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Hoarding Lifesaving Knowledge While Millions Die: The Political Economy of Global Covid-19 Vaccine Apartheid

Kenneth Stancil
University of Kentucky, stancil.kenny@gmail.com
Author ORCID Identifier:
https://orcid.org/0009-0007-9731-2738
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Kenneth Stancil, Student

Dr. Matthew Wilson, Major Professor

Dr. Michael Samers, Director of Graduate Studies

HOARDING LIFESAVING KNOWLEDGE WHILE MILLIONS DIE: THE POLITICAL ECONOMY OF GLOBAL COVID-19 VACCINE APARTHEID

THESIS

A thesis submitted in partial fulfillment of the
requirements for the degree of Master of Arts in the
College of Arts and Sciences
at the University of Kentucky

By

Kenneth Stancil

Lexington, Kentucky

Director: Dr. Matthew Wilson, Professor of Geography

Lexington, Kentucky

2023

https://orcid.org/0009-0007-9731-2738

ABSTRACT OF THESIS

HOARDING LIFESAVING KNOWLEDGE WHILE MILLIONS DIE: THE POLITICAL ECONOMY OF GLOBAL COVID-19 VACCINE APARTHEID

Coronavirus vaccines saved millions of lives, but experts estimate that the suboptimal production and inequitable distribution of shots resulted in nearly 3 million preventable Covid-19 deaths in 2021 and 2022 as well as millions of indirect deaths during the pandemic. These avoidable fatalities are inseparable from the grotesquely unequal vaccination rates between rich and poor nations. Dose hoarding by high-income countries contributed to vaccine inequality, but the "vaccine apartheid" inflicted on low-income countries reflects an even more fundamental injustice: knowledge hoarding by profit-maximizing pharmaceutical corporations—aided and abetted by wealthy governments—which deprived generic manufacturers of the right to produce additional lifesaving jabs and led to artificial scarcity and needless suffering. The knowledge underlying Covid-19 vaccines stems from billions of dollars in public funding, but corporate-friendly intellectual property rules enabled Big Pharma to monopolize these technologies in what amounts to a lethal manifestation of "accumulation by dispossession."

KEYWORDS: Covid-19, Vaccine Apartheid, WTO, TRIPS Agreement, Big Pharma, Accumulation by Dispossession

Kenneth Stancil

10/17/2023

Date

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By
Kenneth Stancil

Dr. Mattthew Wilson
Director of Thesis

Dr. Michael Samers
Director of Graduate Studies

10/17/2023
Date

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Like all seemingly individual achievements, my thesis is the result of collective effort. It could not have been written without the help of many people. First, I want to thank the people of Colorado for funding an excellent public education system. Without them, I would not have had such amazing K-12 teachers, all of whom taught me skills I use every day. I would also like to thank the people of Kentucky for funding such a fantastic public university. Thanks to the University of Kentucky for providing me with a Lyman T. Johnson fellowship, which, combined with a teaching assistantship, supported my first two years of graduate study.

I came to UK in the fall of 2013 to pursue a master's degree in Geography after finishing my undergraduate studies at Pacific Lutheran University. Thank you to my professors and friends in Tacoma, Washington for teaching me how to think critically, to struggle for a just society, and to believe in myself. I would especially like to thank Drs. Peter Grosvenor, Susan Harmon, Ann Kelleher, Brian Naasz, Kevin O'Brien, Giovanna Urdangarain, and Tamara Williams for all their support.

An especially formative intellectual and political experience came in the fall of 2011, when I studied abroad in Chile—the "laboratory of neoliberalism" where Milton Friedman and his University of Chicago acolytes' upwardly redistributive economic model was first imposed by Pinochet's military junta—at the height of the student movement for free, quality higher education. Thanks to Victor Tricot for guiding us through an intense semester of learning about the origins and impacts of neoliberalization, along with attempts to construct a more egalitarian and humane political economy. Thanks as well to my wonderful host family (Nano, Leticia, Paula,

Fernando, and Andrea) for all the informal, but equally crucial, lessons. One of the best decisions of my life was to attend a public lecture in Santiago by the renowned geographer David Harvey, who brilliantly recounted the causes and spatially uneven consequences of the global financial crisis, with an emphasis on processes of "accumulation by dispossession." In an offhand remark, Harvey predicted that a capitalist class desperate for profitable investment outlets would try to privatize every square inch of the Earth. If nothing else, he observed, monopolizing access to life-sustaining resources would provide endless opportunities to extract rent.

That talk altered the trajectory of my life. During my Global Studies capstone course a few months later, I researched how elite U.S. university endowments helped propel a rise in land grabbing across Africa, Asia, and Latin America—one manifestation of what social scientists described as a "triple capitalist crisis of food, fuel, and finance" that materialized following the 2008 crash. Enamored as I had become with the discipline, I decided to pursue an MA in Geography.

Thank you to everyone in the UK geography department for your unwavering support over many years. Thanks especially to my advisor, Dr. Matt Wilson, and my committee members, Dr. Sue Roberts and Dr. Rich Donohue, for your words of encouragement and incisive feedback on this project. Any remaining errors in what follows are mine alone. Matt W.'s support extends beyond these pages. He, along with Dr. Matt Zook, helped put me back on track to finish my degree after I spent several years pursuing other interests. Dr. Michael Samers has also been immensely helpful in recent months as DGS. Thank you all.

Originally, I sought to investigate a form of land grabbing closer to home: the acquisition by private equity firms of thousands of single-family houses around the U.S. in the wake of the foreclosure crisis. Thanks to my previous advisor, Dr. Andy Wood, for helping me during my initial stint in the department. Thanks as well to all the professors who taught me so much during those years. I appreciate the time I was able to spend in the classroom with Sue, Andy, Michael, Matt W., and Drs. Jeremy Crampton, Tad Mutersbaugh, Rich Schein, and Tony Stallins. Thanks also to Lori Tyndall, who managed the department at the time, and to our cartographers, Dick Gilbreath and Jeff Levy. Another formative experience I had—for which I must thank Sue, Andy, Michael, and Matt Z.—was assisting with logistics during the 2016 Summer Institute in Economic Geography. That was a truly amazing learning experience, and I am so fortunate to have been able to observe it up close.

I value the many friendships I made through UK Geography, the Political Ecology Working Group, and other departments on campus. Thank you for everything Jay Bowen, Jeeyen Koo, Patrick Bigger, Taylor Shelton, Lily Brislen, Chris Oliver, Nate Millington, Jessa Loomis, Malene Jacobsen, Dan Cockayne, Curtis Pomilia, Ryan Cooper, Jackie Monge, Tim Brock, Victoria Dekle, Jairus Rossi, Ali Meyer-Rossi, Derek Ruez, Brittany Cook, Jonghee Lee-Caldararo, Jessi Breen, Lindsay Shade, Christine Smith, Mitch Snider, Hugh Deaner, Kelsy Yeargain, Christine Woodward, Ian Spangler, Robby Hardesty, Jess Linz, Eric Huntley, Virginia Shapland, Karla Encalada-Falconi, Ate Poorthuis, and Igor Venceslau. Thanks as well to Emily Jones, Greg Butler, and Aaron Kappeler for being such great friends.

Due to positive experiences I had as a teaching assistant—which occurred as I had a crisis of confidence about my job prospects in academia—I changed paths to secondary social studies education before I completed my original thesis project. Thank you to Drs. Kathy Swan and Ryan Crowley from the UK College of Education for making me feel so welcome in the MIC program. I enjoyed teaching at Lafayette High School and want to thank Whitney Walker and Tim Mitsumori in particular for showing me the ropes. There are so many other people whom I should thank from Lafayette but suffice it to say that some of my most cherished professional memories were made during my time there.

A few months into the Covid-19 pandemic, I joined Common Dreams, a progressive online news outlet, as a staff writer. Thank you to Craig Brown and Jon Queally for hiring me. That likely would not have happened had it not been for a couple of op-eds I wrote for Common Dreams in March 2020. I owe Dr. Cedric Johnson a huge thank you for providing helpful feedback on those pieces. I would not have had any ties to Cedric without Dr. Adolph L. Reed Jr., whom I connected with via email after encouragement from Dr. Herb Reid in the UK political science department. Adolph and his son, Dr. Touré F. Reed, have been consistent sources of support, giving me more confidence in my abilities.

At Common Dreams, one of the issues I began to cover regularly was the inequitable distribution of Covid-19 vaccines. Thank you to Andrea Germanos, Julia Conley, Jess Corbett, and Jake Johnson for editing those articles and hundreds of others on different topics. It quickly became apparent that not only had wealthy governments purchased an outsized share of doses, but that pharmaceutical rentiers were taking

advantage of corporate-friendly intellectual property rules to monopolize publicly funded technologies and stymie generic production. It was not land grabbing, in this instance, but the enclosure of the knowledge commons reflected the same dynamic of accumulation by dispossession.

With an eye toward becoming a data journalist, I enrolled in the UK geography department's New Maps Plus program in the spring of 2021 to gain some skills in creating interactive visualizations. Given that I was often writing about the topic at work, I decided to make global Covid-19 vaccine apartheid the focus of a pair of final projects as I completed coursework for my graduate certificate in Digital Mapping. Thank you to Ryan Cooper, Boyd Shearer, Jay Bowen, and Rich Donohue for helping me with various iterations of that web map. Thanks also to Ali Meyer-Rossi for inviting me to guest lecture in her class in the fall of 2021 and again in the spring of 2022. Those experiences convinced me that I had more to say about this topic and proved to be a major impetus for expanding a budding storymap into a full-fledged thesis.

Finally, I want to thank my parents, Phil and Shelly, for everything they have done to care for me over the years. Thanks as well to my brother, J.T., for always having my back. I love you all! Last but certainly not least, thanks to my partner, Steph Federico, for all the ways she has made my life better over the past eight years. It feels impossible to adequately convey my gratitude on these pages, but I must try: Thank you, Steph. Without you, I never would have finished this project. I love you.

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INTRODUCTION. COVID-19 VACCINES: GLOBAL PUBLIC GOODS OR BIG PHARMA'S PRIVATE PROPERTY?

"Decent research, and certainly critical research (for all research, given the way the world is today, must be critical, or it is dishonest) must look at structural causes, and can only understand them by contrast with alternative lines of development not taken but possible."—Peter Marcuse[1]

Throughout the Covid-19 pandemic, vaccine inequality persisted despite epidemiologists' warnings that allowing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to spread unabated in low-income countries increased the risks of new, potentially vaccine-resistant variants emerging. Why was such a dangerous state of affairs sanctioned and by whom? As we shall see, intellectual property (IP) monopolies hindered the rapid scaling up of generic manufacturing needed to meet global needs in a timely fashion and should be regarded as the fundamental source of the deadly injustice known as "vaccine apartheid."[2]

Geographers have contributed to our understanding of the Covid-19 pandemic, including the massive and enduring gap in inoculation rates between rich and poor countries (Sparke and Anguelov 2020, Sparke and Williams 2022). Notably, Sparke and Levy (2022) provide a useful framework for analyzing global inequalities in access to vaccines. As they argue, "vaccine diplomacy"—bilateral donations made largely for geostrategic reasons—and "vaccine charity"—multilateral donations organized through

---

1 Marcuse (2010)

2 The first use of the phrase "vaccine apartheid" in relation to the Covid-19 pandemic that I found came from South Africa's WTO delegation during a December 10, 2020, debate over the TRIPS waiver proposal they co-led with India.

the COVAX initiative backed by international health agencies as well as the pharmaceutical industry—are woefully inadequate approaches to immunization that have "worked together to undermine the promise of universal access through vaccine liberty" (86).

Covid-19 vaccines preserved millions of lives (Watson et al. 2022). However, an estimated 1.3 million additional lives could have been saved in 2021 had shots been distributed equitably—defined as "protecting either equal proportions of each country or the oldest individuals first across the globe" (Moore et al. 2022: 2418). An estimated 1.5 million deaths could have been averted in 2022 if universal vaccination, defined as three doses of a messenger RNA (mRNA) shot, had been achieved in low- and lower-middle-income countries (Savinkina et al. 2022). The number of avoidable deaths associated with vaccine apartheid soars when considering excess mortality (Oxfam 2022).

Of course, universal inoculation with three mRNA jabs per person presupposes adequate supply and efficient allocation. But two key factors impeded such an outcome: 1) "Vaccine nationalism," or dose hoarding by high-income countries; and 2) "IP nationalism," or knowledge hoarding by pharmaceutical corporations, with help from rich governments.

In contrast to "vaccine diplomacy" and "vaccine charity," Sparke and Levy's "vaccine liberty" (which I prefer to call "vaccine justice"[3]) refers to more radical efforts to boost supply and ensure equitable distribution by sharing knowledge and technology to ramp up generic production. It runs directly counter to the neoliberal IP regime whose

[3] It is not hard to imagine anti-vaxxers adopting the slogan of "vaccine liberty," if they have not already. "Vaccine justice" seems to more accurately capture the spirit and objectives of those working to achieve universal access to disease prevention tools.

hegemony has been secured via the World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Because the swift development of lifesaving Covid-19 vaccines depended on substantial infusions of public resources, the de facto privatization of the underlying knowledge and technology constitutes "deadly rent-seeking" as Stiglitz and Wallach (2021) put it, or a lethal manifestation of what David Harvey (2003) calls "accumulation by dispossession." Furthermore, the circumstances surrounding the monopolization of Covid-19 vaccine IP reflects Brett Christophers' argument that the upshot of neoliberalism is the "rentierization" of capitalism (2020).

This thesis builds on our collective understanding of the production of and resistance to spatially uneven patterns of vaccination during the Covid-19 pandemic. It began as an interactive mapping project aimed at visualizing the problem (Stancil 2022).[4] While useful insofar as it documents the scope of vaccine inequality and some attempts to combat it, that storymap is necessarily limited in explanatory power. The following text, which I see as complimentary to my earlier effort, aims to examine the causes and consequences of, as well as alternatives to, the bifurcation of the world into two separate spheres: one in which lifesaving doses are oversupplied and ultimately wasted and another in which people are unconscionably told to wait for leftovers as preventable suffering mounts.

The overarching questions that I seek to answer are: 1) Why have less than one-third of people in impoverished nations received at least one dose of a Covid-19 vaccine to date? 2) What attempts were made to improve access? 3) What is being done to

[4] See appendices for additional information about this interactive visualization.

prevent something similar from happening again? The gist of my argument is that high-income nations' dose-hoarding and their authorization of knowledge hoarding by pharmaceutical corporations—whose Covid-19 vaccines, tests, and treatments couldn't have been developed in a matter of months without huge injections of public funding—resulted in artificial scarcity, needlessly prolonging the pandemic while helping to transform several executives into billionaires (People's Vaccine Alliance 2021c).

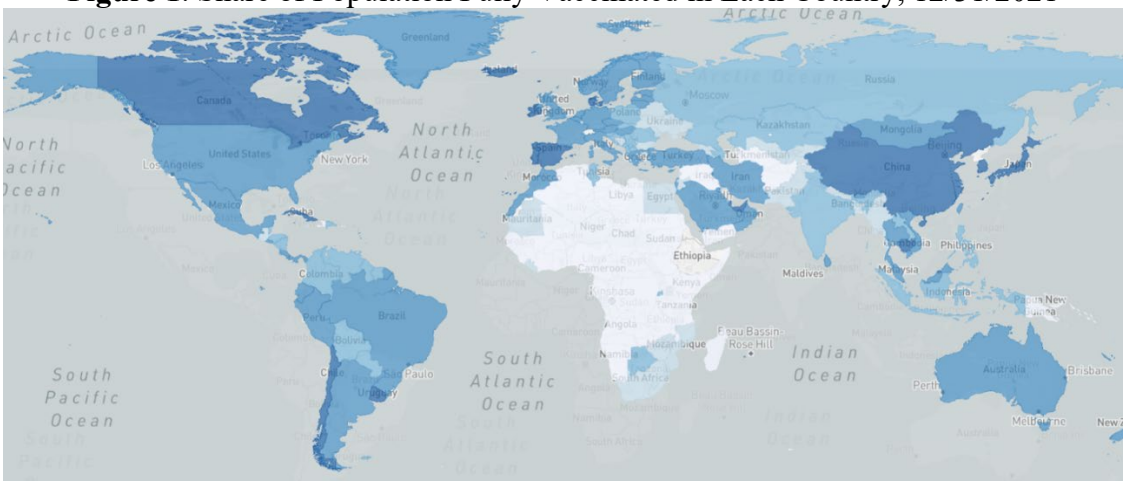
Policymakers from wealthy countries refused to force profitable drugmakers to relinquish their monopoly power over publicly funded technology even as the pandemic's global death toll surpassed 15 million (WHO 2022b). Excess mortality—an estimate of the difference in the number of deaths that occur amid a crisis compared with what would have been expected under "normal" conditions—has been disproportionately high in poorer countries (Oxfam 2022). Alarming surges in poverty, hunger, and other forms of immiseration—also felt most heavily in developing nations—are likewise inseparable from vaccine apartheid, which exacerbated the coronavirus-driven economic crisis and delayed recovery, helping to intensify inequality and push the world closer to a global debt crisis (UNDP 2022).

My use of GIS and digital mapping yielded the following maps, which show the ongoing scale of vaccine inequality. The vaccine rollout began in earnest at the start of 2021. By the end of that year, nearly half the world's population was fully inoculated, by which I mean they had completed the initial protocol (e.g., 1 shot of Johnson & Johnson, 2 shots of NIH-Moderna or Pfizer-BioNTech). However, the vaccination campaign was plagued by profoundly unequal access. While nearly 70% of people in high-income

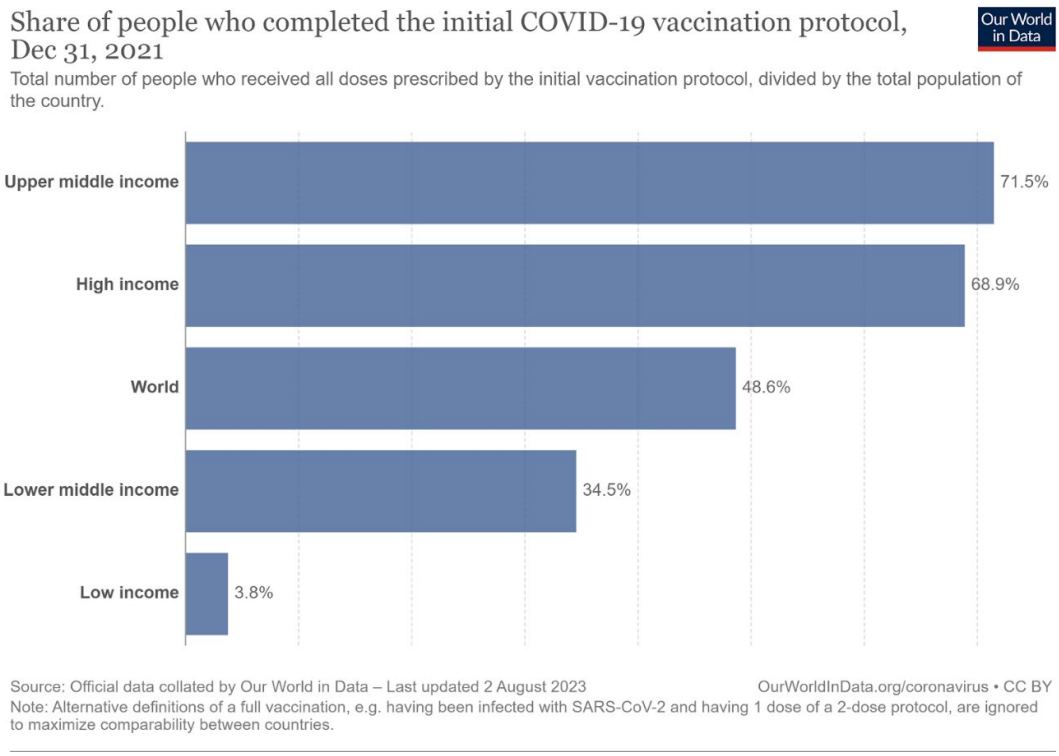
countries had received their initial jabs by the end of 2021, less than 4% of people in low-income countries had (Mathieu et al. 2021).

Epidemiologists repeatedly stated that vaccine equity is not only a moral obligation but a matter of self-interest, using the common refrain, "Nobody is safe until everybody is safe." The longer SARS-COV-2 circulates, the more chances it has to mutate, and eventually a vaccine-resistant variant could emerge, they warned (People's Vaccine Alliance 2021b). Such warnings were to little avail; the stockpiling of doses and stockading of knowledge prevailed. In an ironic twist of fate, the late-November 2021 arrival of Omicron forced the postponement of a WTO Ministerial at which well-vaccinated wealthy countries were expected to continue their defense of the IP monopolies arguably responsible for the highly contagious variant's emergence (Baker 2021, Prasad et al. 2022).

Figure 1. Share of Population Fully Vaccinated in Each Country, 12/31/2021



Map by Kenny Stancil. See Appendix 1 for a link to the interactive version, data sources, and code.



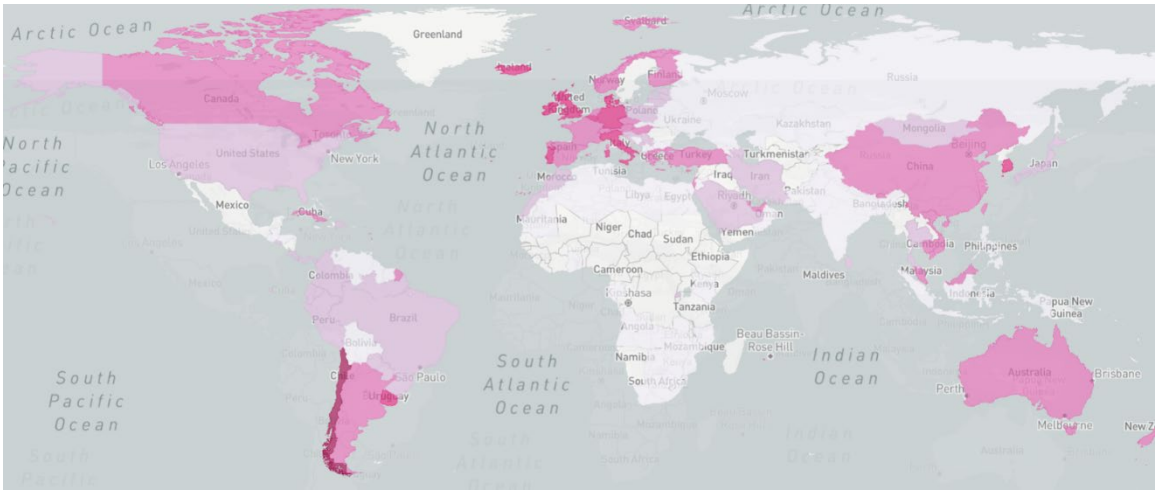
The World Health Organization (WHO) recommended first doses for healthcare workers and vulnerable populations in low-income countries before booster doses for relatively healthy populations in high-income countries (WHO 2020e). But rather than adhere to the WHO's guidelines for vaccination prioritization, third and fourth shots were administered in many countries before billions of people, particularly on the African continent, had obtained their first. This placed further constraints on global vaccine supply—especially of the most effective mRNA jabs, eventually including updated bivalent versions—which was already artificially limited by IP monopolies.

WHO Director-General Tedros Adhanom Ghebreyesus in early August 2021 called for a moratorium on booster doses until the end of September "to enable at least 10% of the population of every country to be vaccinated" (Adhanom 2021e). The following month, he lamented that "there has been little change in the global situation since then" and called for extending the moratorium "until at least the end of the year, to

enable every country to vaccinate at least 40% of its population" (Adhanom 2021f). By December 2021, roughly one month after the Omicron variant had been detected, Tedros told reporters that "no country can boost its way out of the pandemic" (Adhanom 2021g). He added that "blanket booster programs are likely to prolong the pandemic, rather than ending it, by diverting supply to countries that already have high levels of vaccination coverage, giving the virus more opportunity to spread and mutate."

And yet, by March 11, 2022, the second anniversary of the WHO's pandemic declaration, high-income countries had provided 190 shots per 100 people, compared with 17 per 100 in low-income countries (Mathieu et al. 2021).

Figure 2. Number of Booster Doses Administered Per 100 People in Each Country, 3/11/22



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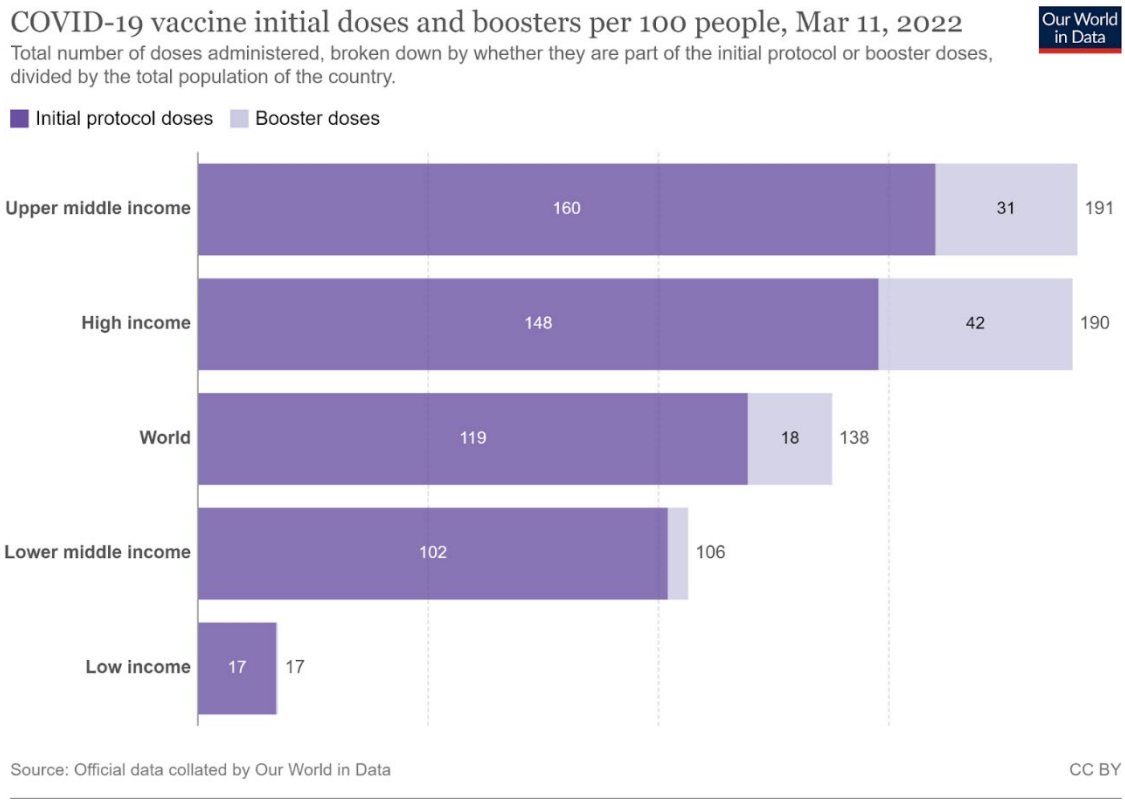
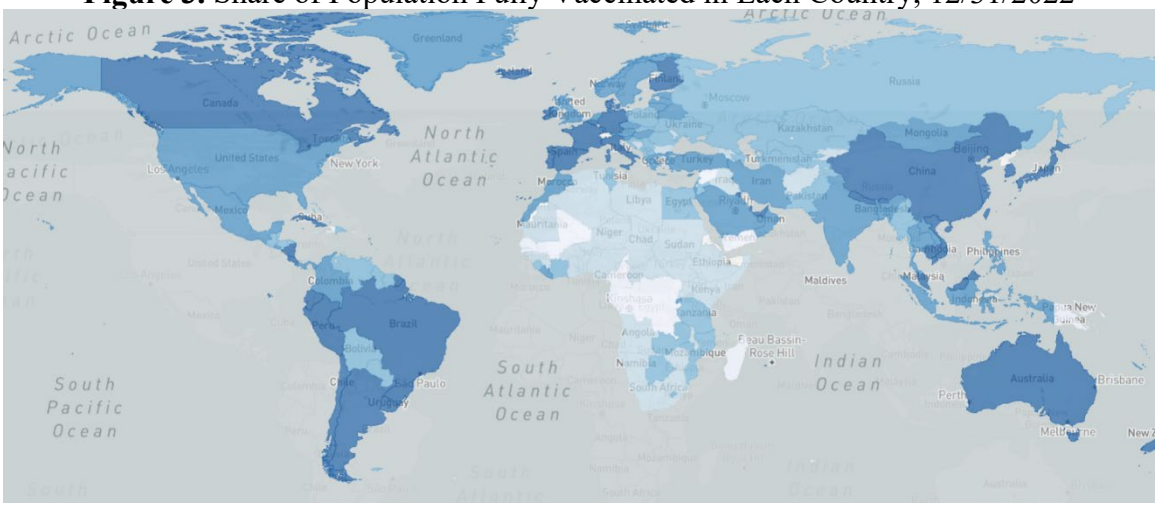


Vaccine inequality persisted throughout the year. After U.S. President Joe Biden claimed in mid-September 2022 that "the pandemic is over"—an assertion he made as Covid-19 killed nearly 11,000 people across the planet each week (Mathieu et al. 2020)—WHO senior adviser Bruce Aylward told *Reuters*: "When I hear them say, 'Well, we're so comfortable here,' it's like, 'Great, now you can really help us get the rest of the world done'" (Rigby 2022).

Days earlier, Tanriover and Akova (2022: 1655) wrote in a commentary for *The Lancet Infectious Diseases* that "the best chance to stop this pandemic is to make vaccines available for everyone, everywhere. The efforts to provide booster doses should be balanced with the efforts to attain vaccine equity." By the end of the year, however, 74% of people in high-income countries had completed their initial Covid-19 vaccination protocol, compared with just over 21% in low-income countries (Mathieu et al. 2021).

Figure 3. Share of Population Fully Vaccinated in Each Country, 12/31/2022



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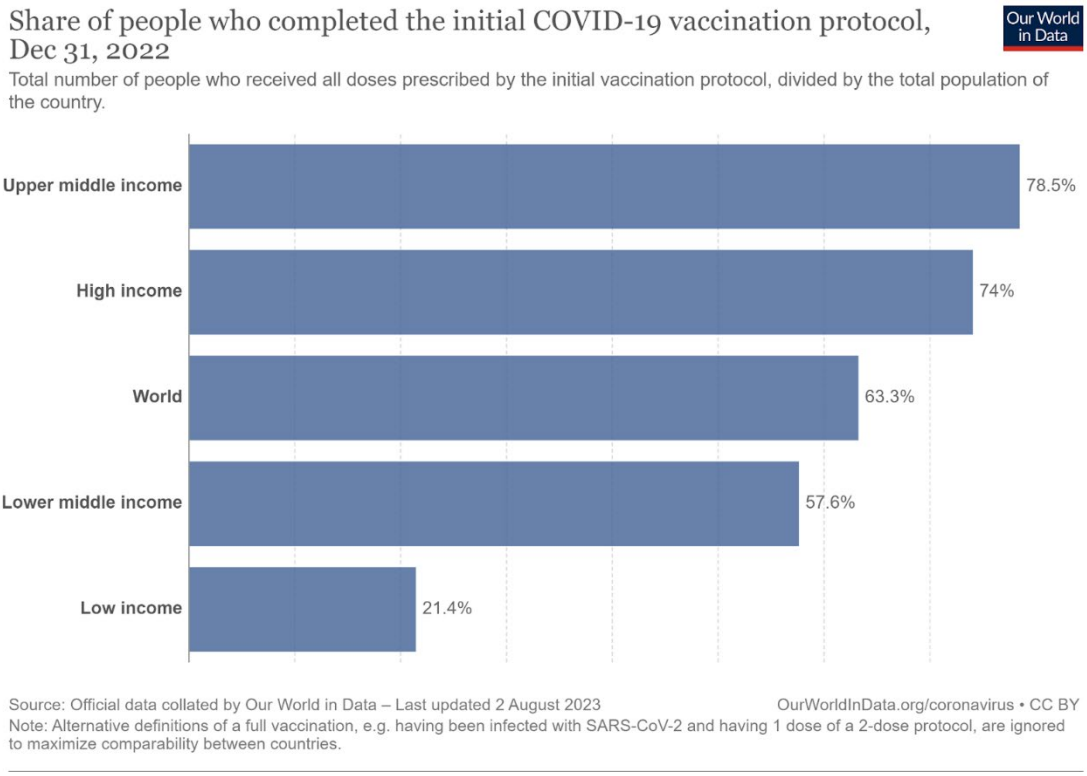
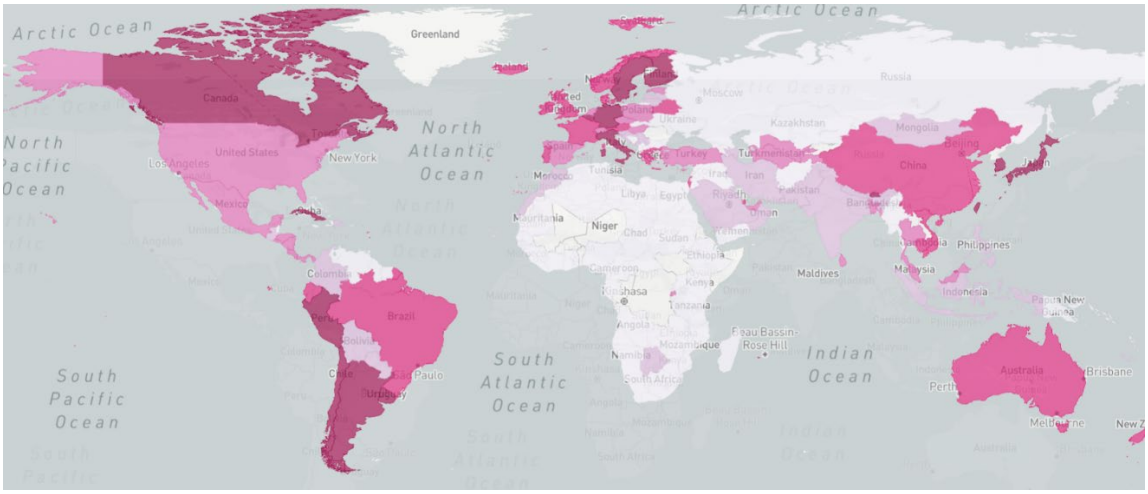


The injustice continued in 2023, with high-income countries having allocated 224 shots per 100 people compared with 38 per 100 in low-income countries (Mathieu et al. 2021).

Figure 4. Number of Booster Doses Administered Per 100 People in Each Country, 3/11/23



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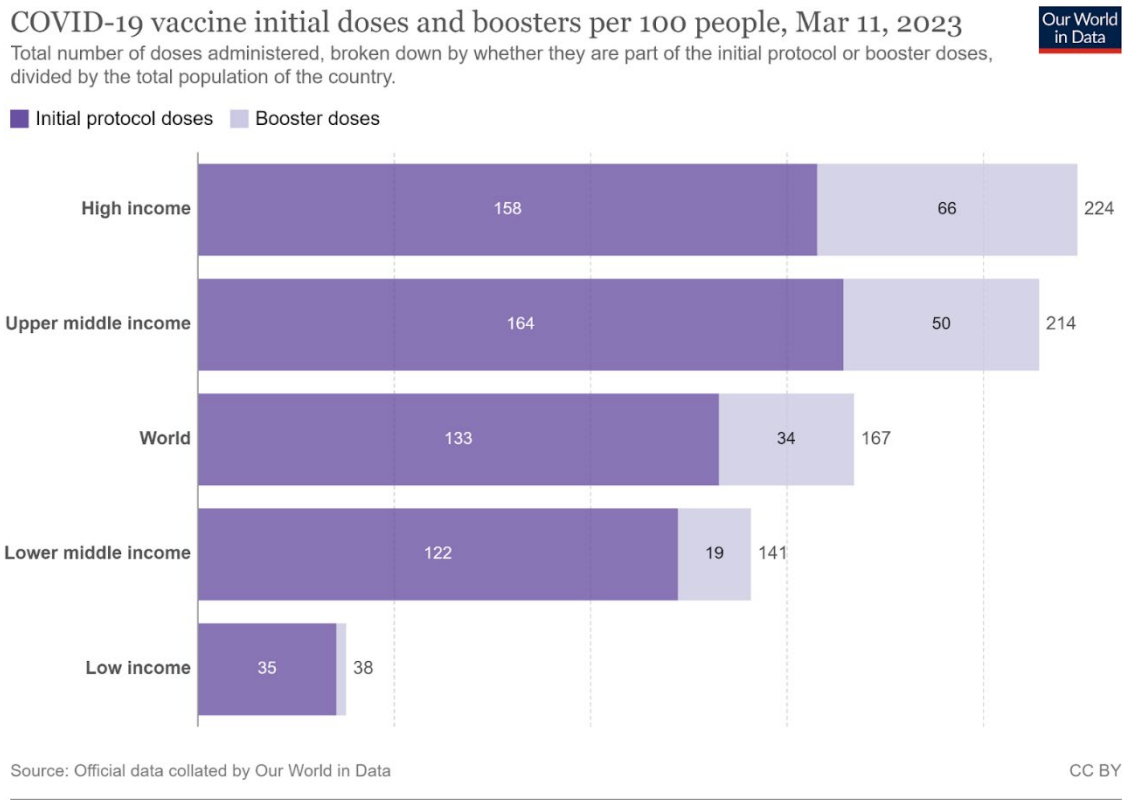

Coronavirus vaccines saved millions of lives (Watson et al. 2022), but public health experts estimate that the suboptimal production and inequitable distribution of

shots contributed to nearly 3 million avoidable Covid-19 deaths in 2021 and 2022 (Moore et al. 2022, Savinkina et al. 2022) as well as millions of indirect deaths (Oxfam 2022).

As Buranyi (2021) observed: "This system, where a company that holds the patent on a drug can monopolize its production, even in a global emergency, is a recent invention. During the second world war, the U.S. government forced pharmaceutical companies to share recipes for antibiotics. In the worldwide campaign against smallpox, the WHO maintained a register [of] manufacturing techniques and recipes, evaluating them and helping to share the technology globally. We collectively recognized that some things are more important than the legal protection of profit."

This thesis is comprised of three chapters. Chapter 1 covers the monopolization of Covid-19 vaccine IP. The first section of the chapter focuses on how Big Pharma turned publicly funded mRNA technology into its own private property—and billions of dollars in profits. It is based on my examination of peer-reviewed research and white papers on U.S. government contributions to the development and procurement of mRNA Covid-19 vaccines as well as profit data compiled by de Haan and ten Kate (2023).

I focus on the U.S. National Institutes of Health (NIH)-Moderna and Pfizer-BioNTech jabs for several reasons. First, Moderna and Pfizer-BioNTech are arguably the biggest beneficiaries of public support, taking into account funding (Lalani et al. 2021, Lalani et al. 2023, Rizvi 2020a, Rizvi and Maybarduk 2020), the intellectual contributions of government scientists (Allen 2020, Frank et al. 2021, Rizvi 2020b), and the fact that mRNA technology has lucrative applications beyond Covid-19. Second, they were the biggest coronavirus profiteers, selling the largest proportion of shots to high-income countries (de Haan and ten Kate 2023, People's Vaccine Alliance 2021d).

Finally, in light of the U.S. government's ownership stake in the NIH-Moderna vaccine that it co-invented (Rizvi 2020b), Moderna represents the biggest missed opportunity for widespread technology transfer (Rizvi 2021a).

Following Stiglitz and Wallach (2021), who denounce the hoarding of vaccine knowledge as a form of "deadly rent-seeking," I conceptualize it as a lethal expression of "accumulation by dispossession" (Harvey 2003). Such practices have gained prominence in the neoliberal era, which, according to Christophers (2020), is bringing about the "rentierization" of capitalism.

In the second section of Chapter 1, I summarize how the United States' once-peculiar acceptance of pharmaceutical IP became globally hegemonic via the WTO's TRIPS Agreement (Drahos and Braithwaite 2007, Sell 2003, Tyfield 2008, Wallach and Woodall 2004, Zaitchik 2022). I also recount how the fight to expand access to HIV treatments at the turn of the century led to some pro-access flexibilities ('t Hoen 2002, 't Hoen 2009, 't Hoen 2016). The limitations of those provisions were clear during the Covid-19 pandemic and prompted a campaign to suspend coronavirus-related IP enforcement.

Chapter 2 covers the protection of Covid-19 vaccine IP monopolies. The first section of the chapter details the unsuccessful fight to waive certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of Covid-19. To accomplish this, I analyzed minutes from WTO TRIPS Council meetings; synthesized reporting by investigative journalists; scrutinized public archives and open data from sources like Knowledge Ecology International; and reviewed public statements and press releases; letters from lawmakers and advocacy groups; and white papers.

It is difficult to see the yearslong battle and ultimate defeat of the proposed TRIPS waiver as anything other than an attempt by wealthy countries with robust private pharmaceutical industries to defend the current IP regime at all costs even as they faced a legitimacy crisis. A compromise deal was eventually struck in what critics say was a face-saving attempt to demonstrate the WTO's relevance (People's Vaccine Alliance 2022b). Access to medicines campaigners insist that the resolution should not be called a TRIPS waiver because it does not resemble the original proposal. It applies only to patents—not trade secrets—and only to vaccines, thus excluding tests, treatments, and other key medical tools (Public Citizen 2022). It should be stressed that IP encompasses not only patents but also undisclosed information, including know-how, trade secrets, and data (Gurgula and Hull 2021).

In the second section of Chapter 2, I analyze how the Biden administration failed to use the full extent of the U.S. government's authority to license taxpayer-funded—and in some cases, publicly owned—vaccine technologies to manufacturers around the world and to invest in expanded vaccine production to combat Covid-19 and other infectious diseases. I used similar methods as in the preceding section, with a particular reliance on grey literature produced by Public Citizen.

Hawksbee et al. (2022: 3) proffer a guess, compelling in my view, as to why more was not done to share lifesaving knowledge during the pandemic, and I quote at length:

> Why are companies insistent that strong intellectual property rights must remain in place even for vital vaccines they cannot produce enough of during a global public health crisis?
>
> One reason is that many of the Covid-19 vaccines currently on the market or in development incorporate new generic vaccine platforms that—with relatively simple changes—could yield not only further vaccines but treatments for other diseases. A letter being circulated among U.S. legislators warns that a waiver

> would allow China to "profit from our innovation," beating the U.S. to develop products based on the new platforms.
>
> This might explain why certain leading companies are so keen to monopolize not only intellectual property rights, but also the productive capacity and, perhaps even more importantly, the knowledge, or "trade secrets," needed to produce the vaccines. Pfizer's chief executive officer noted the "dramatic potential" of the mRNA technology and stated, "We are now ahead and we plan to maintain the gap" in future development. By collaborating with BioNTech, Pfizer can say that now "we have our own expertise developed." Little wonder that Pfizer are so reluctant to help competitors obtain for free the same knowledge.

The needless manifestation of vaccine apartheid during the Covid-19 pandemic revealed once again that the Global South cannot rely on the benevolence of the Global North, the geography of vaccine production must be expanded, and governments must reassert democratic control over publicly funded knowledge. Chapter 3 examines a WHO-led effort to facilitate mRNA technology sharing and ramp up domestic vaccine manufacturing capacity in developing countries to prevent future abandonment by rich countries and Big Pharma.

CHAPTER 1. MONOPOLIZING COVID-19 VACCINE IP

"Big Pharma companies don't really do the research and development of new medicines anymore. What they effectively are now is hedge funds that buy up intellectual property."—Nick Dearden, Global Justice Now[5]

On March 11, 2023, three years after the WHO declared Covid-19 a pandemic, just 28.1% of people in low-income countries had received a single dose of a coronavirus

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5 The People's Vaccine (@peoplesvaccine). "'Big Pharma companies don't really do the research and development of new medicines anymore. What they effectively are now is hedge funds that buy up intellectual property.'" 25 Mar. 2023, 9:18 a.m. Tweet.

vaccine, compared with 79.5% of people in high-income countries (Mathieu et al. 2021). As of this writing in October 2023, lifesaving shots have reached less than one-third of humanity's poorest members. What explains this injustice?

Months before the first Covid-19 vaccine had received emergency use authorization, wealthy governments reached opaque deals with pharmaceutical corporations to acquire far more jabs than could be administered to their populations (Collins and Holder 2021, Global Health Centre 2021a). Tens of millions of these shots eventually expired and wound up in the trash rather than in people's arms (Eaton 2022, Airfinity 2022), revealing the unethical and epidemiologically reckless nature of what has been criticized as "vaccine nationalism" (Riaz et al. 2021, Md Khairi et al. 2022).

While dose hoarding by well-heeled governments has certainly contributed to the problem, knowledge hoarding by pharmaceutical corporations is the most significant cause of the massive inoculation gap between rich and poor nations because it has suppressed the global supply of jabs available for distribution (Ghosh 2021, Stiglitz and Wallach 2021, WTO 2021a). Big Pharma's IP monopolies have been shielded by the same wealthy governments that gobbled up an excessive number of shots, eliciting critiques of "IP nationalism" (Ho 2022). The maldistribution of available Covid-19 vaccines along North-South lines is indefensible. That the affluent, stockpiling nations have teamed up with pharmaceutical giants to withhold the IP, manufacturing know-how, and technology needed by qualified generic drugmakers around the world to ramp up production is even more preposterous and underlies charges of "vaccine apartheid" (Prasad et al. 2022).

1.1 Turning Publicly Funded mRNA Knowledge into Private Profits: A Case of Accumulation by Dispossession

Not only did Big Pharma prioritize prosperous countries capable of pre-ordering Covid-19 vaccines over impoverished countries that were pushed to the end of the queue at the beginning of the pandemic, but it has continued to deprive generic manufacturers of the knowledge required to make additional doses. Monopolizing IP has enabled a few powerful firms to augment their profits (Oxfam 2021). It has also exacerbated preventable suffering. Adding insult to injury, the lifesaving vaccine knowledge unjustly locked away by corporations and their lawmaking allies was made possible by decades of support from the public sector, which provided billions of dollars for research and development (R&D), production, and procurement—only to find itself on the outside looking in due to a lack of attached strings and/or unwillingness to use existing authorities to break up IP monopolies (Kapczynski et al. 2023, Lalani et al. 2022).

No matter how much Moderna and Pfizer-BioNTech assert that the speedy delivery of mRNA Covid-19 vaccines is the result of private innovation for which they deserve exclusive credit and lavish remuneration (Nathan-Kazis 2020), the availability of high-quality jabs less than a year into the pandemic is the product of enormous public subsidy and de-risking (Frank et al. 2021, Global Health Centre, 2021b). The U.S. government alone invested more than $2.6 billion in the development of mRNA Covid-19 vaccines, including over $330 million in the three-plus decades before the global public health emergency was declared (Lalani et al. 2023). From 1985 to 2019, the NIH spent $116 million on basic and translational science related to mRNA vaccine technology, while the Biomedical Advanced Research and Development Authority (BARDA) and the Department of Defense spent a combined $220 million on coronavirus

vaccine development (ibid.). From the start of 2020 through March 31, 2022, the U.S. government provided more than $2.3 billion, mostly through Operation Warp Speed (OWS), to support basic and translational science, bankroll clinical trials, and bolster manufacturing capacity (Lalani et al. 2023). An additional $29.2 billion of U.S. public money was used to purchase mRNA Covid-19 vaccines during this same period (ibid.).

While the public funding underpinning the NIH-Moderna vaccine is widely conceded,[6] Pfizer and BioNTech executives have asserted that neither company accepted U.S. government support to develop their joint Covid-19 vaccine (ibid.). This is misleading, however, as Pfizer-BioNTech would not have been able to produce an mRNA jab in record time without the licensed technologies emanating from research funded by U.S. taxpayers (ibid.). Moreover, BioNTech received $445 million from the German government to expedite Covid-19 vaccine development and to increase manufacturing capacity (ibid.).

The table below is based on data compiled by Public Citizen researchers Zain Rizvi and Peter Maybarduk (2020). Rizvi has also documented how years of pre-OWS public investments yielded the mRNA platform on which the NIH-Moderna and Pfizer-BioNTech Covid-19 vaccines depend as well as the prefusion spike protein technology on which those two shots plus three others depend (2020a and 2020b).

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[6] Moderna admitted in August 2020 that the U.S. federal government provided "100%" of the funding for preclinical and clinical research on mRNA-1273, the Covid-19 vaccine candidate jointly invented by NIH and Moderna (Herman 2020). However, the pharmaceutical corporation had previously failed to disclose this information despite being contractually obligated to do so. The belated admission came after researchers from Public Citizen and Knowledge Ecology International sent a letter calling on BARDA acting director Gary Disbrow to enforce a provision requiring Moderna to state what percentage of the vaccine's development costs were covered with public money (Ardizzone and Rizvi 2020).

Table 1. Direct Public Support of mRNA Covid-19 Vaccines

Vaccine Developer	Operation Warp Speed (OWS) Funding	Other Support	U.S. Advanced Purchase Agreements (APAs)	
NIH-Moderna	$2.48 Billion	• Uses NIH spike protein technology • NIH helped invent the vaccine, claims joint ownership, and ran clinical trials • Moderna has said 100% of the activities covered under its BARDA contract—ranging from clinical trials to FDA application fees—are taxpayer-funded	8/11/20, 100 million doses	$1.53 Billion
			12/11/20, 100 million doses	$1.67 Billion
			2/11/21, 100 million doses	$1.65 Billion
			6/15/21, 200 million doses	$3.3 Billion
			7/29/22, 66 million doses	$1.74 Billion
			566 million doses	$9.89 Billion
Pfizer-BioNTech	n/a	• Uses NIH spike protein technology • BioNTech received a €100 million loan from the European Investment Bank and €375 million in funding from the German government • OWS helped with logistics, such as securing raw materials	7/21/20, 100 million doses	$1.95 Billion
			12/22/20, 100 million doses	$ 2.01 Billion
			2/11/21, 100 million doses	$2.01 Billion
			7/21/21, 200 million doses	$4.87 Billion

Table 1, continued

			7/30/21, 500 million doses (int'l donation)	$3.5 Billion
			10/22/21, 50 million doses	$1.23 Billion
			11/19/21, 200 million doses (int'l donation)	$1.4 Billion
			1/19/22, 300 million doses (int'l donation)	$2.05 Billion
			6/29/22, 105 million doses	$3.2 Billion
			1.66 billion doses	$22.22 Billion
Total	*$2.48 Billion*		*2.22 billion doses (incl. 1 billion for int'l donation)*	*$ 32.11 Billion*

Sources: Rizvi and Maybarduk (2020): OWS funding and other support; Lalani et al. (2023) and UNICEF Covid-19 Vaccine Market Dashboard: U.S. government APAs

Given this immense public backing, health justice advocates insist that mRNA Covid-19 jabs are "the people's vaccines" (People's Vaccine Alliance 2023). But rather than take steps to ensure that these taxpayer-funded medical tools are treated as "global public goods" (Oxfam 2020a), policymakers have allowed Moderna and Pfizer-BioNTech to monopolize the know-how and technology required to manufacture them—turning socially generated vaccine blueprints into privately held IP assets (Kang 2020). This de facto privatization of public science—a longstanding problem stemming from

policymakers' failure to keep government-enabled research in the public domain or to at least require grant recipients to meet fair pricing and open licensing conditions—has inhibited mass production by generic drugmakers. The ensuing artificial shortage of jabs has proven simultaneously deadly and profitable.

While Watson et al. (2022) found that Covid-19 vaccines prevented roughly 20 million deaths worldwide in 2021, Moore et al. (2022) estimate that 1.3 million more lives could have been saved that year alone had shots been distributed equitably.[7] Furthermore, had Moderna and Pfizer-BioNTech shared—or been compelled to share—the publicly financed vaccine formulas needed to expand the generic production of mRNA jabs, 1.5 million Covid-19 deaths could have been averted in 2022 (Savinkina et al. 2022).[8]

Instead, these pharmaceutical "rentiers"—defined by Brett Christophers (2020: xvi) as economic actors who receive rental payments "purely by virtue of controlling something valuable"—have ruthlessly defended their IP monopolies, constraining vaccine supply and maximizing shareholder returns. Moderna and Pfizer-BioNTech raked in more than $64 billion in combined profits from Covid-19 shots in 2021 and 2022 (de Haan and ten Kate 2023), with multiple executives and investors joining the billionaire ranks as a result (People's Vaccine Alliance 2021c).

Table 2. mRNA Covid-19 Vaccine Profits, 2021 and 2022

Company	Net Profit	Profit Margin

[7] Defined as "protecting either equal proportions of each country or the oldest individuals first across the globe" (Moore et al. 2022: 2418).

[8] For this to have happened, the authors note, low- and lower-middle-income countries would have needed to achieve universal vaccination, defined as three doses of an mRNA shot.

Table 2, continued

Moderna	$20.6 Billion	54.5%
Pfizer-BioNTech	$44.1 Billion	55.5%
Combined	*$64.7 Billion*	*55%*

Source: de Haan and ten Kate (2023), Moderna (2023)

"The kind of wealth amassed by the pharmaceutical industry can be created only by the political magic of monopoly," Alexander Zaitchik (2022: xi) observes. "If the state ceases to grant, enforce, and extend exclusive rights to the production and sale of drugs and medicines, the power to spin private gold from public investment and human illness combusts and disappears."

Even mainstream commentators have been forced in recent years to admit that "monopoly power is more than an aberration but a systemic problem that arises out of what economists refer to as 'rent-seeking,'" argues David Harvey (2014: 132). And "rent-seeking," Harvey continues, "is nothing more than a polite and rather neutral-sounding way" of describing "accumulation by dispossession."[9] The way Moderna and Pfizer-BioNTech have benefited from state-granted monopoly power over publicly funded mRNA vaccine knowledge during a devastating pandemic is emblematic of the accumulation by dispossession (Harvey 2003) that has flourished on a global scale in the neoliberal era (Tyfield 2008).

Harvey (2005) characterizes neoliberalization as a political project aimed at consolidating capitalist class power by reversing working-class gains made during the

[9] Stiglitz and Wallach (2021) put it pointedly when they referred in May 2021 to Big Pharma's "deadly rent-seeking."

brief period when Keynesianism was hegemonic (i.e., the roughly 30 years between the end of World War II and the end of the Vietnam War). The goal of this ongoing project is to prioritize capital above all else, or as Quinn Slobodian (2018) puts it, to "insulate" capital from democratic attempts to restrain it. Although the incoherence of neoliberalism's "free market" utopian ideology (Peck 2010) has become increasingly obvious amid recent crises, its policy regime, which revolves around using the state to facilitate the upward redistribution of wealth, remains dominant (Bruff 2019).[10]

Neoliberalism's architects have replaced notions of social solidarity with an ideology of individualized wealth accumulation (Brown 2015) and familial wealth transmission (Cooper 2017). [11] Nearly 50 years of assaults on organized labor and the state's welfare and administrative functions have suppressed wages and the social wage (Duménil and Lévy 2004). Historic declines in union membership—coinciding with the geographically uneven reconfiguration of capital and labor associated with globalization—have undermined workers' collective bargaining power and rendered a growing share of employment more precarious, while regressive tax reforms have enabled the super-rich to deprive state coffers and regulatory rollbacks have left people and ecosystems less protected. As the provision of various public goods has deteriorated

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[10] While the neoliberal model has long been associated with force—particularly in the developing world, where U.S.-backed authoritarian governments and Washington-dominated international financial institutions have imposed ruling class agendas on heavily indebted nations—and always faced popular opposition (Jessop 2019), its persistence is increasingly dependent on coercion rather than consent, with mounting evidence of "de-democratization" around the world (Kiely 2017). Proponents of neoliberalism have never tried to conceal their disdain for social and economic democracy, and their hostility to political democracy is something of an open secret (MacLean 2017).

[11] In Colin Crouch's (2009) formulation, for instance, mortgage borrowers' reliance on real estate appreciation to fund their retirement and/or their children's higher education—seen as an investment in improving job prospects and future income—can be thought of as "privatized Keynesianism" because households, rather than the state, are assuming risks to promote their own well-being as their share of GDP declines and entitlements face sustained attacks.

amid relentless budgetary attacks, opportunistic forces (Klein 2007, Mirowski 2014) have sought to commodify and privatize water, healthcare, housing, education, and other social services and infrastructures—forcing cash-strapped households to shell out more money or take out loans to pay for market-allocated necessities, or else go without them and be stigmatized for a presumed lack of personal responsibility.

According to Christophers (2020), the upshot of the neoliberal onslaught is the "rentierization" of capitalism. As detailed above, deunionization has increased the rate of labor exploitation and amplified the need for debt-financed consumption, while successive rounds of deregulation and austerity have paved the way for the privatization and financialization of social reproduction, transforming a growing number of life-sustaining goods into profitable opportunities for creditors to appropriate interest (Ross 2013, Soederberg 2014) and asset owners to extract rents (Christophers 2023).

As Christophers (2020: 73) argues: "The economics of rent have never been only about the scarcity of the asset that the rentier controls. Indeed, the clue is right there in the word 'controls': the conditions under which an asset is held and commercialized are just as important to its capacity to generate rents as the conditions of its materialization in the world." Under what conditions have Covid-19 vaccine IP assets been held and commercialized?

To understand how a few companies came to wield lucrative control over publicly funded medical tools, one must consider the rise and ensuing dominance of state-backed knowledge monopolies—major turning points in the history and geography of neoliberalization (Tyfield 2008). The U.S. government's relatively early acceptance of monopoly medicine—never a foregone conclusion but rather an outcome that followed

decades of contestation—was initially considered heretical (Zaitchik 2022). But by the mid-1990s, Washington's once-peculiar subordination of public health to pharmaceutical industry profits had been globalized via the establishment of the WTO's TRIPS Agreement (Drahos and Braithwaite 2007, Sell 2003, Wallach and Woodall 2004). It is to this transformation that we now turn.

1.2 The Globalization of U.S.-Style Fealty to Big Pharma's Monopoly Power

The U.S. government has not always been committed to advancing a corporate-friendly patent system, let alone long-lasting knowledge monopolies on the production of lifesaving drugs. The concept of "intellectual property" is now accepted as common sense in many quarters. But far from being inevitable or permanent, today's hegemonic interpretations of IP as a positive force or a necessary evil should be seen as the products of decades of pharmaceutical industry organizing—from traditional lobbying to more clandestine influence-peddling efforts in universities and think tanks (Tyfield 2008, Zaitchik 2022). And despite the current entrenchment of IP, it remains an idea fraught with conflict, one that Big Pharma and its allies are continuously working to defend and extend.

Article I, Section 8 of the U.S. Constitution opened the door to widespread patenting. The U.S. government's decision to allow the patenting of medicines remained anomalous well into the twentieth century. For its part, the U.S. medical establishment was long critical of branded drugs, regarding them as deceitful. But from the late 1880s through the interwar years, drugmakers' and doctor's organizations slowly succumbed to pharmaceutical industry pressure and embraced so-called "ethical" patenting practices, which proponents said would improve product safety and fund additional research (Gabriel 2014).

As Big Pharma amassed immense economic and political power in the decades following World War II, Washington witnessed a back-and-forth battle between advocates of diametrically opposed IP policies—Republicans, backed by industry, fought to allow private contractors to control IP stemming from government-industry partnerships with few exceptions while New Deal Democrats, supported by labor and small business, fought for default federal ownership of publicly funded inventions (Zaitchik 2022). Both sides scored partial victories until 1980, when the privatization of public science was consolidated via passage of the Bayh-Dole Act.

Parallel to the post-WWII growth of Big Pharma, an intellectual project that would eventually play an integral role in reshaping the world's political economy made headway (Peck 2010). Friedrich von Hayek and his fellow Austrian School neoliberal thinkers who gathered at Mont Pelerin in 1947 fiercely opposed patents and argued in favor of antitrust regulation to prevent monopolization and maintain the conditions for a competitive market economy. Over time, however, the University of Chicago's so-called Free Market Study proceeded to discard Austrian School principles and redefine concentrated economic power as a natural expression of the market that is less oppressive than power emanating from the government (Zaitchik 2022).

After years of intellectual legwork, buoyed by the formation of industry-funded propaganda networks, neoliberals were well-positioned to pounce when stagflation hit capitalist economies in the 1970s (Harvey 2005). As the U.S. economy contracted, proponents of IP privatization contended that public ownership of patents was hurting the country's ability to compete on an international scale with technological rivals in Europe and Asia. This argument was nonsensical because publicly funded science, particularly

the medical research sought by drug companies, was widely accessible to commercial actors and because other countries had far weaker IP regimes, especially with respect to medicines (Zaitchik 2022).

Nevertheless, it culminated in the passage of the Bayh-Dole Act in 1980. That law, which permits private contractors to retain exclusive ownership over most inventions stemming from government-backed research, decisively broke the patent stalemate of the 1960s and 1970s. To allay the public's understandable fears that the bill would expand Big Pharma's monopoly power, the authors of the legislation restricted patent claims on taxpayer-funded science to small businesses and universities (Tyfield 2008). The effectiveness of this move revealed widespread ignorance of the fact that universities had long been playing a key intermediary role in rationalizing IP management (ibid.). Moreover, in 1983, President Ronald Reagan signed an executive order that expanded the law to include corporations of all sizes.

The inclusion of a clause outlining the government's authority to "march in" to seize and redistribute patents whenever an IP holder fails to provide products to the public on "reasonable terms" provided cover to skeptical congressional Democrats who helped pass the legislation in 1980. More than forty years later, the U.S. government has yet to exercise its march-in rights despite ample pressure to do so (Dayen 2023).

Big Pharma thus played a key role in neoliberalizing the United States—that is, in turning the U.S. government into a machine for transferring wealth from bottom to top, including from poor countries to rich ones, from workers to corporate executives, and from public to private hands (Harvey 2005). As that process gained traction, it wasted no time in pushing to globalize neoliberalism, or at least one of its key components: robust

IP protections underpinning the so-called "knowledge economy" (Drahos and Braithwaite 2007, Sell 2003, Tyfield 2008). The WTO quickly became one of the main vehicles that corporate lobbyists in and beyond the pharmaceutical industry used to foist their upwardly redistributive agenda on the world.

Regarding the WTO and its dozens of agreements, Wallach and Woodall (2004: 3) argue that "if such an autocratic, anti-democratic system had been imposed on elected governments around the world by force, human rights monitors and UN inspectors would have been dispatched." However, the pro-corporate forces behind the WTO pulled off a "silent coup d'état" by turning the "obscure and largely uncontroversial" General Agreement on Tariffs and Trade (GATT) into a "Trojan Horse" to advance an "expansive non-trade agenda" (ibid. 3). Finalized in 1947—on the heels of the formation of the International Monetary Fund and the World Bank Group at the 1944 Bretton Woods Conference—the GATT governed postwar international trade until it was superseded by the WTO in 1995.

Far from facilitating so-called "free trade," the WTO aims to globalize "corporate-managed trade" rules that "have little to do with trade and even less to do with the nineteenth-century free trade philosophies of Adam Smith or David Ricardo," according to Wallach and Woodall (2004: 4, 2). The body's neoliberal agenda has precipitated a "race to the bottom" on labor and environmental standards and exerted a "chilling effect" on progressive lawmaking (ibid. 10-11); extended private property rights into new arenas, enabling, for example, agrochemical corporations to expropriate genetic materials and related knowledge by patenting seed varieties cultivated by small farmers over generations—a practice condemned as "biopiracy" (Fredriksson 2017); and shifted

domestic decision-making "from accountable, inclusive, and democratic fora to distant, secretive, and unaccountable WTO venues" (Wallach and Woodall 2004: 8).

1.2.1 Birth of the WTO: The Uruguay Round, 1986-1994

The origins of the WTO can be traced to 1986, when "new 'trade' negotiations" were launched "without fanfare" at a GATT summit in Uruguay (ibid. 3). Supporters of the Uruguay Round GATT negotiations and the WTO that arose from them "promised that the new system would pose no threat to domestic sovereignty, public-interest policies, or democracy" (ibid.). According to Wallach and Woodall (2004: 3-4), proponents "also promised enormous economic gains worldwide if the Uruguay Round was implemented… But the more we dug into the negotiations, the more alarmed we got… [T]rade was being hijacked to launch an offensive on democratic, accountable governance and decades of public-interest gains won by consumer, environmental, labor, and other citizens' movements worldwide." They continued:

> In 1991, when we were leaked a copy of the secret draft text, the fight began in earnest. The new rules were being written surreptitiously, and under the influence of the world's largest multinational corporations, with five hundred U.S. corporations officially designated as formal U.S. government advisers. Agreements were written in "GATTese," a language understood mainly by trade lawyers. Secrecy of all WTO documents, sessions, and enforcement tribunals is one of few procedural rules mandated in the WTO text.
>
> […]
>
> As awareness grew in the U.S. and around the world about what the Uruguay Round "trade" talks were really about, environmental, labor, consumer, and other public-interest groups started raising an alarm. In many nations, especially in the developing world, the establishment of this powerful global commerce agency was incredibly controversial and caused massive protests. In several countries, opposition was so strong that the WTO was only "approved" after extraordinarily antidemocratic maneuvers—including the failure to translate the text so elected officials in many nations literally had no idea what they were approving, and short-notice late-night parliamentary votes in several nations. But in the U.S., most people—including many people in Congress—had no idea what was really

at stake. In late 1994, Congress approved the agreement and passed the Uruguay Round Implementing Act. This legislation included hundreds of pages of changes to U.S. law to make existing policy conform to the WTO's rules. The WTO then went into effect worldwide on January 1, 1995.

Long-simmering opposition to the WTO finally boiled over nearly five years later during the so-called "Battle of Seattle," where tens of thousands of people rallied against a proposed expansion of corporate-friendly rules during the body's Third Ministerial Conference in late 1999. Naomi Klein (2007: 353) points out that while "college-age protesters received the bulk of the media coverage, the real rebellion took place inside the conference center, when developing countries formed a voting block and rejected demands for deeper trade concessions as long as Europe and the U.S. continued to subsidize and protect their domestic industries."

1.2.2 The TRIPS Agreement: Privatizing Knowledge

Among the most widely criticized aspects of the WTO is its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The agreement sets "minimum standards" for the protection and enforcement of IP rights (e.g., 20-year patent terms) and requires WTO members to enact national legislation that meets those standards (Taubman et al. 2012). It should be stressed that IP encompasses not only patents but also undisclosed information, including know-how, trade secrets, and data (Gurgula and Hull 2021). Moreover, the IP rules the WTO requires its members to adopt mirror the pro-monopoly legal regimes favored by the ruling classes in many wealthy countries with well-developed industries, including but not limited to the pharmaceutical sector (Drahos and Braithwaite 2007, Sell 2003). In 2002, the World Bank estimated that if the TRIPS Agreement were fully implemented, developing nations would transfer more

than $20 billion in rent to major technology-creating nations—namely the U.S., Germany, and France—for access to various forms of IP (World Bank 2002).

As Wallach and Woodall (2004: 85) note, “At this agreement’s core is a value-laden decision: creating a new category of property rights and protecting them is given priority over broad public access to new technologies.” WTO members can bring claims to the supranational organization if they suspect non-compliance with the TRIPS Agreement. The WTO itself lacks the authority to impose penalties, but when violations are deemed to have occurred by one of the body’s secret tribunals, the complaining party’s government typically levies trade sanctions against the offending country until changes are made (Abbott 1996). Such anti-democratic arm-twisting has proven effective in advancing capitalist class interests.

Prior to TRIPS, “pharmaceutical patent law, policies, and practices differed immensely among countries, particularly between developed and developing countries” (‘t Hoen 2016: 20). Many developing countries either refused to patent medicines or they limited patent terms, enabling generic pharmaceutical industries to thrive in a handful of nations in the Global South (ibid. 6).[12] Lifesaving products that would have been prohibitively expensive or unavailable had they been shrouded in IP protections were instead made available at discounted prices. Exceptions for medicines “were also common in Western countries,” (ibid. 20). “For example, the following European countries excluded pharmaceutical products from patentability: France (until 1960), Switzerland (until 1977), Italy (until 1978), Sweden (until 1978) and Spain (until 1992).”

[12] Some developing countries "already had IP laws when TRIPS came into being, often modeled after the laws of their former colonizers" (‘t Hoen 2016: 83).

Since TRIPS, many developing nations have been forced "to refashion their patent rules dramatically in favor of the multinational drug companies" even though "these countries had followed the lead of virtually every other industrialized country in enacting weak patent rules while they were still industrializing" (Wallach and Woodall 2004: 95). The deadline for least developed countries (LDCs) to make their domestic laws TRIPS-compliant has been extended three times—from an original target date of 2006 to the present cutoff point of 2034 (WTO 2021i). However, dozens of low- and middle-income countries (LMICs) were required to meet most TRIPS mandates by 2000. Several LMICs postponed the introduction of pharmaceutical IP until 2005, citing a WTO provision that gave developing nations 10 years to implement IP protections in areas, such as food and medicine, for which they did not exist when TRIPS entered into force (WTO 2006). In any case, the underlying North-South power imbalance remains. In the words of Ellen 't Hoen (2016: 6), a key participant in the access to medicines movement, the WTO's IP rules have resulted in "the gradual globalization of an incentive system that leaves unprofitable health needs unmet and creates huge challenges to accessing treatments that do exist."

To substantiate their claim that the TRIPS Agreement "was largely written by the multinational pharmaceutical industry," Wallach and Woodall (2004: 94-95) quote part of a speech that Pfizer's emeritus chair, Edmund T. Pratt Jr., delivered in 1995 to the U.S. Council for International Business:

> The [Intellectual Property Committee, which Pfizer helped found] helped to convince U.S. officials that we should take a tough stance on intellectual property issues, and that led to trade-related intellectual property rights being included on the GATT agenda when negotiations began in Punta del Este, Uruguay, in 1986… The current GATT victory, which established provisions for intellectual property protection, resulted in part from hard-fought efforts of the U.S. government and

> U.S. businesses, including Pfizer, over the past three decades. We've been in it from the beginning, taking a leadership role.

The deadly consequences of what Pratt described as the U.S. ruling class' "GATT victory" became apparent almost as soon as the ink had dried. In the mid-1990s, just as the WTO was being finalized, the arrival of improved antiretrovirals (ARVs)—the result of substantial public investments—transformed AIDS from a lethal disease into a chronic illness—but only for those able to afford the treatments (Farmer 1999, 't Hoen et al. 2002). As 't Hoen (2016: 7) points out, the drugs had to be purchased from "originator companies, which produced them in small quantities carrying paralyzing price tags of $10,000 to $15,000 per person per year, and controlled the patents to maintain their monopoly." Such high prices made access uneven in rich countries and virtually nonexistent in poor countries hit hardest by HIV (Farmer 2005). Lifesaving medicines existed, and yet millions of people died because they remained needlessly out of reach. The inadequate supply and forbidding cost of branded ARVs were inseparable from the freshly minted neoliberal IP regime, whose monopoly protections delayed the production and importation of cheap generics ('t Hoen 2016).

1.2.3 The AIDS Crisis, Access to Medicines, and the Doha Declaration

By the late-1990s, the WTO's prioritization of profits over people had become frontpage news around the globe. Bad press accompanied a lawsuit that the South African Pharmaceutical Manufacturers Association and 39 mostly multinational pharmaceutical corporations filed in February 1998 against the government of South African President Nelson Mandela. Big Pharma, backed initially by the U.S. and the E.U., alleged that the recently enacted Medicines and Related Substances Control Amendment Act, a 1997 law aimed at increasing access to medicines through generic substitution and parallel

importation, violated the South African Constitution and the TRIPS Agreement (Bond 2001, ‘t Hoen 2002).[13] In South Africa at the time, an estimated 2.7 million people were living with HIV and every day, roughly 1,400 people were becoming infected with HIV and more than 350 people were dying from AIDS (UNAIDS). Meanwhile, only 90 South Africans were receiving ARV therapy in 2000 (UNAIDS 2020). Similar situations were unfolding in other developing nations, with particularly devastating crises across Africa—where in early 2000, 24.5 million people were living with HIV and only one in a thousand had access to ARV drugs (‘t Hoen 2016: 7). This injustice was a flashpoint at the WTO’s 1999 gathering in Seattle.

Health justice activists also spent months demonstrating at then-U.S. Vice President Al Gore’s 2000 presidential campaign events to draw attention to Washington’s complicity in exacerbating the AIDS epidemic (Bond 2001, ‘t Hoen 2002, Wallach and Woodall 2004). The impact of this organizing became apparent in May 2000, when U.S. President Bill Clinton issued an executive order indicating support for African governments’ use of compulsory licensing to produce and import generic HIV drugs without fear of retaliation (‘t Hoen 2016). Compulsory licenses allow for a patented good to be manufactured without the consent of the patent holder (Reichman 2009). Not coincidentally, pharmaceutical companies announced price reductions just days later (‘t Hoen 2016).

In February 2001, however, the U.S. filed a WTO challenge against Brazil for using compulsory licensing to ensure that ARV therapy is available to every citizen infected with HIV. Thanks to immense public pressure, the administration of then-U.S.

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[13] Notably, South Africa had only committed to TRIPS in the late 1980s under the apartheid government of P.W. Botha (Zaitchik 2022: 208).

President George W. Bush quickly withdrew its challenge to Brazil's policy, which has saved millions of lives ('t Hoen 2002, Wallach and Woodall 2004).

The February 2001 announcement by Cipla, an Indian generic medicine manufacturer, that it would produce a triple-ARV for $350 per patient per year was a game-changer ('t Hoen 2016). Faced with a public relations nightmare, the 39 pharmaceutical giants dropped their suit against South Africa two months later (Swarns 2001). The introduction of generic competition, which lowered ARV drug prices to less than $1 a day, sparked the establishment of international funding mechanisms that have proven key in scaling up access to affordable, high-quality AIDS treatments—improving and prolonging millions of lives over the past two decades. But access to an array of essential medicines remains profoundly unequal, and more people would be alive today were it not for the WTO's globalization of IP barriers ('t Hoen 2016).

Difficulties exporting and importing generic ARVs at the turn of the century revealed the necessity of clarifying the substance of so-called TRIPS flexibilities to ensure that developing countries could use the agreement's provisions to promote public health without negative repercussions or threats thereof ('t Hoen 2002). Following a sustained campaign waged by global justice advocates, a declaration was issued during the WTO's Fourth Ministerial Conference in Doha, Qatar, affirming that the TRIPS Agreement contains flexibilities allowing members to limit IP rights in the name of increasing access to medicines.

The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), officially adopted on November 14, 2001, acknowledges "the gravity of the public health problems afflicting many developing and least-developed countries,

especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics" (WTO 2001, paragraph 1). It states that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (paragraph 4).

Paragraph 5 of the Doha Declaration makes clear that the TRIPS Agreement allows WTO members to grant compulsory licenses for the production of generic medicines. It is legal under Article 31 of the agreement as long as IP owners are "paid adequate remuneration," per Article 31(h). Furthermore, Article 31(b) stipulates that the requirement to first seek a voluntary license "may be waived by a member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." However, Article 31(f) states that production under compulsory licenses is restricted to production "predominantly for the supply of the domestic market."

Thus, paragraph 6 of the Doha Declaration acknowledges that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." Consequently, the TRIPS Council was instructed to "find an expeditious solution" to the production for export issue and report to the WTO General Council before the end of 2002.

That deadline came and went, however, as the Big Pharma lobby and several wealthy countries worked to undermine proposals that would authorize WTO members to import affordable drugs produced elsewhere under compulsory licenses—a necessary practice for developing countries that lack adequate manufacturing capacity (‘t Hoen 2002, Wallach and Woodall 2004).

Eventually, in August 2003, the TRIPS Council agreed to an interim waiver of Article 31(f) (WTO 2003). This measure, alternately called the “August 30th decision” and the “Paragraph 6 system,” created a cumbersome and widely criticized process through which medicines can be produced under compulsory licenses for export (Abbas and Riaz 2017, Correa 2004, Vincent 2020, Zaman 2022). It was subsequently incorporated into the TRIPS Agreement as Article 31*bis*, a permanent provision that came into force in January 2017.[14]

The tool that would become Article 31*bis* has only been used once in the 20 years since it was established. In July 2007, Rwanda notified the WTO of its intention to use the mechanism to import ARV treatments produced under compulsory license. Three months later, Canada issued a compulsory license to manufacture the drugs for export to Rwanda. Even though Canada followed the necessary procedures required by the WTO, “it took nearly three years for Rwanda to receive the full shipment” of requested HIV medicines (Zaman 2022: 303). Apotex, the participating drugmaker, said that it “will not

14 As Garrison (2020) explains: Dozens of high-income countries "unilaterally committed that they would not make use of the [Article 31*bis*] system as importers. This not only impacts access to affordable generic medicines in these opt-out HICs but, since the economies of scale that could have been harnessed by exporting to these comparatively wealthy HICs are curtailed, the price of the generic medicines that could be produced for other WTO members may well be higher than it could have been."

go through the complicated and costly process again unless regulations are amended" (ibid.). Revisions have yet to be made.

The coronavirus pandemic was the first global health crisis to occur after the ratification of Article 31*bis*. According to Abbas (2021: 71), "The export-oriented compulsory licensing mechanism… is excessively formal and does not suit a pandemic situation which requires swift action." Chimpango (2021: 167) further argues that "the formal amendment and the rest of the exemptions that are provided for under TRIPS for purposes of dealing with public health emergencies such as Covid-19, have made little, if any difference, in facilitating equitable access to pharmaceuticals by low-income countries."

TRIPS flexibilities other than Article 31*bis* have been used more than 100 times by dozens of countries since 2001. Most of these instances have involved compulsory licenses for public non-commercial use in domestic markets (e.g., Article 31) and the least-developed country waiver, or Paragraph 7 mechanism, which permits LDCs to not grant or not enforce patents on pharmaceutical products (Medicines Law & Policy 2022).

't Hoen pointed out that "in many cases, countries were able to use the TRIPS flexibilities to access lower-priced generic drugs because these drugs could still be produced in countries such as India where product patent protection was not introduced until 2005" (2009: xvii). But in the 18 years since the WTO compelled India to abandon the 1970 law that helped make it the "pharmacy of the developing world," generic medicine manufacturing and trade has grown more complicated.[15] As 't Hoen warned

15 For instance, "Generic versions of drugs brought to market before TRIPS went into [full effect in 2005] could still be manufactured. But newer, better tolerated treatment regimens preferred by the WHO faced patent barriers" ('t Hoen 2016: 10).

more than a decade ago, “The effectiveness of compulsory licensing will wear off unless a more satisfactory solution is found to encourage competition, and in particular, to ease countries’ ability to export medicines produced under a compulsory license” (ibid. xviii).

Ultimately, “the TRIPS Agreement, which forced countries to give up the diversity and flexibility in IP law that had existed before, is highly detrimental to access to medicines,” ‘t Hoen wrote (ibid.). “While the Doha Declaration can offer relief in dealing with access problems and high drug prices, full implementation is still far from a reality.” When developing countries have exercised their compulsory licensing rights, they have faced the wrath of their wealthy counterparts as well as the pharmaceutical industry. Retaliation “has been particularly harsh when TRIPS flexibilities are used in countries with emerging economies” because “the growth opportunities for the industry lie in these emerging markets” ‘t Hoen noted (ibid.). Additional challenges have been created by the rise in TRIPS-plus provisions—or IP rules that are even more stringent than those of the WTO—in “free trade agreements” negotiated this century (Sell 2011).

The pro-access measures in the Doha Declaration “resulted from an ad hoc case-by-case approach that was often highly dependent on an active civil society” ‘t Hoen observed (2009: viii). “A sustainable policy that tackles the fundamental problem of a monopoly-based innovation and access system is still far away.”

1.2.4 Covid-19 and the Struggle to Suspend TRIPS

During the Covid-19 pandemic, the WTO once again protected Big Pharma’s IP monopolies and profits at the expense of universalizing access to lifesaving medical tools, worsening an already destructive health and economic crisis. Days after India and South Africa unveiled their proposal to waive certain provisions of the TRIPS Agreement

for the duration of the coronavirus crisis, Médecins Sans Frontières (MSF)/Doctors Without Borders (2020a) welcomed it as "a landmark move… akin to efforts by governments nearly 20 years ago, which spearheaded the use of affordable generic HIV/AIDS medicines."

't Hoen (2020), who played a key role in that earlier fight when she was director of policy advocacy at the MSF Access Campaign, agreed: "The proposal is reminiscent of the discussion in the TRIPS Council at the height of the HIV crisis when Zimbabwe told the WTO membership, on behalf of the African countries, that the organization could no longer ignore the access to medicines issue." In 2001, she observed, "the African countries' proposal to address the IP issues of the access to HIV medicines crisis was at first rejected by rich countries who claimed that such discussions would jeopardize strong patent protection needed to encourage innovation. In the current Covid-19 dominated world, those same counter-arguments will be on offer" (ibid.). As Chapter 2 seeks to demonstrate, 't Hoen's prediction could not have been more accurate.

CHAPTER 2. PROTECTING COVID-19 VACCINE IP MONOPOLIES

"Why should the knowledge that is required to end a pandemic be kept secret?"—Zain Rizvi, Public Citizen[16]

"I don't understand how governments of the world are able to outsource their responsibility for public health to a few companies that are able to hold them all ransom."—Mustaqeem De Gama, counselor at the South African mission to the WTO[17]

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16 Cited in Abowd (2021)

17 Cited in Shah (2020)

While the WTO's pro-monopoly framework helps advance Big Pharma's goal of profit maximization, it runs counter to the more broadly held objective of welfare maximization (Wallach and Woodall 2004, Krikorian and Torreele 2021). As multiple scholars have argued, IP constitutes a key social determinant of health even if it does not receive the same amount of attention as more widely recognized structural factors driving unequal outcomes (Rutschman 2021, Sparke and Anguelov 2012).

Ultimately, sharing the know-how required to ensure universal access to essential medicines—or hoarding it—comes down to a simple question of priorities. Should society give primacy to human well-being or to commercial interests? Is it preferable to save as many lives as possible or to allow pharmaceutical corporations to make as much money as possible? Doing everything possible to quickly scale up the production of Covid-19 vaccines and other tools would preserve millions of lives. The main "cost"—billions of dollars in foregone profits—would be borne by the likes of Moderna and Pfizer-BioNTech; it's worth reiterating that those firms relied on the public sector to bring mRNA technology to life (Allen 2020, Kiszewski et al. 2021), after which they sought to enclose the knowledge commons.

Ethically and epidemiologically, it is undeniable that protecting public health should take precedence over protecting IP monopolies (Adhanom 2021b, Prasad et al. 2022, Thambisetty et al. 2022). Even from the standpoint of minimizing economic losses, broadly sharing knowledge and ramping up the manufacturing of generic medicines would represent a logical improvement over the status quo. In June 2020, the IMF's World Economic Outlook predicted that the Covid-19 pandemic would unleash $12 trillion in global losses in 2020 and 2021 (Gopinath 2020). Meanwhile, Oxfam estimated

that it would cost $70.6 billion to provide everyone on the planet with a coronavirus vaccine, including research, production, procurement, and distribution (Oxfam 2020b). In other words, universal inoculation could be achieved for 0.59% of the pandemic's projected cost to the global economy—and doing so would curb much of the forecasted damage. For those who were not sufficiently moved by the scourge of avoidable mortality, was a potential opportunity cost in the trillions not a compelling enough reason to cut into Moderna and Pfizer-BioNTech's 55% profit margins? It would appear that it was not.

2.1 The Defeat of the TRIPS Waiver

India and South Africa made the life-and-death implications of IP policy clear when, relatively early in the Covid-19 pandemic, they unveiled a proposal to temporarily waive certain provisions of the TRIPS Agreement (WTO 2020a). Despite widespread support for the measure, it was eventually defeated by a coalition of rich countries whose governments consider ironclad IP rights to be absolutely necessary for the maintenance of increasingly rentierized manifestations of capitalism (Christophers 2020).

For their part, IP holders—often the private appropriators of public science (Mazzucato 2015, Senate Committee on Health, Education, Labor, and Pensions 2023)[18]—have a financial stake in constraining generic competition because monopoly

[18] A recent Congressional Budget Office report confirmed that "the federal government is the primary funder of basic research in biomedical sciences" (Austin and Hayford 2021: 18). It continues: "That research ultimately increases the supply of new drugs because drug companies rely on the findings from that research… That basic research creates knowledge that, in effect, reduces private companies' R&D costs and stimulates private investment in R&D, because it expands the set of potentially profitable drug development opportunities" (ibid.). Pharmaceutical companies have spent about 19% of their net revenues on R&D over the past two decades, which is a greater share than the roughly 15% spent on R&D in other research-intensive industries such as software and semiconductors (ibid. 5). However, even though the pharmaceutical industry's average "R&D intensity" has grown slightly in recent years, its investments in this area have not kept pace with revenue increases (ibid. 12). Another recent report attributed a significant

power confers the power to extract monopoly rent (Harvey 2014), and inadequate supply in the face of high demand further inflates prices. That is exactly what the rentiers at Moderna and Pfizer-BioNTech—supported by pro-corporate lawmakers who feared that setting a precedent for waiving IP rules could threaten future profitmaking—did throughout the Covid-19 pandemic (Hawksbee et al. 2022). As predicted, the results were catastrophic.

2.1.1 Forsaken Calls for Global Solidarity and International Cooperation

The start of the Covid-19 pandemic was accompanied by lofty rhetoric about the need for "global solidarity" to fight the novel coronavirus as well as the importance of "international cooperation to ensure global access to medicines, vaccines, and medical equipment," as the United Nations General Assembly put it in resolutions dated April 2 (2020a) and April 20 (2020b), respectively.

The latter resolution called upon member states and other relevant stakeholders "to immediately take steps to prevent, within their respective legal frameworks, speculation and undue stockpiling that may hinder access to safe, effective, and affordable essential medicines, vaccines, personal protective equipment, and medical equipment as may be required to effectively address Covid-19."

That call went unheeded. By mid-September, wealthy nations representing just 13% of the world's population had already pre-ordered 51% of the doses promised by five leading Covid-19 vaccine candidates (Oxfam 2020b). The situation hardly improved

portion of the pharmaceutical industry's revenue gains to price-gouging U.S. consumers, "evergreening" products to avoid generic competition, and other anti-competitive practices aimed at maintaining monopoly prices (House Committee on Oversight and Reform 2021). It also showed that pharmaceutical corporations are spending more on stock buybacks and dividend bumps than R&D (ibid.).

over time. In February of 2021, UN Secretary-General António Guterres (2021) condemned the "wildly uneven and unfair" allocation of Covid-19 vaccines, noting that just 10 rich countries had secured 75% of the world's supply before people in more than 130 countries had received a single dose.

The UN General Assembly's resolution dated April 20, 2020, encouraged member states "to bolster coordination, including with the private sector, towards rapid development, manufacturing, and distribution of diagnostics, antiviral medicines, personal protective equipment, and vaccines, adhering to the objectives of efficacy, safety, equity, accessibility, and affordability."

That sentiment was echoed less than a month later at the 73rd World Health Assembly. On May 19, 2020, the WHO's decision-making body (2020a) acknowledged "the role of extensive immunization against Covid-19 as a global public good for health in preventing, containing, and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible, and affordable vaccines are available" (paragraph 6). Among other things, the WHO called for "the universal, timely, and equitable access to, and fair distribution of, all quality, safe, efficacious, and affordable essential health technologies and products, including their components and precursors, that are required in the response to the Covid-19 pandemic as a global priority, and the *urgent removal of unjustified obstacles* thereto, consistent with the provisions of relevant international treaties," including TRIPS Agreement flexibilities affirmed by the Doha Declaration (paragraph 4, emphasis mine).

To that end, the body called on its member states "to collaborate to promote both private sector and government-funded research and development, including open

innovation, across all relevant domains, on measures necessary to contain and end the Covid-19 pandemic, in particular on vaccines, diagnostics, and therapeutics, and to share relevant information with WHO" (paragraph 7.12). Furthermore, it called on international organizations and other stakeholders "to work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines, and vaccines for the Covid-19 response, including existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable, and affordable access to them, consistent with the provisions of relevant international treaties," including TRIPS Agreement flexibilities affirmed by the Doha Declaration (paragraph 8.2). It also urged WHO Director-General Tedros Adhanom Ghebreyesus "to ensure global access to medicines, vaccines, and medical equipment to face Covid-19, and in consultation with member states and with inputs from relevant international organizations, civil society, and the private sector, as appropriate, to identify and provide options that respect the provisions of relevant international treaties," including TRIPS Agreement flexibilities affirmed by the Doha Declaration, "to be used in scaling up development, manufacturing, and distribution capacities needed for transparent equitable and timely access to quality, safe, affordable and efficacious diagnostics, therapeutics, medicines, and vaccines for the Covid-19 response" (paragraph 9.8).

Notably, the WHO's language was too radical from the perspective of then-U.S. President Donald Trump's administration (USA 2020), which quickly issued a statement to "disassociate itself from" paragraphs 4, 8.2, and 9.8 of the resolution, all of which called for removing IP obstacles, pooling and licensing patents, and otherwise using

existing WTO flexibilities to promote public health. According to the White House, the language in those paragraphs "does not adequately capture all of the carefully negotiated, and balanced, language" in the TRIPS Agreement and the Doha Declaration and "instead presents an unbalanced and incomplete picture of that language at a time where all actors need to come together to produce vaccines and other critical health products." "The United States recognizes the importance of access to affordable, safe, high-quality, and effective health products and the critical role that intellectual property plays in incentivizing the development of new and improved health products," the statement reads. "Paragraphs 4, 8.2, and 9.8 send the wrong message to innovators who will be essential to the solutions the whole world needs."

On May 29, WHO chief Tedros and Costa Rican President Carlos Alvarado Quesada issued a "Solidarity Call to Action." Endorsed by more than three dozen countries—though only a handful of them are wealthy—it stated that stopping the pandemic "is only achievable when everyone, everywhere can access the health technologies they need for Covid-19 detection, prevention, treatment, and response." (WHO 2020b). Soon after the call was published, the WHO, Costa Rica, and other partners—the UN Development Programme, UN Technology Bank, Medicines Patent Pool, and Unitaid—launched the Covid-19 Technology Access Pool (C-TAP) to facilitate the sharing of IP, knowledge, and clinical data (WHO 2020c).

The objective of C-TAP is to boost production through voluntary licensing agreements and the exchange of know-how between the developers of vaccines, tests, and treatments, on one side, and qualified manufacturers with untapped capacity, on the other. Billionaire Pfizer CEO Albert Bourla immediately disparaged the concept as "nonsense"

and “dangerous” (Silverman 2020), exemplifying the position of Big Pharma, which has so far refused to participate in the program. It took until November 23, 2021 for the first global, transparent, non-exclusive license for a Covid-19 medical tool to be finalized, when the Spanish National Research Council agreed to share the serological antibody technology essential to multiple tests with C-TAP (Medicines Patent Pool 2021).

2.1.2 The TRIPS Waiver Proposal

In light of continued vaccine stockpiling by wealthy nations and nonexistent private sector participation in C-TAP, India and South Africa on October 2, 2020 introduced a motion at the WTO to temporarily waive certain provisions of the TRIPS Agreement. At that point, Covid-19 had already killed more than 1 million people. Health justice advocates warned, presciently, that failing to do everything possible to enable the production of as many Covid-19 medical tools in as many places as possible would exacerbate the pandemic’s global death toll and negative economic impacts. The proposed TRIPS waiver sought to empower generic manufacturers to expand the worldwide supply of tests, personal protective equipment, ventilators, therapeutics, and jabs without fear of legal retribution.

“An effective response to Covid-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment, and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need,” the document reads (WTO 2020a). “Shortages of these products ha[ve] put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the Covid-19 pandemic. The

longer the current global crisis persist[s], the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak."

"As new diagnostics, therapeutics, and vaccines for Covid-19 are developed, there are significant concerns [about] how these will be made available promptly, in sufficient quantities, and at affordable price[s] to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases," it continues. "To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of Covid-19 patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need."

However, "there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products," the document states. "It is also reported that some WTO members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses."

"Beyond patents, other intellectual property rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available" in the TRIPS Agreement, says the document. "A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31*bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products."

Referring to the aforementioned urgent calls for "global solidarity" and "the unhindered global sharing of technology and know-how in order that rapid responses for the handling of Covid-19 can be put in place on a real-time basis," the proposal asks the TRIPS Council to swiftly recommend to the WTO General Council the adoption of "a waiver from the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of Covid-19."[19]

The India and South Africa-led effort to temporarily suspend[20] all coronavirus-related IP barriers—including patents, industrial designs, copyrights, and trade secrets—was inspired by a keen awareness of the deadly consequences of giving pharmaceutical corporations the power to determine where lifesaving medical tools are produced and in what quantities (Doctors Without Borders 2020a).

As South Africa (WTO 2021d) pointed out during the first TRIPS Council meeting held to discuss the IP waiver on October 16, 2020: "We have seen this before. At the height of the HIV crisis, prices set for ARVs to treat HIV were simply too high and out of reach for many developing countries." Due to IP monopolies, it took years for affordable generics to reach the impoverished nations hardest hit by the epidemic and most in need of treatments. "As death rates due to AIDS plunged in rich countries, infected people across the developing world were left to die," the South African

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19 The Part II sections of the TRIPS Agreement to be waived included provisions on 1) Copyright and Related Rights; 4) Industrial Designs; 5) Patents; and 7) Protection of Undisclosed Information.

20 According to the original proposal, "The waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity" (WTO 2020a). A May 25, 2021 update to the text added the following paragraph on the proposed duration: "This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver." (WTO 2021f).

delegation lamented. “Our leaders vowed that [it] would never happen again; the Doha Declaration on TRIPS and Public Health reaffirmed flexibilities to accommodate access to medicines. Even in light of this political undertaking and its translation into the Paragraph 6 system, prices of many lifesaving diagnostics, therapeutics, vaccines, and other medical products remain out of reach of most governments and [their] people.”

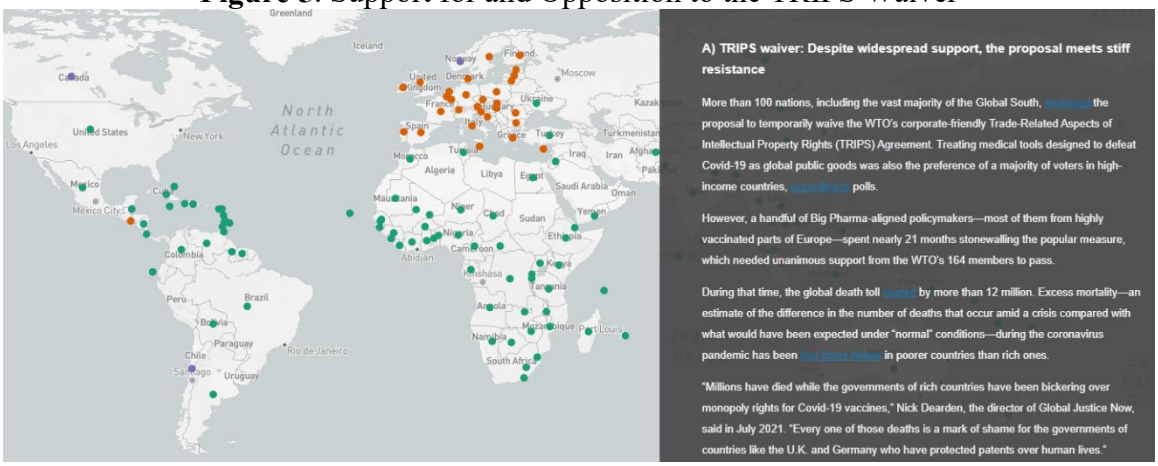
When the highly pathogenic avian influenza H5N1 resurfaced in 2004, “developed countries had priority access, while affected developing countries did not,” South Africa continued. “Within five years another pandemic flu (H1N1) emerged and once again rich countries placed large pre-orders of a vaccine buying almost all doses that could possibly be manufactured. Many countries promised to donate vaccines [but] most of them reneged and moved to secure their own countries’ supply. With Covid-19 history is repeating itself.”

More than 100 nations representing roughly 80% of the global population, including nearly all low-income countries, endorsed India and South Africa’s proposed TRIPS waiver (Doctors Without Borders 2020b). So too did the WHO (Adhanom 2020), hundreds of civil society organizations, Nobel laureates, ex-world leaders, and the Pope. Treating the knowledge and technologies underlying Covid-19 medical tools as global public goods was also the preference of a majority of voters in high-income countries, according to multiple surveys (People’s Vaccine Alliance 2021a, Progressive International 2021).

However, several delegations—most of them representing highly vaccinated rich nations with large pharmaceutical industries—refused to back the measure as originally presented. Because the WTO typically operates on the basis of “consensus,” a minority of

the body's 164 members can impede the will of the supermajority.[21] With few exceptions, positions on the TRIPS waiver were divided sharply between the Global South, where support was almost unanimous, and the Global North, home to the pharmaceutical giants whose profits would be diminished if IP monopolies were weakened. The Biden administration voiced support for a temporary suspension of some coronavirus-related IP. In practice, however, it did not actively promote the TRIPS waiver proposal put forth by India and South Africa. As discussed in more detail below, the U.S. slow-walked negotiations (Lazare 2021a, Lazare 2021b, Stangler 2021) and sought to limit any deal to vaccines (Lazare 2022a), effectively joining European countries in blocking an ambitious IP waiver.

Figure 5. Support for and Opposition to the TRIPS Waiver



Map by Kenny Stancil. See Appendix 2 for a link to the interactive version, data sources, and code.

TRIPS waiver opponents—pharmaceutical industry lobbyists and their lawmaking allies alike—relied on several dubious claims to justify their antagonism to the popular proposal (Gold 2022, Mazzucato et al. 2021, Stiglitz and Wallach 2021,

[21] When consensus cannot be reached, a three-quarter majority vote is required.

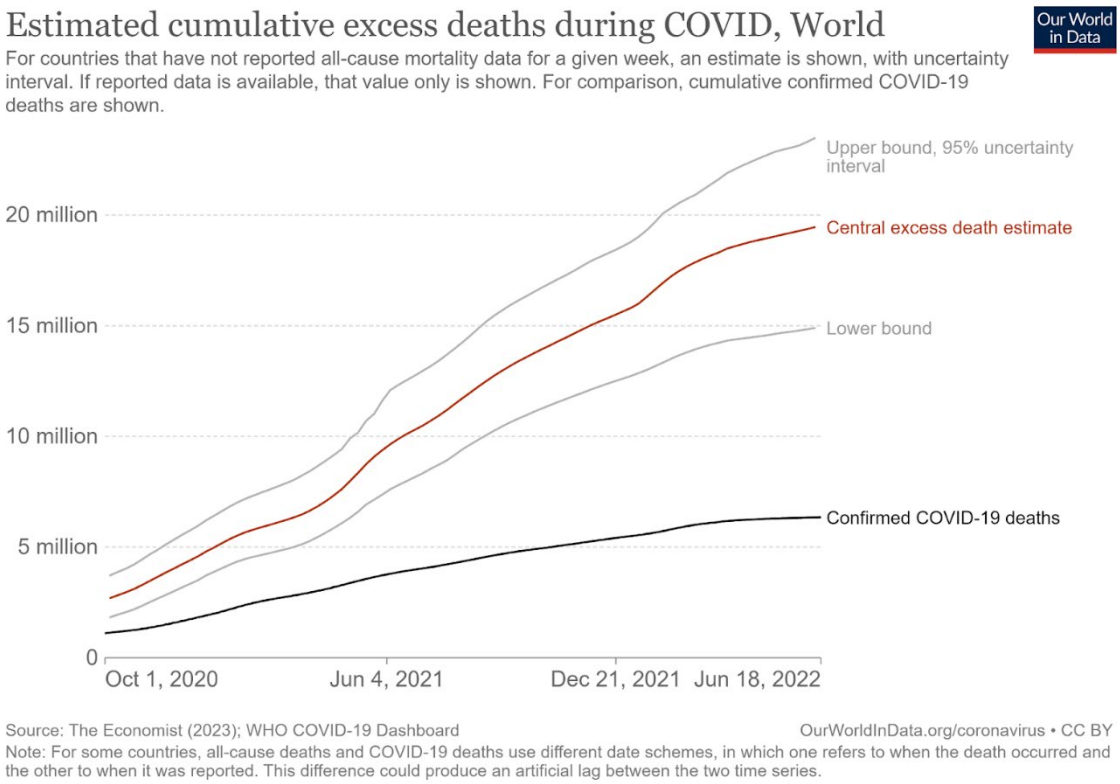
Thambisetty et al. 2022). First and foremost, they insisted that removing IP protections would disincentivize future innovation, thus undermining public health in the long run (Cueni 2020, Shah 2020, WTO 2021d). Second, they denied that IP constitutes a "genuine barrier" to boosting the supply of Covid-19 medical tools (ibid.). They blamed other factors, cited extant TRIPS flexibilities, and pointed to COVAX donations as well as IP holders' licensing arrangements with dozens of companies as proof of their purported goodwill (ibid.). However, they failed to acknowledge that cumbersome TRIPS carve-outs, a troubled charity model beset by monopoly-driven shortages, and voluntary licenses—geographically limited in scope, non-transparent, and exclusive—were incapable of increasing supply at the rate needed to swiftly protect roughly 8 billion people (ibid.).

To defend its restrictive licensing practices, Big Pharma maintained that many generic drugmakers, especially in poor nations, lack the ability to safely scale up vaccine production (Merelli 2021, PhRMA 2021), even as evidence mounted to the contrary (Buranyi 2021, Furlong 2021, Lerner and Fang 2021, Nolen 2021, Prabhala and Alsalhani 2021, Rowland et al. 2021, Schouten 2021) and even though such arguments ignored campaigners' parallel demands for the dissemination of manufacturing know-how and technology (Burki 2021, Zarocostas 2021). Defenders of the WTO's IP regime also invoked geopolitical arguments aimed at reframing the global public health emergency as "just another front in the new cold war between America and its rivals" (Savage 2021), ludicrously fear-mongering about China and Russia obtaining access to mRNA technology as if the platform were a nuclear weapon and not a lifesaving medical tool.

During the nearly 21 months that TRIPS waiver opponents spent stonewalling the widely supported initiative, two ultra-contagious coronavirus variants emerged and the global death toll soared. How high depends on which metric one looks at. From the time the proposal was unveiled on October 2, 2020, until a compromise—heavily criticized by access to medicines campaigners (Public Citizen 2022)—was reached on June 17, 2022, the number of deaths attributed directly to Covid-19 climbed by more than 5 million, from 1.11 million to 6.34 million (Mathieu et al. 2020). As of this writing in October 2023, the world is nearing 7 million official Covid-19 deaths. But this count underestimates the full extent of the lethal devastation wrought by the pandemic.

Excess mortality—the difference in the number of deaths that occur amid a crisis compared with what would have been expected under "normal" conditions—provides a much more comprehensive approximation of the scale of coronavirus-fueled carnage. Throughout the TRIPS waiver debate, the number of excess deaths surged by about 17 million, from just over 2.5 million to roughly 19.5 million (Mathieu et al. 2020). In October 2023, the tally of excess deaths surpassed 27 million, underscoring the severity of the Covid-19 pandemic and its far-reaching material reverberations. Two years into the pandemic, an estimated 54% of excess deaths had occurred in poorer nations (Oxfam 2022). On a per capita basis, people in low- and lower-middle-income countries died at a 31% higher rate than their counterparts in high-income countries (ibid.). This contradicts widely held beliefs about the geography of coronavirus-related mortality, which many assume was worse in rich nations.

Figure 6. Hoarding Lifesaving Knowledge While Millions Die



2.1.3 The TRIPS Waiver Debate

Before the TRIPS Council met to formally discuss India and South Africa's proposal for the first time in mid-October 2020, there was an outpouring of support from civil society.[22] One letter signed by more than 400 organizations (Doctors Without Borders 2020c) stressed that existing TRIPS flexibilities, long regarded as onerous, were inadequate in the face of a worldwide respiratory viral emergency:

> While the TRIPS Agreement contains flexibilities that can promote access, many WTO members may face challenges in using them promptly and effectively. For instance, compulsory license offers a "product by product" and "country by country" approach with variations in national laws, whereas the pandemic requires collective global action to tackle IP barriers and facilitate technology transfer. Where the IP barrier is beyond patents, national laws may not provide for

[22] See the Third World Network for a compilation of statements and letters issued in support of the TRIPS waiver proposal. https://www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm

> sufficient flexibilities. Further, Article 31*bis*, a mechanism to supply countries with insufficient manufacturing capacity, does not provide an expedited solution and many countries have also opted out of using the mechanism.
>
> [...]
>
> In a global pandemic where every country is affected, we need a global solution. Adoption of a waiver at the WTO level will suspend implementation, application, and enforcement of the relevant provisions of the TRIPS Agreement in relation to prevention, containment, and treatment of Covid-19. It enables an expedited, open, and automatic global solution to allow uninterrupted collaboration in development, production, and supply, and to collectively address the global challenge facing all countries. It's time for governments to take collective responsibility and put people's lives before corporate monopolies.

The coalition called on WTO members to "unequivocally support" the TRIPS waiver. Australia, Brazil, Canada, the European Union, Japan, Norway, Switzerland, the United Kingdom, and the United States promptly rejected it, however. The proposal then became mired in fruitless negotiations that took place over the course of nearly two years at dozens of informal and formal meetings of the TRIPS Council and the WTO General Council, many of which were preceded and followed by civil society protests.

2.1.3.1 October-December 2020: Early Arguments

During its opening salvo at the formal TRIPS Council meeting on October 16 (WTO 2021d), India tried to preemptively refute the arguments of waiver opponents. Regarding the notion that robust IP protections are a sine qua non for innovation, without which new products would cease to be created, Indian delegates reminded their colleagues that "governments across the globe are supporting [the] development of new health technologies, in particular vaccines, by pouring billions of dollars of public funds into research and development." Billions of dollars in advanced purchase agreements, which provided pharmaceutical companies with a guaranteed market, also played a crucial role in bringing about Covid-19 medical products in record time. "Therefore,"

India continued, “the often-repeated argument that monopoly rights are needed to allow the inventors to recoup their investment does not seem to apply.”[23]

To those who suggested that IP is not a significant obstacle to ramping up the production of Covid-19 tests, treatments, vaccines, and more, India said: “There can be no denying the fact that the development of and equitable access to the tools… required to fight the Covid-19 pandemic are limited by IP barriers. It is quite evident from an array of lawsuits filed by private companies in different parts of the world for IP infringement on Covid-19 products. In the past few months, we have also seen that IP rights do come in the way of scaling up production of test kit reagents, ventilator valves, N95 respirators, therapeutics, fluorescent proteins, and other technologies used in [the] development of vaccines, etc.”[24]

Moreover, while some TRIPS Council members claim that “voluntary licenses are the most appropriate solution to scale up manufacturing in response to Covid-19,” India added, “the fact remains that not a single IP holder has shown willingness to commit to the Covid-19 Technology Access Pool (C-TAP) and the ACT-Accelerator voluntary initiatives launched under the aegis of WHO.” Given the pharmaceutical industry’s refusal “to routinely offer nonexclusive licenses with worldwide coverage to facilitate global access, clearly the solution to ending the pandemic does not lie in voluntary licenses,” India stressed.

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23 South African delegates echoed their Indian allies, saying: “Never has there been a weaker case for the granting of monopolies. Governments have been funding the development of Covid drugs and vaccines, and no company is able to meet the global demand” (WTO 2021d).

24 Following an informal TRIPS council meeting, South Africa on November 23 submitted evidence of IP barriers impeding the development and supply of Covid-19 medical tools (WTO 2020b). Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela, and Zimbabwe supplied additional evidence in a January 15 response (WTO 2021a) to questions raised by Australia, Canada, Chile, and Mexico on November 27 (WTO 2020c).

Because TRIPS waiver opponents frequently argued that existing flexibilities made India and South Africa's intervention unnecessary, waiver proponents repeatedly highlighted their practical limitations. For instance, in a communication that contains responses to questions raised at TRIPS Council meetings held in October, November, and December, delegates from Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, Venezuela, and Zimbabwe noted that "the 'case by case' or 'product by product' approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic" (WTO 2021b).

In addition, some countries "face limitations with respect to their national laws, pressures from their trading partners, or lack the practical and institutional capacity required to exercise TRIPS flexibilities during the pandemic quickly and effectively," the 10 WTO members wrote (ibid.). To illustrate their point, the delegates noted that in 2020, "in the midst of a raging pandemic," then-U.S. Trade Representative Robert Lighthizer issued a Special 301 report condemning several governments for strengthening their laws on compulsory licenses or making use of such tools. They added that the E.U.'s 2020 IP enforcement report, published just before the start of the Covid-19 pandemic, also criticized many developing countries' compulsory licensing provisions (ibid.).

During an informal TRIPS Council meeting on December 3, Mozambique asked: "After years of discouraging WTO members especially developing countries to take steps to improve their patent law so that compulsory licenses may be issued in the interest of public health, how does the European Union expect all WTO members to be ready to use compulsory licenses?" (WTO 2021c). South Africa followed up by asking if, in light of their newfound fondness of TRIPS flexibilities, the E.U., Switzerland, and the U.S.

planned hereafter to refrain from pressuring developing countries against issuing compulsory licenses (ibid.).

Unlike existing TRIPS flexibilities, the proposed waiver would provide "an expedited, open, and automatic global solution that allows for uninterrupted collaboration in development and scale up of production and supply," proponents emphasized (WTO 2021b).

The cases for and against the TRIPS waiver were reinforced by progressive advocacy groups and Big Pharma supporters, respectively. On December 8, for instance, two days before a formal TRIPS Council meeting, health justice campaigners held a global day of action to build support for an IP waiver. That same day, the International Federation of Pharmaceutical Manufacturers and Associations, one of the industry's most powerful lobbying groups, argued that "diluting national and international IP frameworks during this pandemic is counterproductive" (IFPMA 2020). Thomas Cueni, director-general of the group, said that "at a time when the focus should be on science and innovation, undoing the very system that supports it is dangerous and counterintuitive" (ibid.). He expanded in a *New York Times* op-ed two days later, writing that if the IP waiver proposal succeeds, it "would jeopardize future medical innovation, making us more vulnerable to other diseases" (Cueni 2020). He also tried to defend the status quo by pointing to voluntary licensing agreements that Johnson & Johnson and AstraZeneca had reached with Aspen Pharmacare in South Africa and the Serum Institute in India, respectively.[25]

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[25] At the start of the pandemic, Oxford said that its "97% publicly funded" vaccine would be open license (Safi 2021). But following pressure from the foundation headed by billionaire philanthrocapitalist Bill Gates—whose fortune is owed to software IP enforcement and who now uses his wealth to push global

At the TRIPS Council gathering on December 10, South Africa reiterated the rationale for a comprehensive IP waiver on coronavirus medical tools. Specifically, officials from Cape Town contended that the opaque and exclusive licensing agreements that IP holders were voluntarily entering into with some companies to help increase the supply of Covid-19 shots for certain populations—a far cry from C-TAP's vision of internationally accessible open science—paled in comparison to what was needed to meet worldwide demand and ultimately perpetuated global vaccine inequality.

"Usually these agreements are for manufacturing of limited amounts and solely supplying a country's territory or a limited subset of countries," South Africa observed (WTO 2021d). "Ad hoc, non-transparent, and unaccountable bilateral deals that artificially limit supply and competition cannot reliably deliver access during a global pandemic. These bilateral deals do not demonstrate global collaboration but rather reinforc[e] 'vaccine apartheid' and enlarg[e] chasms of inequity. Disparity in access is certain to continue unless concrete steps are taken to address intellectual property barriers."

2.1.3.2 Big Pharma's Voluntary Licensing Arrangements Exclude Dozens of Capable Manufacturers

Wealthy WTO members consistently cited the existence of voluntary licensing arrangements when arguing against the proposed TRIPS waiver. IP holders did collaborate with other companies in some instances. But as Erfani et al. (2021: 2) warned, "voluntary licenses have not and will not keep pace with public health demand." Because

health policy in a neoliberal direction—the university "reversed course [and] signed an exclusive vaccine deal with AstraZeneca that gave the pharmaceutical giant sole rights and no guarantee of low prices" (Hancock 2020).

IP holders "determine the terms of voluntary licenses, they are often granted to LMICs that can afford them, leaving out poorer regions" (ibid.). While AstraZeneca reached a deal with the Serum Institute of India, for instance, South Asia is home to several qualified vaccine manufacturers that were not tapped. Noting that "there is limited financial incentive" for Covid-19 vaccine developers to license the technologies over which they exert monopoly control, Erfani et al. added that "relying on the moral compass of companies that answer to shareholders… will have limited effect on vaccine equity. Their market is driven by profit margins, not public health."

The following table, based on data compiled by Knowledge Ecology International (2022), documents voluntary licensing deals that five leading Covid-19 vaccine developers inked with other manufacturers in 2020 and 2021. Not all of the partnerships involved producing entire batches of new vaccines. A substantial percentage, especially for NIH-Moderna and Pfizer-BioNTech jabs, involved only fill and finish.

Table 3. Voluntary Licensing Agreements to Produce Selected Covid-19 Vaccines, 2020-2021

Date Deal Announced	Developer	Manufacturer	Manufacturer Country
March 16, 2020	Pfizer-BioNTech	Polymun	Austria
April 23, 2020	Johnson & Johnson	Emergent BioSolutions	United States
April 29, 2020	Johnson & Johnson	Catalent	United States
May 1, 2020	NIH-Moderna	Lonza	Switzerland
May 14, 2020	Johnson & Johnson	Vibalogics	Germany
May 28, 2020	NIH-Moderna	CordenPharma	France

Table 3, continued

May 28, 2020	Oxford-AstraZeneca	Oxford Biomedica	United Kingdom
June 3, 2020	Novavax	AGC Biologics	Denmark
June 4, 2020	Oxford-AstraZeneca	Serum Institute	India
June 4, 2020	Novavax	PolyPeptide Group	Switzerland
June 11, 2020	Oxford-AstraZeneca	Emergent BioSolutions	United States
June 15, 2020	Oxford-AstraZeneca	Novasep	France
June 15, 2020	Oxford-AstraZeneca	Catalent	United States
June 16, 2020	Oxford-AstraZeneca	Cobra Biologics	United States
June 25, 2020	NIH-Moderna	Catalent	United States
June 30, 2020	Oxford-AstraZeneca	Bio-Manguinhos/Fiocruz	Brazil
July 9, 2020	NIH-Moderna	ROVI	Spain
July 17, 2020	Oxford-AstraZeneca	R-Pharm	Russia
July 21, 2020	Oxford-AstraZeneca	SK Bioscience	South Korea
July 23, 2020	Novavax	Fujifilm Diosynth Biotechnologies	Japan
August 2, 2020	Oxford-AstraZeneca	Wockhardt, CP Pharmaceuticals	United Kingdom
August 6, 2020	Oxford-AstraZeneca	Shenzhen Kangtai Biological Products	China
August 6, 2020	Oxford-AstraZeneca	Vaccines Manufacturing and Innovation Centre	United Kingdom
August 6, 2020	Novavax	Serum Institute	India

Table 3, continued

August 13, 2020	Novavax	SK Bioscience	South Korea
August 13, 2020	Johnson & Johnson	Biological E	India
August 17, 2020	Oxford-AstraZeneca	mAbxience	Argentina
August 17, 2020	Oxford-AstraZeneca	Laboratorio Liomont	Mexico
September 3, 2020	Oxford-AstraZeneca	Albany Molecular Research	United States
September 7, 2020	Oxford-AstraZeneca	CSL Behring Ltd.	Australia
September 10, 2020	Pfizer-BioNTech	Dermapharm	Germany
September 14, 2020	Pfizer-BioNTech	Siegfried	Switzerland
September 15, 2020	Novavax	Biofabri	Spain
September 25, 2020	Johnson & Johnson	Grand River Aseptic Manufacturing (GRAM)	United States
September 25, 2020	Novavax	Endo International	United States
October 7, 2020	Pfizer-BioNTech	Rentschler Biopharma	Germany
October 27, 2020	Oxford-AstraZeneca	Siam Bioscience	Thailand
November 2, 2020	Johnson & Johnson	Aspen Pharmacare	South Africa
November 10, 2020	Pfizer-BioNTech	Croda	United Kingdom
November 18, 2020	Pfizer-BioNTech	Delpharm	France
December 8, 2020	Oxford-AstraZeneca	HALIX	Netherlands
December 15, 2020	Johnson & Johnson	Reig Jofre	Spain
December 30, 2020	Oxford-AstraZeneca	JCR Pharmaceutical	Japan

Table 3, continued

December 30, 2020	NIH-Moderna	Recipharm AB	Sweden
January 11, 2021	NIH-Novavax	Baxter	Germany
January 13, 2021	Pfizer-BioNTech	Baxter	Germany
January 20, 2021	Oxford-AstraZeneca	Insud Pharma	Spain
January 27, 2021	Pfizer-BioNTech	Sanofi	France
January 29, 2021	Pfizer-BioNTech	Novartis	Switzerland
February 1, 2021	Oxford-AstraZeneca	KM Biologics	Japan
February 1, 2021	Pfizer-BioNTech	Allergopharma	Germany
February 2, 2021	Novavax	Biologics Manufacturing Centre, Canada	Canada
February 5, 2021	Oxford-AstraZeneca	Daiichi Sankyo	Japan
February 5, 2021	Pfizer-BioNTech	Merck	United States
February 10, 2021	Oxford-AstraZeneca	IDT Biologika	Germany
February 11, 2021	Pfizer-BioNTech	Evonik	Germany
February 22, 2021	Johnson & Johnson	Sanofi	France
February 25, 2021	Novavax	Takeda	Japan
March 2, 2021	Johnson & Johnson	Merck	United States
March 3, 2021	Novavax	Mabion SA	Poland
March 8, 2021	NIH-Moderna	Baxter	United States
March 15, 2021	Johnson & Johnson	IDT Biologika	Germany
March 23, 2021	Novavax	Jubilant	United States
March 25, 2021	Pfizer-BioNTech	Thermo Fisher	Italy
March 29, 2021	Novavax	GSK	United Kingdom
April 26, 2021	NIH-Moderna	Sanofi	France
May 4, 2021	Novavax	Siegfried	Switzerland
May 8, 2021	Pfizer-BioNTech	Fosun Pharma	China
May 22, 2021	NIH-Moderna	Samsung Biologics	South Korea
May 26, 2021	Oxford-AstraZeneca	Nipro Corp	Japan

Table 3, continued

May 27, 2021	Pfizer-BioNTech	Exelead	United States
June 1, 2021	NIH-Moderna	Thermo Fisher	United States
June 7, 2021	Pfizer-BioNTech	AGC Biologics	Germany
July 21, 2021	Pfizer-BioNTech	Biovac	South Africa
August 26, 2021	Pfizer-BioNTech	Eurofarma	Brazil
September 8, 2021	NIH-Moderna	National Resilience, Inc	Canada
October 21, 2021	Pfizer-BioNTech	Novartis	Switzerland
December 1, 2021	Oxford-AstraZeneca	WuXi Biologics	China

Source: Knowledge Ecology International (2022)

At the TRIPS Council meeting held on October 16, 2020, South Africa warned that these largely secretive licensing deals allow IP owners to "limit the production, quantity, and export of products produced under license to certain geographical areas, thereby excluding large parts of the world population" (WTO 2021d). "If we are serious to address access issues," South Africa stressed, "production cannot be concentrated in the hands of only a few" IP holders.

At the December 10 meeting, India added: "Multinational corporations holding Covid-19 vaccine IP have not shown any willingness to openly license or transfer technologies to all competent vaccine developers globally. The pharma industry has objected to participation in WHO's Covid-19 Technology Access Pool. Existing licenses are non-transparent, restricted, and limited."

As 't Hoen (2022) lamented, "If vaccine companies had agreed to collaborate with the Covid-19 Technology Access Pool to share IP, provide manufacturing know-how, regulatory information needed to obtain marketing authorization, and technical assistance, eligible producers in various countries would have been able to start producing and supplying Covid-19 vaccines."

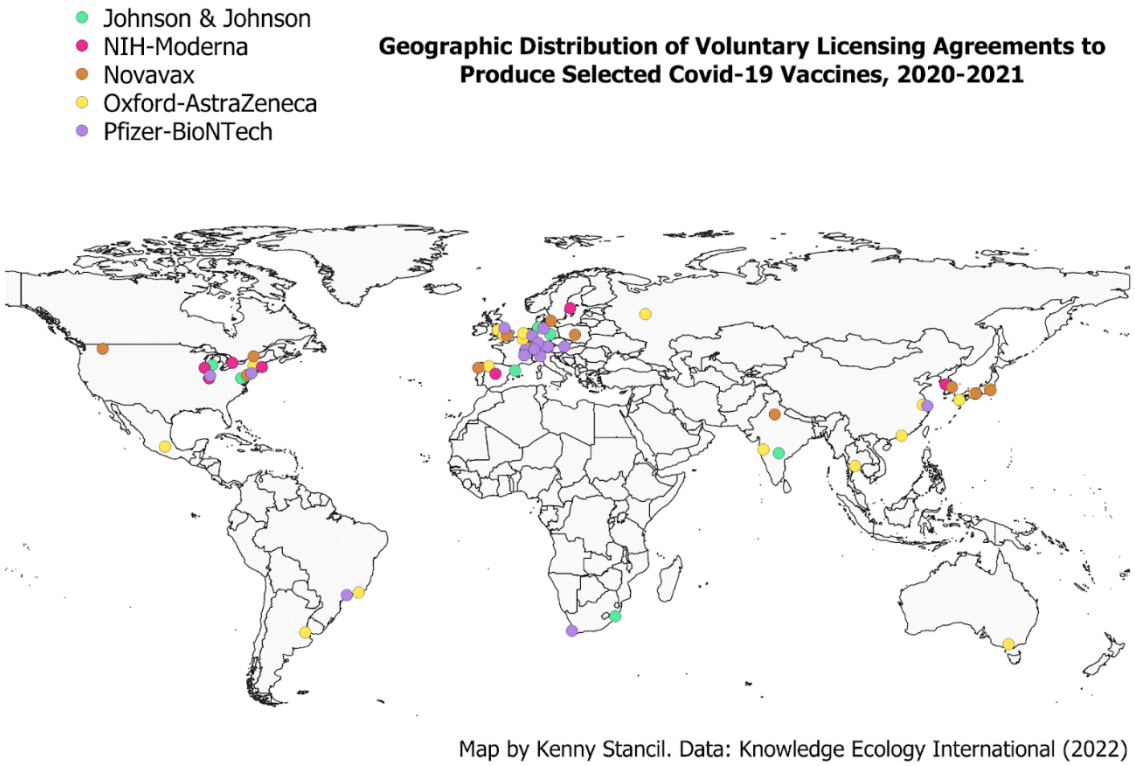
As the following table and map show, Big Pharma's voluntary licensing agreements had a locational bias in favor of high-income countries.

Table 4. Geographic Distribution of Voluntary Licensing Agreements to Produce Selected Covid-19 Vaccines, 2020-2021

Developer	Number of VLAs	% LMICs
NIH-Moderna	10	0%
Pfizer-BioNTech	19	16%
Johnson & Johnson	10	20%
Novavax	14	7%
Oxford-AstraZeneca	25	32%
Total	78	18%

Source: Knowledge Ecology International (2022)

Figure 7. Geographic Distribution of Voluntary Licensing Agreements to Produce Selected Covid-19 Vaccines, 2020-2021



One might say that this reflects the concentration of vaccine manufacturing in high-income countries, but qualified producers in both the Global North and the Global South were unnecessarily excluded by VLAs.

In March 2021, Biolyse, a small pharmaceutical firm in Canada, announced that it could produce 2 million Covid-19 vaccine doses per month for export to poor countries (Schouten 2021). After its request for a voluntary license from Johnson & Johnson was rejected, Biolyse asked the Canadian government to issue a compulsory license that would enable it to make a patented product without permission from the IP holder in exchange for a royalty fee. Lawmakers declined, and the secret recipe was never divulged.

"We've been passed over," Biolyse vice president John Fulton told *The Guardian* in April 2021 (Buranyi 2021). "We've got this production capacity and it's not being put to use. If we had started this last year, we could have shipped millions of doses by now. This is supposed to be like a wartime effort, everyone in it together. But that doesn't seem to be the case."

Biolyse was far from alone. Abdul Muktadir, the managing director of Incepta, a Bangladeshi pharmaceutical company, said in March 2021 that he had emailed executives at Moderna, Johnson & Johnson, and Novavax to offer his company's assistance but never heard back from any of them (Rowland et al. 2021).

"Now is the time to use every single opportunity in every single corner of the world," Muktadir told the *Washington Post* (ibid.). "These companies should make deals with as many countries as possible." "Incepta is a very, very large, capable, high-quality manufacturing place," said Muktadir, who estimated that he had enough capacity to fill

vials for 600 million to 800 million Covid-19 vaccine doses per year. “We are left out because we are in Bangladesh.”

In addition to Biolyse and Incepta, Teva—the world’s largest generic drugmaker, located in Israel—and Bavarian Nordic in Denmark asked to help with Covid-19 vaccine production but were rebuffed (Furlong 2021). Indonesia, Pakistan, Senegal, South Africa, and South Korea are also home to facilities that could be retooled to manufacture Covid-19 vaccines (ibid., Lerner and Fang 2021).

In October 2021, the *New York Times* identified 10 companies in Asia, Africa, and Latin America that are well-positioned to make mRNA Covid-19 vaccines—the most effective shots with the stingiest IP holders (Nolen 2021). Further discrediting Moderna and Pfizer-BioNTech’s specious arguments against broadly licensing mRNA technology, experts from the AccessIBSA project and Doctors Without Borders in December 2021 identified 120 pharmaceutical manufacturers across Asia, Africa, and Latin America that possess the technical requirements and quality standards needed to produce mRNA vaccines but had not been offered a chance to do so (Prabhala and Alsalhan 2021). China’s Fosun Pharma was not on their list because it had already received a full manufacturing license from BioNTech, making it an extremely rare exception.

Table 5. Global South Manufacturers Capable of Making mRNA Covid-19 Vaccines

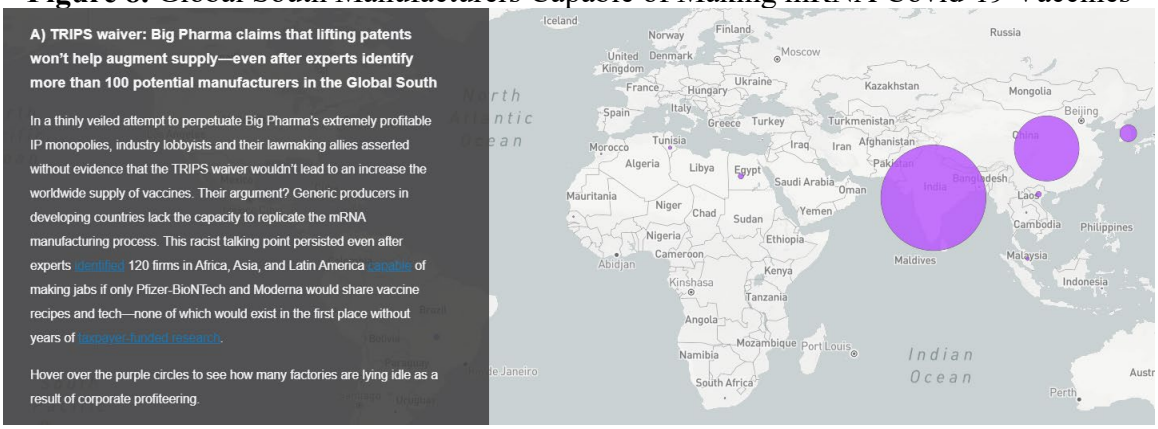
Region	Number of Manufacturers	Contracts with mRNA Producers	Idle Factories During a Deadly Pandemic
Asia	106	Samsung Biologics (S. Korea) - fill and finish for Moderna	105

Table 5, continued

Africa	8	n/a	8
Latin America	6	n/a	6
Total	120	1	119

Source: Prabhala and Alsalhan (2021)

Figure 8. Global South Manufacturers Capable of Making mRNA Covid-19 Vaccines



Map by Kenny Stancil. See Appendix 3 for a link to the interactive version, data sources, and code.

All of this goes to show that one of Big Pharma's most common refrains against the TRIPS waiver—that suspending IP protections would make no positive difference because qualified vaccine manufacturing capacity had been exhausted and any remaining facilities were subpar—was simply not true. By simultaneously opposing the waiver and turning down opportunities for voluntary collaboration, pharmaceutical giants proved that IP monopolies impose serious barriers to ramping up the supply of coronavirus-related medical tools.

Perhaps the most bald-faced expression of Big Pharma's lie came from none other than Bill Gates himself. In an April 2021 interview with *Sky News*, Gates—the billionaire who derived his fortune by weaponizing software copyrights and now uses his ill-gotten

gains to neoliberalize education, food, and health policies, including the COVAX initiative his philanthropic foundation helped create—explained why he opposes sharing the blueprints needed to make more jabs. “It’s not like there’s some idle vaccine factory, with regulatory approval, that makes magically safe vaccines,” said Gates.

In fact, there were dozens of them, kept idle by knowledge hoarding. Failing to exercise the world’s “full manufacturing muscle,” as the head of the WHO put it in March 2021, was a massive, lethal mistake (Adhanom 2021c). This underutilization is all the more regrettable because, as Rizvi (2021) explained, the production of mRNA vaccines “is very different. It requires far less physical space, it is far less capital intensive, the processes are shorter and simpler than traditional vaccine manufacturing. A lot more manufacturers can do it.” According to Rizvi, “You can set up a new production line for only around $60 million. That potential has not been fully realized because a few corporations have dictated who can make mRNA vaccines, how they can make them, where they can make them, and at what price.”

The perpetuation of the Moderna and Pfizer-BioNTech mRNA duopoly cost lives. Savinkina et al. (2022) estimate that 1.5 million deaths could have been averted globally in 2022 if, in the context of the spread of the Omicron variant, universal vaccination—defined as three doses of an mRNA shot—had been achieved in low- and lower-middle-income countries.

2.1.3.3 January-March 2021: Pressure Mounts on Biden

Following the November 2020 election of U.S. President Joe Biden, there was hope that Washington might change course. This was especially the case in light of a promise Biden had made as a candidate a few months earlier. Asked by Medicare for All

activist Ady Barkan during a July interview if he would commit to sharing U.S.-based vaccine technology with other countries and ensuring "there are no patents to stand in the way" of mass generic production, Biden said: "Absolutely, positively. This is the only humane thing in the world to do" (Biden 2020). "Were I president now, and I propose we do it now, set aside $25 billion to put together a plan now—now, this instant—how we will distribute that vaccine when it's made available, to guarantee it gets to every American and access is made available to the rest of the world."

Biden's inauguration coincided with a sharp rise in coronavirus infections and mortality across the globe. The 7-day rolling average of daily Covid-19 deaths hit 14,587 on January 20, 2021 and reached an all-time high of 14,824 on January 28 (Mathieu et al. 2020). Two days before Biden took his oath of office, WHO chief Tedros warned that "the world is on the brink of a catastrophic moral failure—and the price of this failure will be paid with lives and livelihoods in the world's poorest countries" (Adhanom 2021a). "More than 39 million doses of vaccine have now been administered in at least 49 higher-income countries. Just 25 doses have been given in one lowest-income country. Not 25 million; not 25 thousand; just 25."

Biden's first week in the White House also saw a dire forecast from the International Chamber of Commerce (2021). A study commissioned by the ICC and published on January 25 warned that a failure to ensure equitable access to Covid-19 vaccines could unleash up to $9.2 trillion in global economic damage, with as much as $4.5 trillion of the projected losses falling directly on wealthy countries. Despite the gravity of the study's conclusions, its authors did not endorse the TRIPS waiver proposal. Instead, they called on wealthy countries to close a roughly $27 billion funding gap for

the WHO-backed Access to Covid-19 Tools (ACT) Accelerator—including its vaccine pillar, COVAX—noting that doing so could yield a return on investment of up to 166 times.

While health practitioners welcomed the Biden administration's first-week move to join the COVAX initiative shunned by his predecessor, they made clear that the public-private partnership's goal (WHO 2020d) of allocating two billion Covid-19 vaccine doses to low-income countries in 2021—enough for one billion people, a small fraction of humanity—was woefully inadequate and failed to address the most glaring problem: a shortage of jabs (Talmazan 2021, Mueller and Stevis-Gridneff 2021) fueled by IP monopolies that inhibit qualified generic drugmakers from increasing global supply (Public Citizen 2021a).

During the TRIPS Council meeting on February 23, the U.S. touted Biden's February 18 pledge to donate $4 billion to COVAX. The E.U. also praised the move in what was a common refrain for opponents of the IP waiver (WTO 2021e). In a seemingly condescending pro-IP statement, the U.S. said that it looked forward "to engaging in further fact-based discussions on the questions that a number of members have raised about the proposal, with the aim of finding multilateral solutions to amplify the public health and humanitarian responses to the ongoing crisis, while bearing in mind the importance of incentives for innovation" (ibid.).

In response, more than 400 progressive advocacy groups sent a letter to the White House on February 26 urging the Biden administration to immediately support the TRIPS waiver (Citizens Trade Campaign 2021). At a press conference that day, Lori Wallach—then-director of Public Citizen's Global Trade Watch and now director of the Rethink

Trade program at the American Economic Liberties Project—described the fight against the pandemic as "a race against time" and asked: "What is the possible upside of the U.S. blocking this WTO waiver supported by most countries given there is manufacturing capacity around the globe to greatly increase supplies of vaccines, tests, and treatments if formulas and technologies are shared?" (Public Citizen 2021b). Akshaya Kumar, director of crisis advocacy at Human Rights Watch, pointed out that "instead of arguing about how to ration better, we could be rationing less" (ibid.). "Sharing the recipe for vaccines by pooling intellectual property and issuing global, open, and non-exclusive licenses," Kumar added, "could help scale up manufacturing and expand the number of vaccine doses made."

Deploying a metaphor to make the same point, Abby Maxman, president of Oxfam America, said that "rather than slicing the existing pie of vaccines even more finely, we need to share the recipe so that we have enough for everyone," (ibid.). "We need a people's vaccine… that is free to everyone around the world, that is fairly distributed based on need and not on nationality or ability to pay." Brook Baker, senior policy analyst at Health GAP, stressed that "intellectual property barriers are real, and they're blocking millions of people around the world from accessing lifesaving Covid-19 vaccines," adding: "By obstructing the TRIPS waiver proposal, President Biden is breaking his promise to share Covid-19 vaccine technologies with the world."

Biden was also pressured from the other side. The U.S. Chamber of Commerce's Global Innovation Policy Center on March 2 released a statement disparaging the TRIPS waiver proposal as "misguided and a distraction from the real work of reinforcing supply chains and assisting countries to procure, distribute, and administer vaccines to billions of

the world's citizens" (U.S. Chamber of Commerce 2021). On March 5, the Pharmaceutical Research and Manufacturers of America chimed in to encourage Biden to maintain U.S. opposition to the proposed TRIPS waiver (PhRMA 2021). The leading industry lobbying group's letter credited IP protections for the rapid delivery of Covid-19 vaccines, neglecting to mention the billions of dollars in public funding underpinning their development.

The same day, WHO chief Tedros reiterated his support for waiving IP as part of a suite of actions that would put the world on the "war footing" necessary to defeat the Covid-19 pandemic (Adhanom 2021c). At the March 10 meeting of the TRIPS Council, South Africa took issue with those who "suggest that even if the waiver is passed tomorrow, there are no companies in the developing world that can produce any number of products relevant to Covid-19, including mRNA vaccines" (WTO 2021j). "This is a gross misrepresentation of reality," South Africa continued. "Developing countries have advanced scientific and technical capabilities as would be demonstrated by the licensing agreements entered into by various pharmaceutical companies with producers in the developing world."

Supply shortages are "caused by the inappropriate use of intellectual property rights by right[s] holders themselves, who enter into restrictive agreements that serve their own narrow monopolistic purposes putting profits above life," South Africa added. "The situation in the developing world is not characterized by a lack of capacity, but a lack of opportunity… The more manufacturers we have, the quicker we will reach our goal to vaccinate everyone in the shortest possible time."

Wealthy countries were unmoved and rejected the TRIPS waiver yet again. Soon after, Mustaqeem De Gama, a counselor at the South African mission to the WTO who helped draft the proposal and was involved in talks, told the *New York Times* that "every minute we are deadlocked in the negotiating room, people are dying" (Gebrekidan and Apuzzo 2021).

On March 18, Katherine Tai, Biden's pick for U.S. Trade Representative, was sworn in, finally replacing Trump appointee Lighthizer. Soon after, the White House received dueling letters from members of Congress, with more than 100 House Democrats calling on the president to back the measure and four Senate Republicans urging him to maintain the government's opposition to it (Palmer 2021).

2.1.3.4 April-May 2021: Amid Delta Wave, a White House Surprise

April marked an apparent turning point. The lethal destruction wrought by the Delta variant provided real-world evidence that vaccine equity is not only a moral imperative but a matter of self-interest, as WHO chief Tedros had recently stressed (Adhanom 2021c). Vaccine apartheid was giving SARS-CoV-2 more chances to circulate and mutate, turning impoverished countries into breeding grounds for potentially vaccine-resistant variants that could come back to haunt the wealthy countries squandering jabs and knowledge.

In this context, the Biden administration faced increased pressure, including from mainstream sources such as the *Times* editorial board (New York Times 2021), to express U.S. support for the TRIPS waiver—and countervailing pressure from Big Pharma and its allies to maintain U.S. opposition to it. More than 100 drug industry lobbyists, including former staff members of the U.S. Office of Trade Representative, were dispatched to

Capitol Hill and the White House in an attempt to persuade lawmakers and officials to oppose the proposed IP waiver, according to disclosure forms filed in the first quarter of 2021 (Fang 2021).

Once again, there were dueling letters from Congress. On April 15, nine Senate Democrats joined Independent Sen. Bernie Sanders of Vermont (2021) in imploring the president to back the proposed IP waiver. “Delaying vaccine deployment in the developing world to lock in profit-boosting patent protections,” they wrote, “threatens the safety of the American public that financed the vaccines in the first place.”

A day later, Republican Sen. Thom Tillis of North Carolina (2021) decried what he called the “disastrous TRIPS waiver” in a letter addressed to Tai and Commerce Secretary Gina Raimondo. In urging the White House to reject the proposal, Tillis argued that “the waiver’s main concrete impact would… be to legitimate the transfer of American technologies to foreign competitors.” According to Tillis, the supposedly unlimited waiver “creates an uncontestable opportunity” for China, India, and other countries to demand immediate access to mRNA technologies they “lag in or totally lack.” “These technologies are not just used for Covid vaccines,” Tillis warned. “Their transfer would allow for the creation of entire industries… that will compete with American companies in the development of cutting-edge healthcare technologies.”

This misanthropic argument was also peddled by drug industry lobbyists, as the *Financial Times* reported: “[C]ompanies have warned in private meetings with U.S. trade and White House officials that giving up the intellectual property rights could allow China and Russia to exploit platforms such as mRNA, which could be used for other

vaccines or even therapeutics for conditions such as cancer and heart problems in the future" (Kuchler and Williams 2021).

Stiglitz and Wallach (2021) provided a rebuttal to the increasingly desperate arguments mustered by Big Pharma and its supporters:

> [W]hen all of its other claims fall through, the industry's last resort is to argue that a waiver would help China and Russia gain access to a U.S. technology. But this is a canard, because the vaccines are not a U.S. creation in the first place. Cross-country collaborative research into mRNA and its medical applications has been underway for decades. The Hungarian scientist Katalin Karikó made the initial breakthrough in 1978, and the work has been ongoing ever since in Turkey, Thailand, South Africa, India, Brazil, Argentina, Malaysia, Bangladesh, and other countries, including the U.S. National Institutes of Health.
>
> […]
>
> For those focused on geopolitical issues, the bigger source of concern should be America's failure to date to engage in constructive Covid-19 diplomacy. The U.S. has been blocking exports of vaccines that it is not even using. Only when a second wave of infections started devastating India did it see fit to release its unused AstraZeneca doses. Meanwhile, Russia and China have not only made their vaccines available; they have engaged in significant technology and knowledge transfer, forging partnerships around the world, and helping to speed up the global vaccination effort.

Supporters of an IP waiver were also growing increasingly desperate. At the April 30 meeting of the TRIPS Council, South Africa said that without such a measure, "it is clear to us that poorer countries will remain dependent on the charity of richer countries and their pharmaceutical industries" (WTO 2021k).

"The waiver will facilitate sharing of technology and know-how in a coherent, transparent, and open manner to companies with idle manufacturing capacity across the world," South Africa continued (ibid.). "Bilateral deals through voluntary licenses agreements (VLAs) have proven to be ineffective as a response thus far."

On May 5, the Biden administration shocked the world by announcing its support for a temporary suspension of IP rights on coronavirus vaccines. “This is a global health crisis, and the extraordinary circumstances of the Covid-19 pandemic call for extraordinary measures,” U.S. Trade Representative Katherine Tai said in a statement (2021). “The administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for Covid-19 vaccines.” Tai added that the U.S. would “actively participate in text-based negotiations” at the WTO to “make that happen.”

The leaders of the UN and the WHO welcomed the move, as did many health justice campaigners, although they criticized Biden’s insistence on a vaccine-only waiver that would shield IP for tests and treatments even as the importance of both grew. Knowledge Ecology International executive director James Love (2021) offered a straightforward explanation for the White House’s position: “One reason why the U.S. will back a waiver on vaccines but not therapeutics or diagnostics, is that vaccines in foreign markets protect us. Therapeutics, diagnostics in foreign markets, don’t.”

Germán Velásquez, a special adviser on policy and health at the South Centre, was more skeptical of Biden’s move, telling *The Lancet* that he thought “the U.S. will try to delay the issue and try to weaken the text” (Zarocostas 2021). Time would prove Velásquez correct.

Following a brief decline in the immediate wake of Tai’s announcement, pharmaceutical stocks rebounded after a spokesperson for German Chancellor Angela Merkel reiterated the country’s opposition to the TRIPS waiver. “The limiting factors in the production of vaccines are the production capacities and the high-quality standards

and not patents," the spokesperson said, repeating Big Pharma's debunked talking points. "The protection of intellectual property is a source of innovation and must remain so in the future" (Burki 2021).

2.1.3.5 June 2021-Feb 2022: Slow Walking into the Omicron Disaster

On June 4, the E.U. submitted a communication to the TRIPS Council that was viewed as a counterproposal to the India and South Africa-led motion for an IP waiver (WTO 2021g). The E.U. alternative revolved around facilitating trade and lifting export restrictions, expanding voluntary licensing agreements, and clarifying and facilitating TRIPS flexibilities regarding compulsory licenses; in other words, the bloc proposed many of the same measures that had already proven inadequate to that point.

As text-based negotiations got underway a couple of weeks later—more than eight months and seven million excess deaths after India and South Africa first introduced their IP waiver proposal—the E.U. on June 18 asked the TRIPS council to adopt a declaration containing essentially the same message as its June 4 document (WTO 2021h). Doctors Without Borders criticized the E.U. plan as "weak and distracting, bringing nothing significantly new to the table, and diluting some of the existing public health flexibilities enjoyed by WTO members" (2021). What ensued was many additional months of fruitless talks as the pandemic death toll climbed, driven by the Delta variant, with Omicron waiting in the wings.

Before and during her mid-July visit to the White House for a summit on "ending the Covid-19 pandemic," Merkel faced immense pressure to support the original TRIPS waiver. By that point, Biden was also starting to face criticism for doing next to nothing

to publicly pressure Washington's allies to follow the U.S. lead in backing at least a partial suspension of coronavirus-related IP barriers.

By fall of 2021, reports indicated that despite the Biden administration's widely publicized expression of support for a vaccine-only IP waiver and its vow to actively participate in text-based negotiations at the WTO, the White House was doing very little to advance talks and declining to pressure the E.U. and other holdouts (Lazare 2021a, Lazare 2021b, Stangler 2021).

In a symbolic development, the arrival of Omicron forced the indefinite postponement of the WTO's Twelfth Ministerial Conference (MC12) scheduled for November 30 through December 3, during which well-vaccinated wealthy countries were expected to keep shielding the IP monopolies that made the highly contagious variant's emergence more likely (Baker 2021, Prasad et al. 2022). Not even Omicron could force a change of heart. During closed-door talks in February 2022, the U.S. and the E.U. were conspiring to ensure that any IP waiver that might emerge from WTO negotiations would exclude diagnostics and therapeutics (Lazare 2022a).

2.1.3.6 March-May 2022: Compromise Text Emerges

Following the postponement of MC12, WTO Director-General Ngozi Okonjo-Iweala and WTO Deputy-Director General Anabel González conducted a set of informal negotiations with India, South Africa, the E.U., and the U.S.—a group that became known as "the Quad" (Balasubramaniam 2022). On March 15, a leaked version of a document titled *TRIPS Covid-19 Solution (the Outcome of the Quadrilateral Discussions at the End of Last Week, to be Presented to WTO Members)* was published and swiftly decried by civil society and academic experts (Love 2022).

As Balasubramaniam explained, “The leaked document resembled the European Union proposal and looked quite different from the original proposal from India and South Africa” (ibid.). At the behest of the U.S., the compromise text was limited to jabs even as inequalities in access to tests and treatments mirrored vaccine apartheid. In addition, it only addressed patents, completely failing to deal with other IP barriers, including trade secrets and manufacturing know-how. Furthermore, it excluded developed countries and some highly industrialized developing countries such as China from utilizing a key compulsory licensing flexibility, thus neutralizing a large chunk of the world’s capacity to manufacture generic shots for export (Lazare 2022b).

The *Nature* editorial board (2022) pointed out that in addition to excluding “access to forms of data that might be needed to make vaccines, but that are not covered in a patent,” the leaked text “also requires companies looking to reproduce a vaccine to draw up a list of all patents that must be waived—something that would take too long to be practical in a pandemic.” As the board observed: “Identifying all of the IP that goes into specific technologies cannot be done quickly. A preliminary analysis by the World Intellectual Property Organization shows that applications were made for 417 Covid-19 vaccine-related patents between the start of 2020 and the end of September 2021. The analysis is preliminary because it takes an average of 18 months between an application being filed with a patent office and the application being published. There are many more patents still to come.”

Sangeeta Shashikant of the Third World Network told *In These Times* that the patent listing requirement reflects an E.U. demand to add an “additional condition” to

Article 31. “These are all conditions that never existed in the TRIPS Agreement,” said Shashikant. “This adds conditionality that was never there to begin with” (Lazare 2022b).

Access to medicines campaigners considered the compromise text irredeemably flawed and urged governments to reject it (Doctors Without Borders 2022b). However, a text nearly identical to the leaked draft was formally submitted to the TRIPS Council on May 3 at the request of Okonjo-Iweala (WTO 2022a).

Once again, global health advocates condemned the proposal as more likely to do more harm than good in the long run and called on governments to reject it (Public Citizen 2022a). Meanwhile, Wallach asked: “How can it be that in the face of a global pandemic that has taken 15 million lives and destroyed billions more livelihoods, in two years the WTO cannot get out of the way of global access to medicines that governments paid pharmaceutical firms billions to develop and distribute?” (Rethink Trade 2022).

2.1.4 The TRIPS Waiver Death

During MC12, held from June 12 to June 17, civil society organizations implored WTO delegates from developing countries to sink the compromise text if they could not win a genuine IP waiver of the sort that India and South Africa had put forth nearly 21 months earlier. Nevertheless, it was adopted on the final day of the meeting (WTO 2022b).

Max Lawson, co-chair of the People’s Vaccine Alliance and head of inequality policy at Oxfam, blasted wealthy countries for the outcome, characterizing their conduct at the WTO as “utterly shameful” (People’s Vaccine Alliance 2022b). “The E.U. has blocked anything that resembles a meaningful intellectual property waiver. The U.K. and Switzerland have used negotiations to twist the knife and make any text even worse. And

the U.S. has sat silently in negotiations with red lines designed to limit the impact of any agreement." Lawson stressed that "this is absolutely not the broad intellectual property waiver the world desperately needs to ensure access to vaccines and treatments for everyone, everywhere… This so-called compromise largely reiterates developing countries' existing rights to override patents in certain circumstances. And it tries to restrict even that limited right to countries which do not already have capacity to produce Covid-19 vaccines. Put simply, it is a technocratic fudge aimed at saving reputations, not lives."

Public Citizen's Global Trade Watch director Melinda St. Louis slammed "the shameful, undemocratic WTO process [that] allowed rich countries representing corporate interests to strongarm a sham agreement that bears no resemblance to the original waiver proposal and will do nothing to help save lives for this or future pandemics" (Public Citizen 2022b). She and Lawson were echoed by several other experts (ibid.). In addition, hundreds of public health, labor, and human rights groups from around the world called on governments to "take immediate actions to bypass the WTO's prioritization of pharmaceutical monopolies over human lives" (Trade Justice Education Fund 2022).

2.2 The Failure of the U.S. to Share Vaccine Technology, Invest in Public Production

Although TRIPS waiver proponents insisted that securing the reforms proposed by India and South Africa would have been a significant victory, they understood perfectly well that it would not solve every problem. They knew, for instance, that having step-by-step manufacturing instructions is just as important as removing the threat of IP lawsuits. Crucially, the waiver would have relieved generic drugmakers of potential legal

liability for IP infringement, but it would not have mandated the sharing of patents or trade secrets (Ho 2022: 142).

Moreover, while TRIPS waiver proponents debunked Big Pharma's lies about the world's presumed lack of surplus vaccine manufacturing capacity, they also made clear the need to supplement any action at the WTO with investments to expand and improve jab production around the globe (Rizvi and Maybarduk 2020, Ghosh 2021, Maybarduk 2021). Demands for a comprehensive international plan to inoculate billions of people in a timely manner were made early in the Covid-19 pandemic.

On May 13, 2020, less than a week before the World Health Assembly gathered to discuss the pandemic, more than 140 experts and world leaders published an open letter calling on delegates at the upcoming meeting "to rally behind a people's vaccine" against Covid-19 (Oxfam 2020a). "Governments and international partners must unite around a global guarantee which ensures that, when a safe and effective vaccine is developed, it is produced rapidly at scale and made available for all people, in all countries, free of charge."

"Our world will only be safer once everyone can benefit from the science and access a vaccine—and that is a political challenge," says the letter. "Now is not the time to allow the interests of the wealthiest corporations and governments to be placed before the universal need to save lives, or to leave this massive and moral task to market forces. Access to vaccines and treatments as global public goods are in the interests of all humanity. We cannot afford for monopolies, crude competition, and near-sighted nationalism to stand in the way."

Signatories implored the WHO to implement a "bold international agreement" that would not only eliminate legal barriers to the generic manufacturing of Covid-19 medical tools but affirmatively require knowledge sharing and technology transfer while proactively investing in scaling up worldwide productive capacity. Specifically, they called for a pact that would:

1. Ensure mandatory worldwide sharing of all Covid-19-related knowledge, data, and technologies with a pool of Covid-19 licenses freely available to all countries. Countries should be empowered and enabled to make full use of agreed safeguards and flexibilities in the WTO Doha Declaration on the TRIPS Agreement and Public Health to protect access to medicines for all.
2. Establish a global and equitable rapid manufacturing and distribution plan—that is fully funded by rich nations—for the vaccine and all Covid-19 products and technologies that guarantees transparent 'at true cost-prices' and supplies according to need. Action must start urgently to massively build capacity worldwide to manufacture billions of vaccine doses and to recruit and train the millions of paid and protected health workers needed to deliver them.
3. Guarantee Covid-19 vaccines, diagnostics, tests, and treatments are provided free of charge to everyone, everywhere. Access needs to be prioritized first for front-line workers, the most vulnerable people, and for poor countries with the least capacity to save lives.

The WHO issued a less ambitious resolution at the World Health Assembly on May 19 (WHO 2020a). Days later, it launched C-TAP, but as discussed in the preceding section, pharmaceutical corporations have completely shunned this voluntary IP-sharing initiative. The second and third goals outlined in the call for a "people's vaccine," meanwhile, went unfulfilled. Wealthy countries not only gobbled up a disproportionate share of doses, but they also rebuffed calls to disseminate the know-how and technology needed to ramp up generic manufacturing and thus global supply.

"By partnering with drug companies, Western leaders bought their way to the front of the line," the *New York Times* reported in March 2021 (Gebrekidan and Apuzzo 2021). "But they also ignored years of warnings—and explicit calls from the World Health Organization—to include contract language that would have guaranteed doses for poor countries or encouraged companies to share their knowledge and the patents they control."

The failure of the U.S. government to mandate that Covid-19 vaccine developers adhere to reasonable pricing, equitable allocation, IP licensing, and technology transfer requirements in exchange for billions of dollars in public support dates to the early days of the global public health emergency. Asked by Rep. Jan Schakowsky (D-Ill.) during a February 2020 congressional hearing if future coronavirus jabs and treatments would be affordable for anyone in need, then-Health and Human Services Secretary Alex Azar—the former president of Eli Lilly, a pharmaceutical giant notorious for engaging in deadly insulin price-gouging—said, "We would want to ensure that we work to make it affordable, but we can't control that price, because we need the private sector to invest" (Beaty et al. 2020).

At that point, as discussed in Chapter 1, the U.S. government had already invested more than $330 million into the creation of mRNA Covid-19 vaccines, including conducting research into mRNA technology as well as developing vaccine candidates for earlier coronaviruses (Lalani et al. 2023). Through Operation Warp Speed (OWS), launched in May 2020, taxpayers provided an additional $9.7 billion to buttress research and development, clinical trials, and factory retrofits for five Covid-19 vaccine candidates—$2.5 billion for NIH-Moderna, $2.1 billion for Sanofi-GSK, $1.9 billion for Johnson & Johnson, $1.6 billion for Oxford-AstraZeneca, and $1.6 billion for Novavax (Rizvi and Maybarduk 2020). Despite Pfizer-BioNTech's insistence that it did not rely on U.S. taxpayer support when developing its Covid-19 vaccine, it is important to remember that both companies benefited from decades of foundational mRNA research.

On top of providing scientific support, the U.S. government also shelled out billions of dollars via advanced purchase agreements for Covid-19 vaccines, significantly reducing the amount of risk borne by pharmaceutical companies. Moderna, for example, signed contracts to sell 200 million doses to the U.S. government for $3.2 billion dollars *before* the NIH-Moderna shot received emergency use authorization from the Food and Drug Administration (FDA) on December 18, 2020 (Lalani et al. 2023, UNICEF). Likewise, Washington agreed to buy 100 million doses of Pfizer-BioNTech's jab for nearly $2 billion months before it received the first green light from the FDA, which happened on December 11 (ibid.). Throughout the spring and summer of 2020, Sanofi-GSK, Johnson & Johnson, Oxford-AstraZeneca, and Novavax also signed deals to provide a total of 370 million Covid-19 vaccines to the U.S. in exchange for a combined $4.9 billion (ibid.).

Even amid this enormous outpouring of public funds, authorities in the U.S. and other rich countries failed to include fair pricing, distribution, IP licensing, and technology transfer provisions in their bilateral Covid-19 vaccine contracts with pharmaceutical firms—enabling corporations to socialize risks and privatize profits (Kapczynski et al. 2023). In the U.S., the failure can be traced back to OWS, which "succeeded in bringing vaccines to market *quickly*," but whose "early contractual agreements for the vaccines failed to include two provisions in particular: non-exclusive licensing and reasonable pricing" (Meyersohn 2023).

2.2.1 Attempts to Persuade Biden to License Publicly Funded/Owned Vaccine Tech

Despite early mishaps by the Trump administration, there are steps the Biden administration could have taken—but did not—to break Pfizer-BioNTech and Moderna's duopoly on mRNA Covid-19 vaccines. Throughout the entire painstaking debate over the TRIPS waiver, vaccine equity advocates were pushing Biden to use the full extent of his executive power to spread lifesaving knowledge, unilaterally if necessary. Regardless of what is decided in Geneva, advocates said, the White House possesses the requisite authority to force pharmaceutical corporations to share Covid-19 vaccine manufacturing know-how with qualified producers worldwide.

This is especially the case with Moderna. Citing information unearthed by Rizvi (2021a), a dozen congressional Democrats led by Sen. Elizabeth Warren (D-Mass.) and Rep. Pramila Jayapal (D-Wash.) wrote in an October 2021 letter addressed to two Biden administration officials that the contract Moderna entered into with BARDA in April 2020 "may give the federal government legal authority to access and share the ingredient list and manufacturing instructions" for the NIH-Moderna Covid-19 vaccine (Warren et

al. 2021). As the lawmakers noted: "The contract grants BARDA 'unlimited rights to data funded under this contract pursuant to [the Federal Acquisition Regulations (FAR)] Clause 52.227-14.' Under FAR, data is defined to include 'recorded information, regardless of form or the media on which it may be recorded,' as well as 'technical data'—a broad definition that appears to include all key information needed to produce the vaccine" (ibid.).

Several months earlier, in a report published in December 2020, Rizvi and Maybarduk of Public Citizen detailed three legal mechanisms the incoming Biden White House could use to require vaccine developers that benefited from publicly funded research to share information with manufacturers while being fairly compensated. Those authorities, which went unused, are described in the following table.

Table 6. U.S. Government's Legal Authorities Related to IP and Information Disclosure

Authority	Provision	Use	Considerations
Worldwide Licenses Bayh-Dole Act, analogous statutes, funding contracts	Bayh-Dole: "The Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."	Give permission to global partners to use government-funded or government-owned medical inventions and data.	• Bayh-Dole contracts have standard set of rights. • Scope of rights in other kinds of funding contracts vary. • Government has vast authority for inventions it owns.
Information Disclosure Defense Production	"The President shall be entitled… by regulation, subpoena, or otherwise, to	Share technical information with global partners.	• National defense includes "military or

Table 6, continued

Act, 50 U.S.C. § 4555	obtain such information from… any person as may be necessary or appropriate, in his discretion, to the enforcement or the administration of this Act… Information obtained under this section which the President deems confidential or with reference to which a request for confidential treatment is made by the person furnishing such information shall not be published or disclosed unless the President determines that the withholding thereof is contrary to the interest of the national defense."		critical infrastructure assistance to any foreign nation." • Recently used to assess industrial capabilities. • President can issue regulations to change scope and purpose of information disclosures.
Government Patent Use 28 U.S.C. § 1498	"Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation	Clear patent barriers domestically, authorize multiple suppliers, and send signal to other countries to use similar authorities.	• Used regularly by federal government to procure everything from military equipment to electronic passports. • Government use cannot be enjoined.

Table 6, continued

	for such use and manufacture."		

Source: Rizvi and Maybarduk (2020)

There were additional calls for the Biden administration to intervene. To take one example, in mid-April 2021, a coalition of 16 progressive advocacy groups wrote a letter to Commerce Secretary Raimondo and White House Covid-19 Response Team Coordinator Jeffrey Zients. In addition to urging support for the TRIPS waiver proposal, the organizations implored the Biden administration to invoke never-before-used march-in rights under the Bayh-Dole Act as well as Section 1498 powers to disseminate publicly funded/owned knowledge to eligible drugmakers worldwide (Revolving Door Project 2021). As the coalition noted:

> The Pfizer and Moderna vaccines rely enormously on a viral protein discovered decades ago by Dr. Barney Graham, and on the concept of RNA modification developed by Drew Weissman and Katalin Karikó.[26] Graham, Weissman, and Karikó's research was all publicly funded. It is thanks to this research, underwritten by ordinary taxpayers, that the United States has been able to produce Covid-19 vaccines in less than one year. Yet despite this, the technologies needed to actually produce these vaccines are solely held by a handful of private, for-profit firms, who have jealously guarded any other institution's access to this life-saving machinery in part through thickets of intellectual property protections. Anyone seeking to produce Covid-19 mRNA vaccines—which is to say, the whole population of the planet Earth—is forced ultimately to barter with these for-profit corporations, who hold unitary control over this technology for purely artificial, legal reasons.

In fact, at least four approved Covid-19 vaccines—those made by Pfizer-BioNTech, Moderna (mRNA-1273), Johnson & Johnson, and Novavax—rely on the prefusion spike protein technology developed by Graham and others at the NIH Vaccine

26 On October 2, 2023, Weissman and Karikó were awarded the Nobel Prize in Physiology or Medicine for their groundbreaking (and publicly funded) research on mRNA vaccines.

Research Center and to which the U.S. government owns rights (Rizvi 2020c). While several companies, including Pfizer-BioNTech, licensed U.S. patent number 10,960,070—better known as the '070 patent—for their vaccines and paid the government royalties, Moderna did neither. In an April 2021 interview with the *Financial Times*, Graham made clear that the government's ownership of the patent gives it the "leverage" needed to push Moderna to share its manufacturing know-how with other vaccine producers worldwide (Mancini and Stacey 2021).

As Morten et al. (2021) expounded:

> Because Moderna lacks permission to use the technology, because the technology is essential to mRNA-1273's function and value as a vaccine, and because mRNA-1273 has been a financial blockbuster for Moderna, the '070 patent provides the U.S. government significant leverage over Moderna. The U.S. government could assert the '070 patent against Moderna in court and could (assuming Moderna's continued financial success) demand hundreds of millions or even over a billion dollars in compensation. The U.S. government could alternatively use the threat of litigation of the '070 patent to bring Moderna back to the negotiation table and convince Moderna to share its own patents, trade secrets, and other intellectual property on mRNA-1273 with the U.S. government and with vaccine manufacturers around the world. The latter option is the better one, to accelerate scale-up of global mRNA vaccine manufacturing, vaccinate the world, and bring the Covid-19 pandemic to a conclusive end.

It was not until February 2023, after the company had raked in tens of billions of dollars in profits and announced plans to more than quadruple the price of its shot, that Moderna paid just $400 million to the U.S. government for the rights to the NIH's spike protein technique (Mueller 2023).

Meanwhile, the NIH and Moderna are still "locked in a high-stakes dispute over which researchers should be named as inventors" on a patent application that takes credit for the mRNA sequence used in the vaccine (Ledford 2021). In November 2021, it was revealed that the company claimed sole inventorship of the crucial vaccine component,

erasing the contributions of three government scientists in its application (Stolberg and Robbins 2021a). As the *New York Times* reported: "Much more than scientific recognition is at stake. If federal researchers were named as co-inventors in the patent, the government would have a nearly unfettered right to license the Moderna vaccine to other manufacturers, which could expand access to it in poorer nations and bring the government millions in revenue" (Stolberg and Robbins 2021b).

After the exclusionary filings were made public, Maybarduk wrote a letter urging then-NIH Director Francis Collins "to publicly clarify the role of the NIH in the invention of the vaccine, and to explain the steps you intend to take to ensure the contributions of federal scientists are fully recognized, including any legal remedies" (Public Citizen 2021e). As Maybarduk stressed: "Co-inventorship creates a presumption of co-ownership. Co-ownership can empower the U.S. government to authorize additional manufacturers to use some mRNA-1273 patents around the world, including through the Medicines Patent Pool, without Moderna's permission" (ibid.).

Asked about the dispute in early November 2021, Collins said, "I think Moderna has made a serious mistake here in not providing the kind of co-inventorship credit to people who played a major role in the development of the vaccine that they're now making a fair amount of money off of" (Steenhuysen 2021). "We are not done," Collins added. "Clearly this is something that legal authorities are going to have to figure out."

2.2.2 An Ignored Plan to Boost Covid-19 Vaccine Manufacturing

In February and May of 2021, Public Citizen (2021c and 2021d) showed that with an investment of just $25.2 billion dollars—roughly 3% of the annual Pentagon budget—the U.S. government could set up regional manufacturing hubs around the world to

produce 8 billion doses of the NIH-Moderna vaccine in one year. According to the group, spending $1.9 billion on retrofitting and constructing vaccine production facilities in various countries, $19.8 billion on materials and labor, and $3.5 billion on technical assistance and compensation for technology transfers would allow lawmakers "to leverage the considerable investment the U.S. public already has made in Covid-19 vaccines, including the ownership rights the U.S. government has in the NIH-Moderna vaccine."

"The U.S. can help lead the world out of the pandemic if our government acts now," Maybarduk said at the time. "A $25 billion investment could support the manufacturing of vaccines for more than half the world's people, in time to spare them years of needless suffering" (Public Citizen 2021c). Sadly, Congress and the White House declined to heed this call. $25 billion—the exact sum that Biden mentioned in his presidential campaign conversation with Ady Barkan—is less than what the U.S. government spent to buy vaccine doses whose development had already been subsidized. The long-term economic and health returns on expanding global vaccine manufacturing capacity—and diversifying its geography—is far superior to outsourcing the task to a handful of pharmaceutical giants and their preferred sub-contractors concentrated largely in wealthy countries. Of course, reclaiming public ownership of vaccine IP and building public factories to produce jabs would undercut Big Pharma's monopoly power and monopoly rents, which is why Big Pharma is opposed to such proposals.

Although Biden vowed to make the U.S. the world's vaccine "arsenal" (Biden 2021), a PrEP4All analysis published in August of 2021 revealed that of the more than $16 billion that Congress appropriated to fight the Covid-19 pandemic, his administration

had spent less than 0.01% of it to ramp up global vaccine manufacturing (Krellenstein 2021). Increased supply was sorely needed. A study published in January 2022 by researchers from PrEP4All, Partners in Health, and various universities found that in the wake of the worldwide surge of Omicron, 22 billion doses of mRNA jabs were needed to achieve global vaccine equity and end the pandemic for good (Krellenstein et al. 2022). As the same analysis noted: "Pfizer-BioNTech and Moderna, neither of which is likely to meet its 2021 projections, claim they will make 4 billion and 3 billion mRNA vaccine doses, respectively, in 2022. Assuming Pfizer-BioNTech and Moderna meet these production goals (an optimistic assumption), the world will face a shortfall of 15 billion doses per year of mRNA vaccine production capacity in 2022" (ibid. 5). If Biden had implemented Public Citizen's blueprint immediately, several billion additional mRNA vaccine doses could have been produced in 2021 and 2022.

CHAPTER 3. PREVENTING FUTURE ABANDONMENT

"I will not stay silent when the companies and countries that control the global supply of vaccines think the world's poor should be satisfied with leftovers."—WHO Director-General Tedros Adhanom Ghebreyesus[27]

"I don't think only Big Pharma can do things. It's like saying only Ikea can make furniture."—Brigitte Kiecken, Biolyse[28]

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27 Adhanom (2021f)

28 Cited in Abowd (2021)

Public Citizen's oft-repeated call for the U.S. government to use the full extent of its authority to share NIH's vaccine technology with qualified drugmakers and invest a mere $25 billion to retrofit existing facilities and establish new vaccine manufacturing hubs around the globe was tragically ignored. Instead, Moderna and Pfizer-BioNTech maintained their duopoly, preempting the production of billions of additional doses at the moment they were needed most.

One unmissable lesson from the past three-and-a half years is that impoverished countries cannot rely on the benevolence of wealthy countries or pharmaceutical corporations. "Covid has put a magnifying glass upon the fissures and cracks in our world," Ayoade Alakija, co-chair of the African Vaccine Delivery Alliance, told the *Washington Post* in July 2023 (Maxmen 2023). "This world is deeply, deeply unjust and inequitable." The world's poor were told to wait patiently for Covid-19 vaccines to be donated. More than two billion people, 89% of whom live in the developing world, are still waiting for their first jab in the second half of 2023 (Schellekens 2023). By one estimate, just one out of seven doses promised by rich nations and the pharmaceutical industry had been delivered by September 2021 (People's Vaccine Alliance 2021d). Data from March 2022 shows that major gaps between pledges and actual donations persisted (Mathieu et al. 2020).

Figure 9. Covid-19 vaccine doses donated to COVAX.

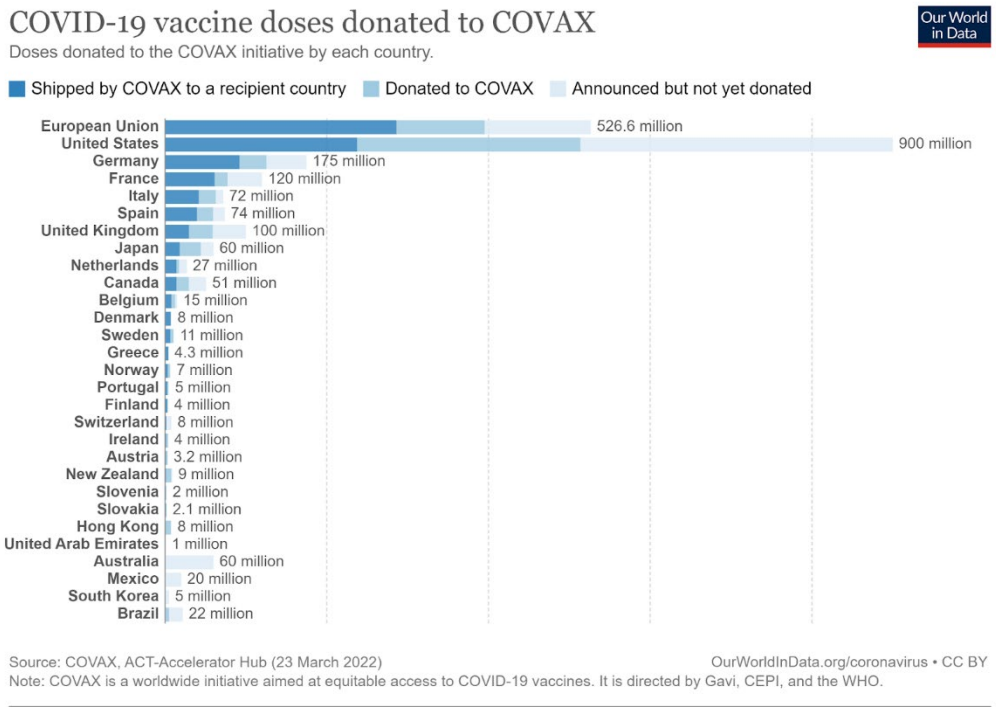
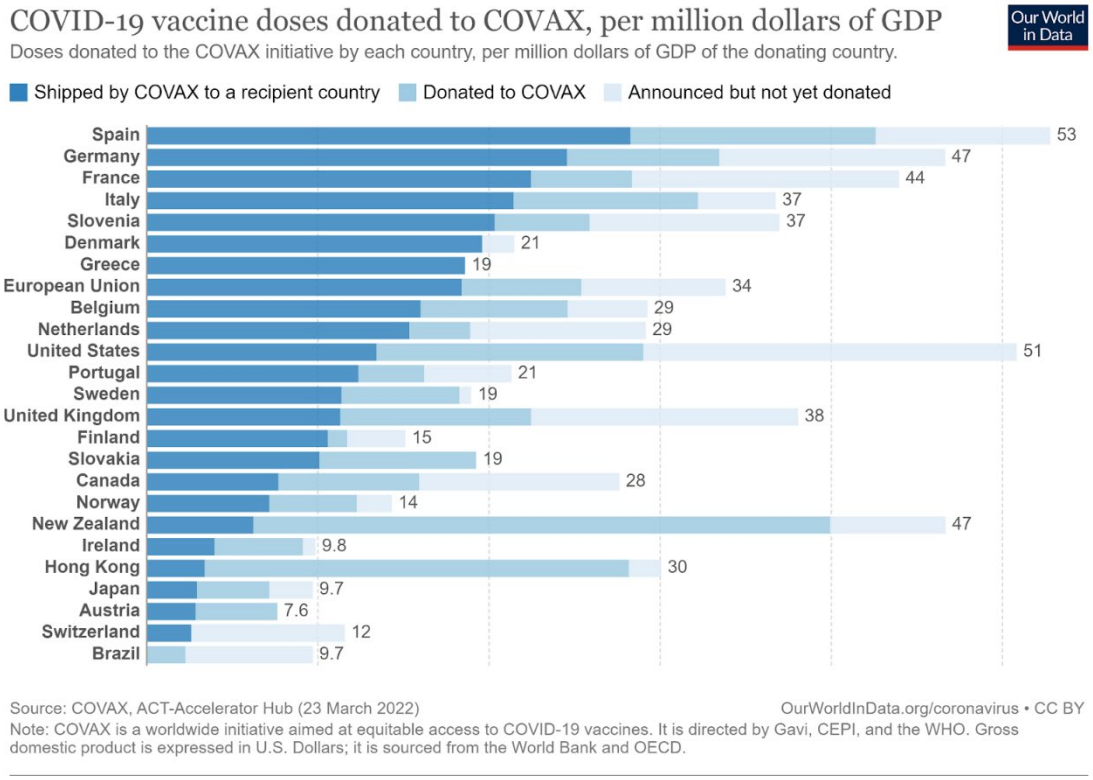


Figure 10. Covid-19 vaccine doses donated to COVAX, per million dollars of GDP.



The reality is that COVAX's "vaccine charity" model hinged on the generosity of the same high-income countries that were selfishly hoarding doses and helping pharmaceutical giants hoard knowledge (Sparke and Levy 2022). Like so many people around the world, the program was doomed by manufactured scarcity. Its narrow focus on distribution overlooked the necessity and possibility of quickly ramping up global supply by the billions.[29] That was the goal of C-TAP, the TRIPS waiver, and other "vaccine justice" initiatives aimed at subverting IP monopolies and boosting generic production (ibid.). Those paths were not taken, and millions of people died as a result (Moore et al. 2022, Savinkina et al. 2022).

Another key takeaway from the pandemic is that Big Pharma's talking points about the sanctity of IP are spurious. If we are to believe the industry's lobbyists, then nobody would ever create anything without the promise of 20-year monopoly control. But during the Covid-19 pandemic, not to mention numerous examples throughout history, multiple vaccines were created out a desire to preserve life, not to extract rent at the expense of it.

Cuba's flourishing public biotech sector, which developed two highly effective Covid-19 vaccines despite the added difficulties thrown up by a 60-year-long U.S. embargo, provides a prominent example of an alternative model for scientific research that puts people over profits (Marcetic 2021). Soon after the Caribbean island started exporting its homegrown doses, it agreed to share technical information with poor nations

[29] This is not to dismiss the importance of rich countries reallocating excess doses during the pandemic (People's Vaccine Alliance 2022a). But they never should have been able to buy so many in the first place, nor should pharmaceutical corporations have been allowed to constrain global supply.

abandoned by Big Pharma and wealthy nations alike, thus demonstrating the lifesaving potential of decommodified medicine.

Another promising example of an internationally collaborative effort that prioritizes public health above all else is Corbevax—an open-source alternative to pharmaceutical giants' privatized jabs that has been called "the world's Covid-19 vaccine" (Texas Children's Hospital 2021). The protein-based shot—jointly created by researchers at Texas Children's Hospital and Baylor College of Medicine—received emergency use authorization from India in late December 2021. Its creators immediately transferred the underlying technology to the Indian pharmaceutical firm Biological E. Limited and other drug manufacturers in Indonesia, Bangladesh, and Botswana, with the goal of facilitating the production and distribution of millions of doses per month in low-income countries. "We're not trying to make money," Dr. Peter Hotez said at the time (Taylor 2021). "We just want to see people get vaccinated," he added, echoing Jonas Salk, the virologist who famously refused to patent his polio vaccine, saying that it was "owned," like the sun, by everyone.

The Covid-19 pandemic further exposed the pitfalls of the existing, highly uneven geography of vaccine manufacturing, which remains concentrated in mostly wealthy countries. Africa and Latin America are home to just 0.17% and 2% of the world's current vaccine production capacity, respectively (Casert 2021). Africa in particular also lacks the economic power to compete for pre-orders. In the wake of being left behind again, African leaders are plotting what Irwin (2021) calls a "vaccines revolution." During a summit in mid-April 2021, the African Union and the Africa Centers for Disease Control and Prevention vowed to increase the share of jabs manufactured on the

continent from 1% to 60% by 2040 (ibid.). It goes without saying that this entails building factories and strengthening R&D.

Such an approach is consistent with the recommendations of Prasad et al. (2022), who argue that "the most efficient and long-term solution" to vaccine apartheid "is working toward strengthening the infrastructure in the LMICs." The Covid-19 pandemic made clear that "LMICs need to build local and regional capacity and infrastructure as relying on the conscience, morality, and excess vaccine production of HICs for this or future pandemics will be a risk not worth taking" (ibid.).

Yamey et al. (2022: 4) concur that "a trickle-down charity model—in which high-income and upper-middle-income nations donate doses to lower-middle-income and low-income nations—is not a fair or sustainable way to achieve vaccine equity." The public health scholar-practitioners call for "a revitalized push towards vaccine self-reliance and decentralized bottom-up manufacturing worldwide, which would be accelerated by the sharing of vaccine intellectual property and technology transfer, financing, workforce development, and regulatory support."

The WHO's mRNA vaccine technology transfer hub, based in South Africa, is one such counter-hegemonic project that emerged during the pandemic and deserves more attention.

3.1 WHO mRNA Technology Transfer Hub: Poor Nations Team Up to Boost Domestic Vaccine Manufacturing

As the C-TAP initiative and TRIPS waiver faltered, the WHO and its partners in April 2021 called for the creation of at least one mRNA vaccine technology transfer hub to build capacity in low- and middle-income countries for the local production of doses

(Maxmen 2022b, WHO 2021a). Two months later, the first consortium—based at Afrigen Biologics in Cape Town, South Africa—was established (WHO 2021b).

In February 2022, scientists at the Afrigen hub duplicated Moderna's mRNA Covid-19 vaccine despite attempts by Big Pharma to undermine their work (Maxmen 2022a, Davies 2022). Rather than support the collaborative endeavor, Moderna filed multiple mRNA vaccine patents in South Africa—after withdrawing equivalent patents in several other countries—thus creating legal risks that could threaten the hub's output for years to come (Doctors Without Borders 2022a). Moderna's October 8, 2020, pledge not to enforce patents during the pandemic is "hardly reassuring," South African civil society groups wrote in February 2022, because the company reserves the right to unilaterally assert when the pandemic is over, at which point it could suppress generic manufacturing (Doctors Without Borders et al. 2022).[30]

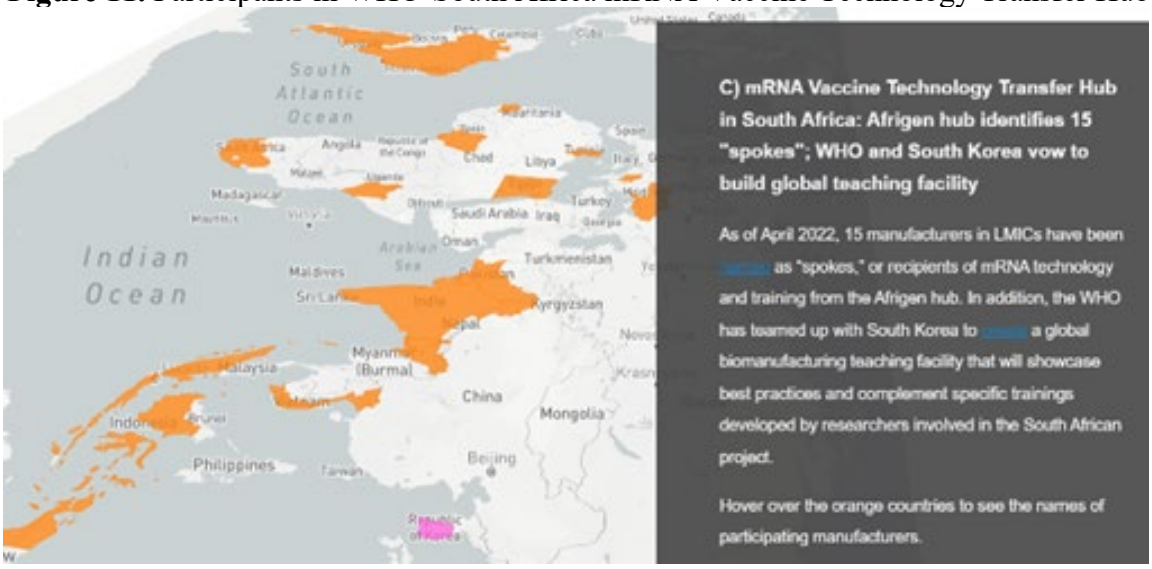
Moderna subsequently promised in March 2022 to never enforce patents related to its Covid-19 vaccine in 92 low- and middle-income countries. South Africa was excluded from the list of exempt nations, though the WHO's mRNA technology transfer hub was included (Furlong 2022). However, like its previous pledge, Moderna's new policy only applies to patents; it does nothing to make other crucial forms of IP, including manufacturing know-how, available. The limits of Moderna's announcement were made plain when the firm's billionaire CEO Stéphane Bancel said that working with the WHO hub would not be a "good use of our time" (ibid.).

By April 2022, 15 manufacturers in LMICs had been tapped as "spokes," or recipients of mRNA technology and training from the Afrigen hub (Medicines Patent

[30] It is important to note that Moderna made this public relations move just days after India and South Africa introduced their TRIPS waiver proposal.

Pool 2022a). In addition, the WHO has joined forces with South Korea to establish a global biomanufacturing teaching facility that will exhibit best practices and enhance specific trainings developed by researchers involved in the South African project (WHO 2022a).

Figure 11. Participants in WHO-South Africa mRNA Vaccine Technology Transfer Hub



Map by Kenny Stancil. See Appendix 4 for a link to the interactive version, data sources, and code.

Table 7. Participants in WHO-South Africa mRNA Vaccine Technology Transfer Hub

Country	Facilities
Egypt	BioGeneric Pharma
Kenya	TBD
Nigeria	Biovaccines Nigeria
Senegal	Pasteur Institute of Dakar
South Africa	Afrigen and Biovac

Table 7, continued

Tunisia	Pasteur Institute of Tunis
Bangladesh	Incepta Vaccine
India	Biological E
Indonesia	Biofarma
Pakistan	National Institute of Health
Vietnam	Polyvac
Serbia	Torlak Institute
Ukraine	Darnitsa
Argentina	Sinergium Biotech
Brazil	Bio-Manguinhos

Source: Medicines Patent Pool (2022a)

In May 2022, NIH agreed to share 11 technologies—including the stabilized spike protein used in several Covid-19 vaccines—with manufacturers from around the globe via the repository, though mRNA tools were excluded (Medicines Patent Pool 2022b).

In July 2022, U.S. government scientists from the National Institutes of Allergy and Infectious Diseases (NIAID) agreed to share technical know-how related to the creation of next-generation vaccines and therapeutics with Afrigen (Afrigen 2022). NIAID spearheaded the use of mRNA and its parent organization, NIH, co-invented Moderna's Covid-19 jab. Together, NIAID and Afrigen seek to accelerate the production of mRNA vaccines—not only to combat the coronavirus pandemic but also to tackle other infectious diseases as well as cancer.

CONCLUSION. NEOLIBERALISM HAS KILLED MILLIONS

"Widespread failures during the Covid-19 pandemic at multiple levels worldwide have led to millions of preventable deaths and a reversal in progress towards sustainable development for many countries."—Lancet Covid-19 Commission[31]

Sparke and Williams (2022: 16) describe Covid-19 as a "quintessentially neoliberal pandemic." First, the crisis "exposed" the deleterious consequences of neoliberal reforms, they contend, much like Hurricane Katrina did 15 years earlier (Johnson 2011, Reed 2008). Moreover, they add, Covid-19 "exploited and exacerbated" the vulnerabilities produced through neoliberalization in "co-pathogenic ways," again paralleling the Katrina disaster. The Covid-19 pandemic provides an occasion to move beyond metaphors about "neoliberal ideas 'infecting' and 'mutating' policymaking," write Sparke and Williams (17), to analyses of "neoliberal policies generating and intensifying an infectious disease."

Mike Davis (2020) and Wallace et al. (2020) explain how the drive to maximize capital accumulation—including through changes associated with neoliberalism—has created socio-ecological conditions favorable to the emergence of viruses with pandemic potential, including SARS-CoV-2.

Decades of capitalist globalization certainly set the stage for the appearance and initial spread of the novel coronavirus. Still, questions remain as to why society was so susceptible to it—albeit unequally—and why many governments were unable or

31 Lancet Covid-19 Commission (2022)

unwilling to respond adequately. As Neil Smith (2006) reminds us, “there is no such thing as a natural disaster.” Instead, disasters are multidimensional processes in which hazardous forces interact with socially produced patterns of differentiated vulnerability (Hoffman and Oliver-Smith 2002). Whereas an event may prove catastrophic in a deeply stratified society with hollowed-out state capacity, a more egalitarian society capable of marshaling sufficient resources before, during, and after the moment of “impact” could significantly reduce the amount of damage inflicted by the same event or a similar one. “In every phase and aspect of a disaster—causes, vulnerability, preparedness, results and response, and reconstruction—the contours of disaster and the difference between who lives and who dies is to a greater or lesser extent a social calculus,” Smith (2006) notes.

Global vaccine apartheid made Covid-19 far more disastrous than it would have been otherwise. Ultimately, it provided further evidence that neoliberal policies designed to maximize profits for a few have killed millions (Lancet Covid-19 Commission 2022). Existing IP rules and proposals for more democratic frameworks are matters of life-and-death (Sachs et al. 2022, Krikorian and Torreele 2021). Charity is not a substitute for justice. Low-income nations do not want, and should not be forced, to wait for rich countries’ leftovers. They want, and ought to have, access to the publicly financed knowledge and technology needed to produce doses and boost the global supply of vital medicines. International solidarity is indispensable to overcoming future pandemics (Daszak 2022). The same dynamics that resulted in the coronavirus vaccine divide and led to earlier manifestations of global health inequality also threaten to reproduce uneven access key resources in general, including the clean energy technologies that must be

deployed as rapidly and broadly as possible to stave off the most catastrophic effects of the fossil fuel-driven climate crisis (Lazare 2022c).

"Never again should a pharmaceutical corporation receive huge sums of funding without some protection built in for the public interest," Rizvi argues (2021b). "Governments can require that corporations, as a condition of accepting funding, set reasonable prices, provide doses to lower and middle-income countries, share technology with international institutions like the World Health Organization."

"These were all possibilities, but very few of them were actually realized because governments did not make those choices," he adds. "And so that, I hope, is one of the lessons we draw from this pandemic. It's about how we let billions of dollars in public funding translate into tens of billions of dollars of private profits."

The Congressional Budget Office has made clear that the adoption of policies designed to lower drug prices would likely reduce the pharmaceutical industry's incentive to develop new products (Austin and Hayford 2021). Notably, the Senate Committee on Health, Education, Labor, and Pensions (HELP) is working to overhaul the current R&D system that is dominated by the pursuit and granting of IP monopolies.

In July 2023, the committee—chaired by Bernie Sanders, for whom Rizvi now works as senior health counsel—advanced an amendment to legislation that seeks to reauthorize the Pandemic and all-Hazards Preparedness Act. If the panel's amendment passes, the National Academies of Sciences, Engineering, and Medicine would have two years to investigate and produce a report on two alternative approaches to financing new drug development: the federal government paying for it directly or awarding innovation prizes (rather than long-lasting patents) to inventors. Instead of being subject to

monopolization, the underlying knowledge would then be put into the public domain, open to generic producers (Schwarz 2023).

The pharmaceutical industry's profit-driven decision-making has led to the underdevelopment of many essential medicines, including vaccines and treatments for AIDS, tuberculosis, and malaria—a trio of infectious diseases that kill millions of people each year. If the U.S. government were to pick up the whole research tab, after which qualified entities would be free to engage in manufacturing, the world might see sorely needed drugs arrive more quickly and at affordable prices.

Meanwhile, public health advocates have praised the draft text of the WHO's emerging pandemic treaty as a welcome departure from the neoliberal IP regime that has curtailed the global supply of lifesaving medical tools and worsened preventable suffering throughout the coronavirus crisis.

"After the collective trauma of the Covid-19 pandemic, we have a glimmer of hope," Mohga Kamal-Yanni, policy co-lead for the People's Vaccine Alliance, said in a recent statement (People's Vaccine Alliance 2023). "This text contains measures to provide everyone, everywhere with access to the tools needed to prevent and combat pandemics."

The draft treaty's IP provisions stipulate that in the event of a pandemic, parties "will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products" (WHO 2023).

Among other things, the text also states that parties "shall encourage all holders of patents related to the production of pandemic-related products to waive, or manage as

appropriate, payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so" (ibid.).

The WHO is clear that the document's creation began in December 2021 in response to "the catastrophic failure of the international community in showing solidarity and equity in response to the coronavirus disease" (2023).

There is, however, a long way to go between now and the 2024 World Health Assembly, where the pact is set to be finalized. "As talks treaty begin in earnest," Kamal-Yanni added (People's Vaccine Alliance 2023), "governments must look to the greed, nationalism, and profiteering that characterized the world's response to Covid-19 and say: 'never again.'"

APPENDICES

APPENDIX 1. UNEQUAL COVID-19 VACCINATION RATES

Map: https://kwstancil.github.io/global-covid-19-vaccine-apartheid-storymap/

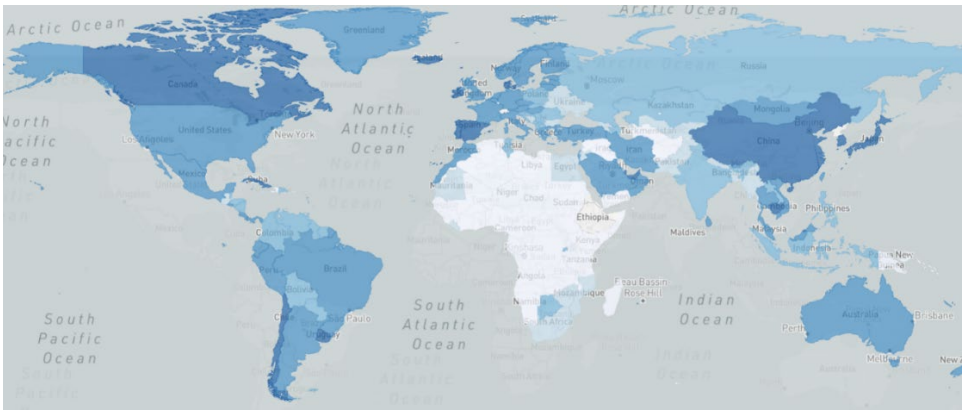
Code: https://github.com/kwstancil/global-covid-19-vaccine-apartheid-storymap

Summary: This choropleth map relies on a time slider to depict unequal access to Covid-19 vaccines around the world since late 2020.

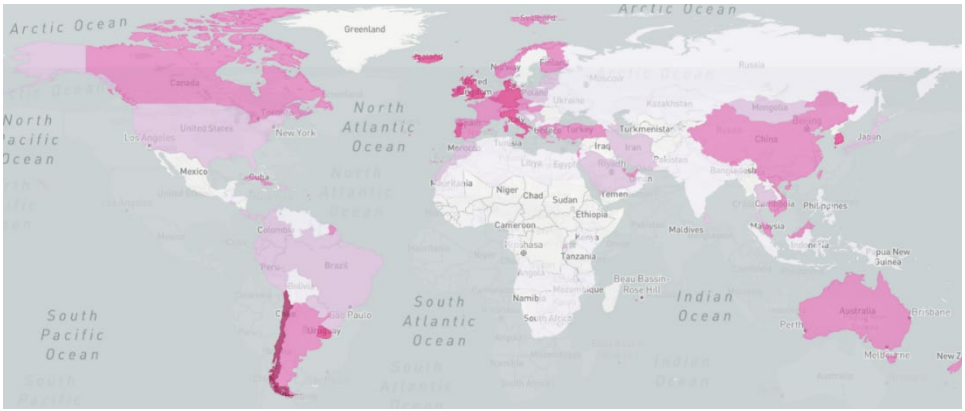
Methods: I used QGIS to generate a GeoJSON file containing national borders. I wrote a script to pull in information about national vaccination rates that is automatically updated by Our World in Data. I used HTML, CSS, JavaScript, and the Mapbox Storytelling template to create the larger interactive visualization of which this map is one part.

Data: Mathieu et al. 2021

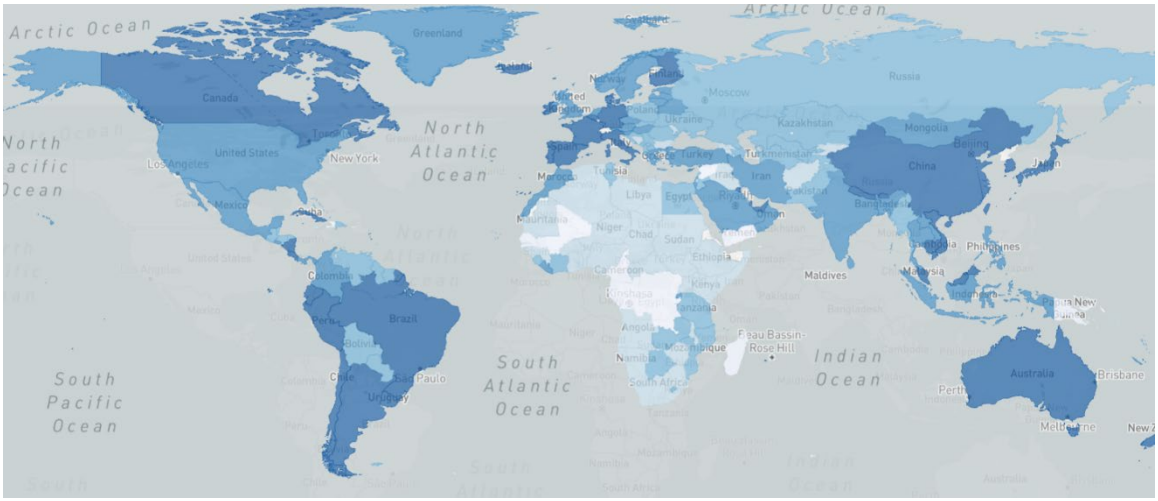
Share of Population Fully Vaccinated in Each Country, 12/31/2021



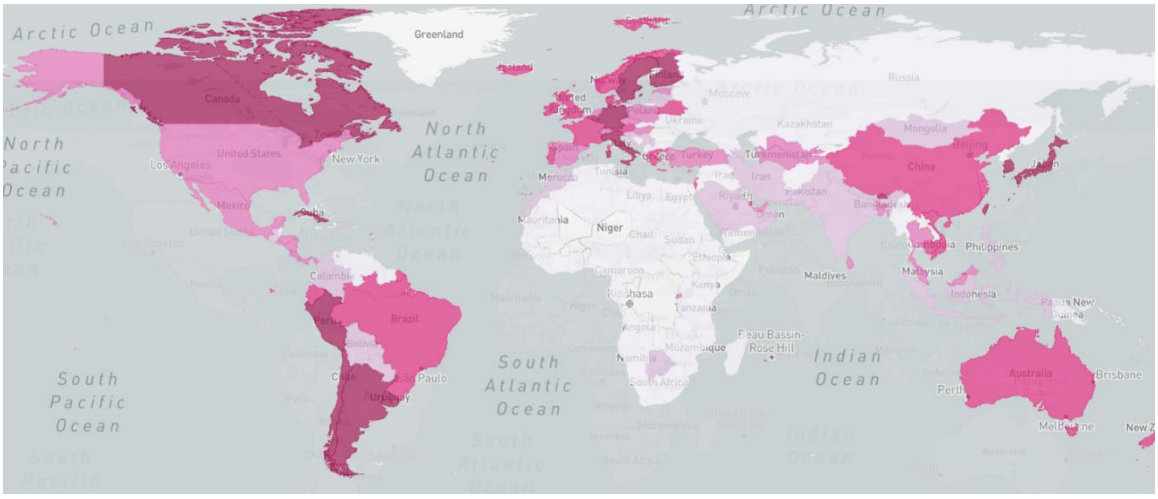
Number of Booster Doses Administered Per 100 People in Each Country, 3/11/22



Share of Population Fully Vaccinated in Each Country, 12/31/2022



Number of Booster Doses Administered Per 100 People in Each Country, 3/11/23



APPENDIX 2. PHARMA MONOPOLY DEFENDERS CHOOSE PROFITS OVER PEOPLE

Map: https://kwstancil.github.io/global-covid-19-vaccine-apartheid-storymap/

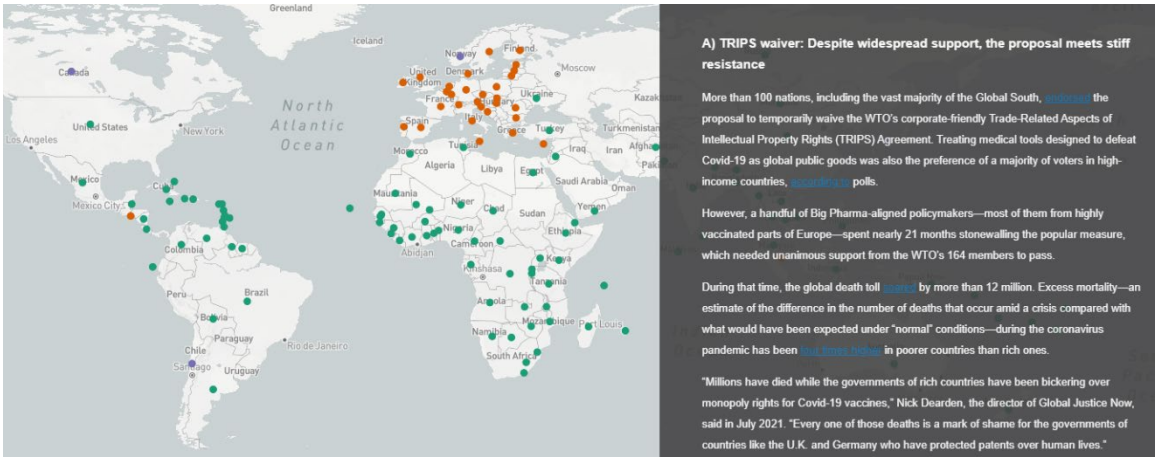
Code: https://github.com/kwstancil/global-covid-19-vaccine-apartheid-storymap

Summary: This dot map highlights whether governments supported or opposed a motion to temporarily suspend IP restrictions to boost the supply of Covid-19 vaccines.

Methods: I used QGIS to generate a GeoJSON file containing governments' positions on the TRIPS waiver proposal. I used HTML, CSS, JavaScript, and the Mapbox Storytelling template to create the larger interactive visualization of which this map is one part.

Data: Doctors Without Borders 2020b

Support for and Opposition to the TRIPS Waiver



APPENDIX 3. IDLE VACCINE FACTORIES AMID A DEADLY PANDEMIC

Map: https://kwstancil.github.io/global-covid-19-vaccine-apartheid-storymap/

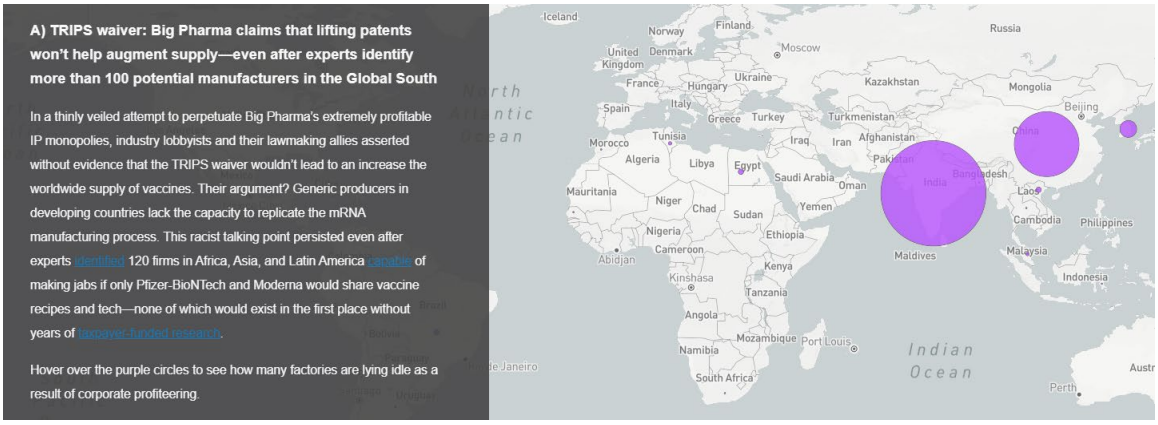
Code: https://github.com/kwstancil/global-covid-19-vaccine-apartheid-storymap

Summary: This proportional symbol map shows where untapped Covid-19 vaccine production potential exists.

Methods: I used QGIS to generate a GeoJSON file containing the locations of factories with idle mRNA manufacturing capacity. I used HTML, CSS, JavaScript, and the Mapbox Storytelling template to create the larger interactive visualization of which this map is one part.

Data: Prabhala and Alsalhan 2021

Global South Manufacturers Capable of Making mRNA Covid-19 Vaccines



APPENDIX 4. EXPANDING DOMESTIC VACCINE PRODUCTION CAPACITY IN DEVELOPING COUNTRIES

Map: https://kwstancil.github.io/global-covid-19-vaccine-apartheid-storymap/

Code: https://github.com/kwstancil/global-covid-19-vaccine-apartheid-storymap

Summary: This map explores efforts to ramp up the manufacturing of open-source and generic Covid-19 vaccines.

Methods: I used QGIS to generate a GeoJSON file containing information about participants in the WHO-led mRNA vaccine technology transfer hub. I used HTML, CSS, JavaScript, and the Mapbox Storytelling template to create the larger interactive visualization of which this map is one part.

Data: Medicines Patent Pool 2022

Participants in WHO-South Africa mRNA Vaccine Technology Transfer Hub

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VITA

EDUCATION

M.A. Secondary Social Studies Education — May 2017, University of Kentucky

B.A. Political Science, Global Studies — May 2013, Pacific Lutheran University

Concentration: Development and Social Justice; Minors: Environmental Studies and Spanish; Study Abroad: SIT Chile - Social, Economic, and Political Transformation, Fall 2011

EMPLOYMENT

Aug 2023-Present, Senior Researcher — Revolving Door Project, remote

Aug 2020-Jul 2023, Staff Writer — Common Dreams, remote

- Synthesized reporting, research, and critical perspectives into multiple articles each day to keep progressives informed of pressing injustices and inspire them to keep working toward a more egalitarian and sustainable society

Jul 2019-Aug 2020, Geospatial Technician — Quantum Spatial, Inc./NV5, Lexington, KY

- Processed remotely sensed information by categorizing and remedying blemishes in orthorectified aerial photographs

Jul 2017-Jun 2019, Social Studies Teacher — Lafayette High School, Lexington, KY

- Planned and delivered instruction and assessed the progress of roughly 330 students in Advanced Government (9th grade), Advanced World History (10th grade), and U.S. History/Advanced U.S. History (11th grade)
- Co-sponsored the Black Student Union (Mar 2018-Jun 2019) and the Speech and Debate Team (Feb 2018-Jun 2019)

Jun 2015-Aug 2016, Researcher and Cartographer — The Food Connection, University of Kentucky

- Assembled, geocoded, and analyzed agricultural data from a variety of sources to create charts and maps in support of The Food Connection's mission to evaluate and strengthen the regional food system

Jan-May 2015, Teaching Assistant — GEO 162: Intro to Global Environmental Issues, University of Kentucky

- Planned and led discussion-based activities in three recitation sections per week, held regular office hours, and graded assignments in collaboration with a fellow graduate student and the course professor

Jun-Aug 2011, Research Assistant — Environmental Studies Program, PLU

- Assessed public opinions about the management of risks associated with toxins in personal care products

Aug 2010-May 2011, Sustainability Director — Associated Students of PLU

- Coordinated campaigns such as "take back the tap," which led to drinking fountain improvements and a phaseout of bottled water sales on campus

PROFESSIONAL/COMMUNITY SERVICE

Jun 2015-Aug 2016, Volunteer — Lexington Housing Studies and Lexington Tenant Organizing Project

- Helped analyze land ownership patterns and housing inequities in Lexington; canvassed neighborhoods at risk of gentrification to ask residents about landlord treatment and gauge interest in the formation of a tenants' union

Aug 2013-May 2015, Member — University of Kentucky Political Ecology Working Group

- Collaborated with fellow graduate students to plan and run two annual conferences attended by hundreds of scholars

Oct 2009-May 2013, Member — PLU Sustainability Committee

- Worked with an ad hoc group of faculty, staff, and students to support initiatives promoting environmental and social justice on campus