa to meet future mRNA vaccine manufacturing demand*, FIERCE PHARMA (Oct. 7, 2021), <https://www.fiercepharma.com/manufacturing/moderna-to-build-500m-plant-africa-as-it-looks-to-meeting-future-vaccine-demand> [https://perma.cc/SD4Z-3CXD]; *Pfizer and BioNTech Announce Collaboration with Biovac to Manufacture and Distribute Covid-19 Vaccine Doses Within Africa*, PFIZER (July 21, 2021), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac> [https://perma.cc/4TET-YMZG].

139. See Rebecca Robbins, *Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor*, N.Y. TIMES (Nov. 9, 2021), <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html> [https://perma.cc/XY2M-8HTH] (describing the Biden administration's frustration with Moderna for not making its vaccine more available to poorer countries).

140. Jamie Smyth & Hannah Kuchler, *Moderna rejects claim US government co-invented crucial Covid jab technology*, FIN. TIMES (Nov. 11, 2021), <https://amp.ft.com/content/8ceca48d-9c9e-4b07-926b-7d119ce47cc0> [https://perma.cc/2H3H-66X9] (contextualizing the inventorship and ownership dispute between Moderna and NIH); Robbins, *supra* note 139 (describing the claims of senior officials in the Biden administration regarding the government's conversations with Moderna).



to medicines activists that the administration was placing pressure on the company behind the scenes.<sup>141</sup>

In October 2021, Moderna responded to criticism of its global access efforts by promising to build its own vaccine manufacturing facility in Africa, producing 500 million doses per year, but shared no timeline for this project.<sup>142</sup> In March 2022, soon after Afrigen's announcement that it had reverse engineered Moderna's vaccine, Moderna announced that it had chosen Kenya as the site of the new facility and that the facility would begin manufacturing in 2023; the operations would include manufacturing the drug substance of the vaccine, with the possibility of expansion into fill-finish.<sup>143</sup> In February 2022, BioNTech announced its own plans to begin building an mRNA vaccine manufacturing facility in Africa in mid-2022.<sup>144</sup> The successful reverse engineering of Moderna's vaccine by Afrigen may have accelerated the companies' timelines for their own initiatives.

From the perspective of the leading vaccine manufacturers, expanding their production to the Global South can address access issues without sacrificing their intellectual property protections. With their own facilities in developing countries, Pfizer and Moderna can avoid engaging with local manufacturers and trusting other entities with their intellectual property, while still increasing distribution of their vaccines in those countries. In addition, local manufacturing by foreign companies can still lead to local capacity building through the development of new facilities and the hiring and training of local scientists. However, this approach still en-

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141. See Bob Herman, *supra* note 118 (recounting Dr. David Kessler's statement that "[t]hese companies understand our authorities and understand we would not be afraid to use them").

142. Giselda Vagnoni & Emily Roe, *Moderna's search for African site set to intensify*, REUTERS (Oct. 12, 2021), <https://www.reuters.com/business/healthcare-pharmaceuticals/modernas-search-african-site-set-intensify-chairman-2021-10-12/> [<https://perma.cc/A9U9-VXXD>].

143. *Moderna to build mRNA vaccine manufacturing facility in Kenya*, REUTERS (Mar. 8, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-build-mrna-vaccine-manufacturing-facility-kenya-2022-03-07/> [<https://perma.cc/A6WA-3WM5>].

144. Ludwig Burger, *BioNTech to ship mRNA vaccine factory kits to Africa*, REUTERS (Feb. 16, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/biontech-ship-mrna-vaccine-factory-kits-africa-2022-02-16/> [<https://perma.cc/8YKY-LLEL>].

trenches global monopolies and may prevent significant competitors from emerging sooner in developing countries.

## VI. LOCAL PRODUCTION AND LOCAL AUTONOMY

Whether led by industry or international organizations, efforts to increase vaccine production in the Global South should also ensure respect for local scientific research and knowledge. Research agendas set by wealthy countries may fail to meet the needs of those in developing countries, especially when illness has some geographic specificity in prevalence or phenotype; for example, neglected tropical diseases predominantly impact the world's poorest and have received little research funding in proportion to their impact.<sup>145</sup> On the one hand, the manner and rate of transmission may make research on regional COVID-19 variants more pressing for wealthy countries, as any highly infectious new variant is likely to spread globally.<sup>146</sup> On the other, the types of vaccines developed may be more suited to the infrastructures of wealthier countries. The mRNA vaccines initially developed, although highly effective, required a chain of cold storage that can be difficult to maintain in lower-resource settings.<sup>147</sup> If research priorities had been set by developing countries, research funding and attention might have been directed more urgently toward overcoming cold storage problems earlier on.<sup>148</sup>

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145. See Joelle Tanguy, *Shortfall in research funding for the most neglected diseases*, DRUGS FOR NEGLECTED DISEASES INITIATIVE (Apr. 16, 2021), <https://dndi.org/viewpoints/2021/shortfall-in-research-funding-for-the-most-neglected-diseases/> [<https://perma.cc/8K8G-MBJ7>] (pointing out a report that demonstrates that only 8.5% of neglected disease R&D funding in 2019 was allocated to neglected tropical diseases, which are rarely seen in high income countries).

146. See Tamara Bhandari, *New evidence COVID-19 antibodies, vaccines less effective against variants*, WASH. UNIV. ST. LOUIS (Mar. 4, 2021), <https://medicine.wustl.edu/news/new-evidence-covid-19-antibodies-vaccines-less-effective-against-variants/> [<https://perma.cc/FA6D-FU9Y>] (explaining the concern over emerging COVID-19 variants as attributed to their rapid spread in the United Kingdom, South Africa, and Brazil).

147. Katie McCallum, *Why Some Covid-19 Vaccines Need to Be Kept So Cold - & What This Means for Availability*, HOUSTON METHODIST (Dec. 3, 2020), <https://www.houstonmethodist.org/blog/articles/2020/dec/why-the-covid-19-vaccine-needs-to-be-kept-so-cold/> [<https://perma.cc/C4SH-FUGX>].

148. See James Dinneen, *Here's how scientists are designing vaccines that can ditch the fridge*, SCIENCE (Apr. 21, 2021), <https://www.science.org/content/article/here-s-how-scientists-are-designing-vaccines-can-ditch-fridge> [<https://>].

Particularly in countries without large existing pharmaceutical sectors, investing in local production can help to build capacity and self-sufficiency. In these countries, scientific institutions may more frequently rely on foreign funding or on partnerships with institutions in wealthier countries.<sup>149</sup> Unequal partnerships can implicate the same autonomy concerns raised by reliance on donors, if scientists in developing countries become “consultants” discouraged from choosing their own research priorities and acquiring independent expertise.<sup>150</sup> In some cases, partnerships with Western institutions have kept scientists marginalized in the field, excluding them from recognition while exploiting their knowledge.<sup>151</sup> Nevertheless, scientists in the developing world still have made significant contributions to scientific knowledge through these research partnerships.<sup>152</sup> When these partnerships are oriented toward capacity-building, training local scientists, and encouraging independent expertise, they can promote equity rather than exploitation. This requires the fair recognition of the efforts and contributions of local scientists, which may be achieved through contracts mandating credit-sharing, for example.<sup>153</sup> As technology transfer occurs between scientists in

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perma.cc/KH47-LSAC] (describing later efforts to formulate vaccines that do not require cold storage).

149. See JOHANNA T. CRANE, *supra* note 52, at 109–11 (describing how the expansion of the Immune Wellness Clinic in Mbarara was funded almost entirely by PEPFAR).

150. See *id.* at 135 (describing how one Ugandan scientist felt that foreign funding meant he had to “dance to the other person’s tune” rather than pursue his own research interests).

151. See Eyder Peralta, *This Congolese Doctor Discovered Ebola But Never Got Credit For It – Until Now*, NPR (Nov. 4, 2019), <https://www.npr.org/sections/goatsandsoda/2019/11/04/774863495/this-congolese-doctor-discovered-ebola-but-never-got-credit-for-it-until-now> [https://perma.cc/X5N2-YPYK] (describing how Dr. Jean-Jacques Muyembe’s contributions to the discovery of Ebola were erased in favor of the Belgian scientists he collaborated with, as well as a broader perception at the Congo National Institute of Biomedical Research that Western scientists take credit for the work of Congolese scientists).

152. See *id.* (describing the significant discovery to which Dr. Muyembe nevertheless contributed).

153. See Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539, 1587 (2017) (describing the click-wrap contracts binding users of the database Epiflu to share credit with originating labs).

high- and low-income countries, institutional policies can help ensure that collaboration is empowering rather than exploitative. For instance, this can be done by ensuring that local scientists have the opportunity to serve as lead authors on collaborative papers, or requiring that institutions remain accountable through publicly reporting metrics related to equitable collaboration.<sup>154</sup> Given that (often racialized) hierarchies of global power impact science, these concerns should not be considered marginal to the aim of expanding production.<sup>155</sup> The power structure of these research arrangements carries an importance that is not limited to theory or irrelevant to the material realities of vaccine production.

#### VII. THE NEED FOR EFFICIENCY AND SPEED IN VACCINE MANUFACTURING AND DISTRIBUTION

Particularly at the beginning of the pandemic, when COVID-19 vaccines had not yet been developed or distributed, concerns about efficient manufacturing and distribution were paramount. The urgent need for vaccines meant that governments were more likely to pursue bilateral deals than unwieldy

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154. See Anton Nurcahyo & Erik Meijaard, *Create and Empower Lead Authors from the Global South*, NATURE (Mar. 21, 2018), <https://www.nature.com/articles/d41586-018-03392-1> [<https://perma.cc/DV7S-6RJ6>] (arguing that authors from the Global South need better instruction and training to achieve lead authorship and overcome bias); Olivier Dangles et al., *Insufficient yet improving involvement of the global south in top sustainability science publications*, 17 PLoS ONE (Sept. 2022) 7, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0273083> [<https://perma.cc/WS4L-W2TD>] (“Another response to the widely acknowledged need to improve fairness in transnational collaborations is the increasing interest in the research fairness initiative—a self-reporting tool to identify strengths and weaknesses in research collaboration policy and practice.”).

155. See STEPHEN JAY GOULD, *THE MISMEASURE OF MAN* 52–54 (1981) (discussing scientific theories of biological determinism used to justify racist ideas about intelligence, and asserting that “[s]cience, since people must do it, is a socially embedded activity” that, far from being neutral and mechanical, can be shaped by culture and ideology); ELLEKE BOEHMER, *COLONIAL AND POSTCOLONIAL LITERATURE: MIGRANT METAPHORS* 38 (2d ed. 2005) (describing how the earliest Enlightenment era scientific expeditions “took for granted a European understanding of the world, and the supporting presence of European military and economic power,” in turn shaping their scientific aims and methods).

multilateral deals that could take longer to negotiate.<sup>156</sup> It also made governments less willing to bargain for additional conditions in funding or purchase agreements, with the primary goal of getting as many doses as possible as soon as possible.<sup>157</sup> While bilateral agreements made sense to governments in the short-term, this approach led to unequal distribution of doses, and was therefore a poor fit for the long-term goal of ending the pandemic.

Efficiency in reaching *equitable* vaccination rates remains an important factor in evaluating long-term policy interventions, however. Low-income countries cannot continue to wait for donated doses as new variants continue to emerge. These concerns may point in favor of local production driven by the strongest industry actors. Given their resources, companies like Moderna and BioNTech may be able to expand their operations more quickly than COVAX's manufacturing hubs because they do not need to seek additional approvals for their vaccines. However, the United States could choose to use domestic policy tools to compel companies to share information, decreasing the timeline that low-income countries will have to wait to acquire vaccines from COVAX's hubs.

One of those proposals concerns an ongoing dispute between the NIH and Moderna over ownership interests in a patent on the mRNA sequence for the coronavirus spike protein.<sup>158</sup> When Moderna filed its application for this patent, it

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156. See Andreas Rinke, *Germany Won't Buy Vaccines Through WHO's COVAX Scheme*, REUTERS (Sept. 18, 2020), <https://www.reuters.com/article/health-coronavirus-who-germany/exclusive-germany-wont-buy-vaccines-through-whos-covax-scheme-sources-idINL8N2GF3JM> [<https://perma.cc/87X2-36ZL>] (suggesting that by the time Germany needed to decide whether to procure vaccines through COVAX, it had already procured vaccines separately on a shorter timeline).

157. See *id.* (stating that Germany decided to “play it safe” by procuring more vaccines than necessary, with a willingness to share later, only if they purchased more than needed).

158. See *Read Moderna's Filing with the United States Patent and Trademark Office*, N.Y. TIMES (Nov. 9, 2021), <https://www.nytimes.com/interactive/2021/11/09/us/moderna-patent-filing.html> [<https://perma.cc/88XB-8CZ3>] (highlighting Moderna's listing of its employees as the sole inventors of a component of the vaccine and its exclusion of government scientists); Sheryl G. Stolberg & Rebecca Robbins, *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/PV6M-57FD>] (describ-

did so without listing any of its National Institute of Allergy and Infectious Diseases (NIAID) scientist collaborators, and explicitly stated that those collaborators had not co-invented the mRNA compositions.<sup>159</sup> To some extent, these questions of inventorship and ownership rest upon the legal fiction of corporate ownership, which maintains the traditional myth of the inventor even as invention becomes more about the production of “capitalized value” than the actual product.<sup>160</sup> To divide inventorship credit between scientists at both Moderna and NIAID who collaborated in development, manufacture, and testing of the vaccine is inherently problematic, particularly given the iterative nature of scientific advancement. Yet the arguments of both parties assume that the sequence’s invention was a discrete event that can be distinguished from the science that came before it.<sup>161</sup>

While Moderna offered after a year of negotiations to give the government co-ownership over the relevant patent applications, including the right to license patents, the company did not publicly disclose the full terms of the offer.<sup>162</sup> Unlike the more straightforward allocation of rights through co-inventorship, co-ownership terms would have to be negotiated and could be conditional.<sup>163</sup> Nevertheless, on December 17, 2021,

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ing the dispute between Moderna and the National Institute of Health and its implications).

159. *Read Moderna’s Filing with the United States Patent and Trademark Office*, *supra* note 158.

160. KAUSHIK SUNDER RAJAN, PHARMOCRACY: VALUE, POLITICS, AND KNOWLEDGE IN GLOBAL BIOMEDICINE 225 (2017).

161. *See* Stolberg & Robbins, *supra* note 158 (“The Vaccine Research Center quickly zeroed in on the gene for the virus’s spike protein and sent the data to Moderna in a Microsoft Word file [. . .] Moderna said at the time that its scientists had independently identified the same gene.”).

162. Alexander Tin, *Moderna Offers NIH Co-Ownership of COVID Vaccine Patent Amid Dispute with Government*, C.B.S. NEWS (Nov. 15, 2021), <https://www.cbsnews.com/news/moderna-covid-vaccine-patent-dispute-national-institutes-health/> [<https://perma.cc/JQF6-QST4>].

163. *See Statement on Intellectual Property*, MODERNA (Nov. 11, 2021), <https://investors.modernatx.com/news-releases/news-release-details/statement-intellectual-property> [<https://perma.cc/2GQP-UV2Q>] (Moderna’s statement on its decision not to pursue issuance of U.S. patent application for the mRNA sequence of the Moderna COVID-19 vaccine, acknowledging that NIH also feels strongly that its scientists should be listed as co-investors); *see also* Heidi Ledford, *What the NIH-Moderna COVID vaccine patent fight means for research*, NATURE (Nov. 30, 2021), <https://www.nature.com/articles/d41586->

Moderna announced that it would pause its pursuit of the patent for the time being in the interest of pursuing an “amicable resolution” with the NIH.<sup>164</sup> However, the outcome of the dispute remains to be determined.

Although the dispute between NIH and Moderna concerns patent rights specifically, the situation has implications for the transfer of trade secrets. For months, advocates have suggested that the government could use the threat of litigation in negotiations with Moderna, inducing them to transfer their technology to COVAX.<sup>165</sup> Government officials including David Kessler, Chief Science Officer of the White House COVID-19 Response Team, have shown an unprecedented willingness to publicly criticize Moderna, and confirmed that the government was encouraging Moderna to license its technology to foreign manufacturers.<sup>166</sup> Together with the U.S. administration’s surprising decision to ostensibly support negotiations toward a TRIPS waiver,<sup>167</sup> these suggest that the administration may be moving toward a bolder stance on intellectual property. Although the NIH has not yet publicly and explicitly threatened litigation, the idea that the government might use that threat as leverage to push for the transfer of trade secrets

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021-03535-x [<https://perma.cc/4WFC-35M5>] (discussing how Moderna has offered NIH co-ownership of the vaccine patent, and how terms of the co-ownership would need to be negotiated).

164. Rebecca Robbins & Sheryl G. Stolberg, *Moderna Backs Down in Its Vaccine Patent Fight with the N.I.H.*, N.Y. TIMES (Dec. 17, 2021), <https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html> [<https://perma.cc/BE68-S4E4>].

165. Christopher Morten et al., *U.S. 10,960,070: The U.S. Government’s Important New Coronavirus Vaccine Patent*, N.Y.U. TECH. L. & POL. CLINIC (2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3889784](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3889784) [<https://perma.cc/Y4TJ-LWGB>] (proposing that the government use the threat of litigation over this patent as leverage in negotiations); *see also* *Advocates Want NIH to Use Its Moderna Vaccine Patent to Push*, WASH. POST (Mar. 25, 2021), <https://www.washingtonpost.com/business/2021/03/25/moderna-vaccine-patent-nih/> [<https://perma.cc/33TG-2WYV>] (asking the government to negotiate aggressively for technology transfer).

166. *See* Bob Herman, *supra* note 119 (recounting David Kessler’s expectation of Moderna to “step up as a company” given the funding and authority the company received from the government).

167. *See* Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> [<https://perma.cc/LQM9-QKCN>].

to foreign manufacturers appears more politically feasible now than it did a year ago. While at least one analysis published during the summer of 2020 suggested that the “isolationist tendencies of the [Trump] administration” made the government’s sharing of intellectual property and know-how with COVAX unlikely, the change in presidential administrations has already yielded surprising shifts.<sup>168</sup>

The Defense Production Act (DPA) is another option which could more directly compel technology transfer, thereby avoiding the need for further negotiations with Moderna. The DPA originally allocated significant economic powers, including setting prices and rationing consumer goods, to the President during wartime in the interest of national defense; since then, the DPA’s use has expanded, and both Trump and Biden have invoked the DPA during the pandemic.<sup>169</sup> Rizvi, Ravinthiran, and Kapczynski have argued that because a) the DPA may have already been used by the U.S. government to redirect vaccine raw materials from AstraZeneca in the United States to the Serum Institute in India and b) the United States contracted with Pfizer to transfer its manufacturing know-how from its German partner BioNTech to the United States, mandating the acceptance and prioritization of technology transfer contracts (such as with COVAX’s manufacturers) is a natural next step authorized by the DPA.<sup>170</sup> However, in a press briefing, the United States responded to advocates and specifically claimed that it did not have the power under the DPA to “intervene with the manufacturer to make them fill the Serum Institute’s order,” only to

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168. See Ana S. Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. UNIV. J.L. & POL’Y 167, 181 (2021) (finding that the possibility of NIH sharing intellectual property regarding the mRNA-1273 with the WHO at odds with the Trump administration’s suggestion to withdraw the U.S. from the WHO).

169. Defense Production Act of 1950, 50 U.S.C. §§ 4501-4568 (2018); see Anshu Siripurapu, *What Is the Defense Production Act?*, COUNCIL ON FOREIGN RELATIONS (Dec. 22, 2021 3:40 PM), <https://www.cfr.org/in-brief/what-defense-production-act> [https://perma.cc/SB7Z-W996] (comparing past administrations use of the DPA to Trump’s and Biden’s orders).

170. Zain Rizvi et al., *Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide*, HEALTH AFFAIRS BLOG (Aug. 6, 2021), <https://doi.org/10.1377/forefront.20210804.101816> [https://perma.cc/PMX3-W9BE].



share its own supplies.<sup>171</sup> Regardless of whether this assessment of the government’s power is accurate—and Rizvi et al.’s statutory interpretation suggests that it might not be—it signals a serious obstacle to generating the necessary political will for Biden to invoke the DPA in this way. Further complicating this proposal, the White House has sent mixed signals about its perception of its legal authority and its political willingness to use that authority under the DPA.<sup>172</sup>

However, using the DPA also comes with its own potential disadvantages, especially if advocates hope for policy changes which could set a clear precedent for future access to medicines, as COVAX hopes to do with its plan for long-term sustainable manufacturing in the Global South. Despite the expansion of the “national defense” definition, the U.S. government has thus far only invoked the DPA in response to emergencies, making it unclear what level future health threats might have to rise to in order to trigger similar action.<sup>173</sup> Furthermore, the Act is set to expire in 2025, and though Congress has voted to renew it over fifty times, the stat-

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171. Background Press Call by Senior Administration Officials on COVID-19 in India, White House (Apr. 26, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/04/26/background-press-call-by-senior-administration-officials-on-covid-19-in-india/> [https://perma.cc/P8QD-9LUW].

172. Press Briefing by Press Secretary Jen Psaki, White House (Oct. 18, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/10/18/press-briefing-by-press-secretary-jen-psaki-october-18-2021/> [https://perma.cc/CR3M-DWS4] (responding to a question about the Defense Production Act saying “that the U.S. government does not have the ability to compel Moderna to take certain actions . . . [W]e don’t have the legal ability to compel” but, when pressed further, saying that she would not “rule out” use of the DPA, reiterating the government’s desire to see Moderna share their know-how with LMIC manufacturers).

173. See Defense Production Act, *supra* note 169, at § 4502; Aidan Lawson and June Rhee, *Usage of the Defense Production Act throughout history and to combat COVID-19*, YALE SCH. MGMT. (June 3, 2020), <https://som.yale.edu/blog/usage-of-the-defense-production-act-throughout-history-and-to-combat-covid-19> [https://perma.cc/CU2Z-XSYX] (describing the history of invocation of the DPA); see also *Biden invokes the Defense Production Act for the baby formula shortage*, NPR (MAY 18, 2022), <https://www.npr.org/2022/05/18/1099937734/biden-invokes-defense-production-act-for-baby-formula-shortage> [https://perma.cc/UP3A-YHCK] (describing Biden’s use of the DPA to combat an infant formula shortage).

ute could still change.<sup>174</sup> As a result, any action the government takes to expand vaccine production would be highly specific to the current moment, leaving the future in jeopardy. On one hand, this might make use of the DPA more politically feasible; advocates could overcome resistance by emphasizing the temporary nature of the measures. On the other hand, any policy measures implemented during the pandemic under the DPA might also be vulnerable to arbitrary decisions about whether the state of “emergency” has ended and might be a less sustainable solution to the problem of incentivizing technology transfer in general.

#### VIII. LESSONS AND QUESTIONS FOR FUTURE PANDEMICS

Will the memory of inequitable distribution of COVID-19 vaccines be enough to change how things are done by the time the next pandemic comes around? History suggests not; in 2009, the vaccine for swine flu was similarly slow to reach low-income countries, and too expensive for them to afford without a donation program.<sup>175</sup> However, negotiations already have begun for a binding international agreement at the WHO on pandemic preparedness and response.<sup>176</sup> The treaty aims to draw lessons from this pandemic to design better financing, procurement, allocation, and technology transfer mechanisms.<sup>177</sup>

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174. CONG. RSCH. SERV., R43767, *THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS 1* (2020).

175. See Martin Enserink, *The challenge of getting swine flu vaccine to poor nations*, SCIENCE (Nov. 3, 2009), <https://www.science.org/content/article/challenge-getting-swine-flu-vaccine-poor-nations> [https://perma.cc/Y34X-P9JS] (describing the operational set up of the WHO H1N1 vaccine distribution).

176. See Public hearings regarding a new international instrument on pandemic preparedness and response, WORLD HEALTH ORG. (Apr. 12, 2022), <https://www.who.int/news-room/events/detail/2022/04/12/default-calendar/public-hearings-regarding-a-new-international-instrument-on-pandemic-preparedness-and-response> [https://perma.cc/BE2U-3LJ6] (calling for public input on a new “international instrument to strengthen pandemic prevention, preparedness and response” for discussion by the Intergovernmental Negotiating Body).

177. Intergovernmental Negotiating Body, Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting, art. 6, WHO Doc. A/INB/4/3 (Feb. 1, 2023) [hereinafter WHO CA+], [https://apps.who.int/gb/inb/pdf\\_files/inb4/A\\_INB4\\_3-en.pdf](https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf) [https://perma.cc/KT8E-CKTC].

The current version of Article 19 requires Member States to allocate at least five percent of current health expenditures to “pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities and working to achieve universal health coverage,” and to allocate a (currently undefined) percentage of GDP to “international cooperation and assistance on pandemic prevention, preparedness, response and health systems recovery, particularly for developing countries.”<sup>178</sup> The draft therefore provides a strong foundation for sustainable financing, but additional provisions related to financing could still be improved. For example, the draft currently does not explicitly address ways to improve research agenda setting or ensure that emergent health threats in developing countries receive equivalent funding to those in wealthier countries. A stronger treaty could clarify a workflow connecting intergovernmental pandemic surveillance, addressed in proposed Articles 11 and 18, with the allocation of funds for research.

Open questions remain, which might further inform the treaty’s financing provisions. For example, how much and when would companies have invested in coronavirus research without the guarantees provided by advance market commitments? And would those incentives have been as successful if they were provided through a single multilateral commitment, as the COVAX partnership initially sought out to do, or were the bilateral agreements with wealthy countries crucial to accelerating research and development?

Draft Article 9 does include conditions on public funding for research and development itself, which have the potential to significantly increase health equity.<sup>179</sup> These conditions include terms regarding pricing, allocation, data sharing, and technology transfer; transparency of funding contracts; and the public dissemination of results of publicly-funded research.<sup>180</sup> While these funding provisions are promising, the treaty could be strengthened through similar conditions for purchase agreements, which played an important role during the coronavirus pandemic.<sup>181</sup> Article 15 of the draft text ad-

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178. *Id.* at art. 19.

179. *Id.* at art. 9.

180. *Id.*

181. *See* Price et al., *supra* note 26.

dresses the need for collaboration among countries, but does not address the conditions which led governments to defect from the multilateral COVAX partnership to negotiate bilateral agreements.<sup>182</sup> This Article might therefore be modified to require that when member states enter into bilateral advance market commitments with manufacturers instead of coordinating with other states, these contracts include similar conditions regarding technology transfer and data sharing. The treaty could also require that any such bilateral agreements are transparent in their terms, ensuring greater public accountability.<sup>183</sup>

Article 7 proposes conditions for equitable production and technology transfer, requiring member states to build on the model established by COVAX's technology transfer hubs.<sup>184</sup> The Article also addresses the need to expand research and manufacturing capacity, particularly in developing countries, to ensure local production of vaccines during the next pandemic.<sup>185</sup> The treaty's guiding principles, outlined in Article 4, include an acknowledgement that

“[s]tates that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, should bear, where appropriate, a commensurate degree of differentiated responsibility. . . supporting every Party to achieve the highest level of proven and sustained capacity. . . especially those [developing country Parties] that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities to respond to pandemics; and (iii) potentially bear a disproportionately high burden.”<sup>186</sup>

While these provisions mark a strong start, the treaty should also specify how wealthier states will contribute to capacity building in developing countries beyond encouraging

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182. *WHO CA+*, *supra* note 177, at 22.

183. See Zain Rizvi, *Sharing the NIH-Moderna Vaccine Recipe*, PUBLIC CITIZEN (Aug. 10, 2021) (pointing out that without the entire unredacted version of the Moderna-BARDA contract, no analysis of public policy options is possible).

184. *WHO CA+*, *supra* note 177, at 14.

185. *Id.*

186. *Id.* at 4(8).

technology transfer, for example through a defined percentage of pooled funds.

Finally, draft Article 7 addresses waivers of intellectual property rights during pandemics, but does not include any specific binding triggers for such waivers; instead, it commits Parties to supporting waivers when “necessary to increase the availability and adequacy of affordable pandemic-related products,” allowing member states which are more zealous about intellectual property protections broad discretion.<sup>187</sup> A stronger treaty could include, if not a binding commitment, at least a more detailed description of the circumstances—for example, benchmark metrics signaling the public health burden of a pandemic—under which a waiver would be considered necessary.

#### IX. CONCLUSION

In future pandemics, vaccine manufacturing must sufficiently address the challenges of necessary investment and equitable and consistent distribution, while ensuring adequate local supply and local autonomy. This will require serious coordination between national governments and binding commitments to vaccine equity. If governments can learn from the failures of vaccine nationalism during the coronavirus pandemic, we may be able to meet future health threats without witnessing the kind of devastation wrought by COVID-19.

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187. *Id.* at 7(4)(a).