Introduction

Intellectual Property and "The Lost Year" of COVID-19 Deaths

Madhavi Sunder and Haochen Sun

The protection of intellectual property (IP) is a question of life and death. COVID-19 vaccines, partially incentivized by IP, are estimated to have saved nearly 20 million lives worldwide during the first year of their availability in 2021.[1] The vast majority of the benefit of this life-saving technology, however, went to high- and upper-middle-income countries.[2] Despite 10 billion vaccines having been produced by the end of 2021, only 4 percent of people in low-income countries were fully vaccinated. Paradoxically, IP may also be partly responsible for hundreds of thousands of lives *lost* in 2021, due to insufficient supply of vaccines and inequitable access during the critical first year of vaccine rollout, most notably in low-income countries that lacked the ability to buy or manufacture vaccines to save their populations. A mathematical modeling study published in *The Lancet* in September 2022 found that 45 percent of deaths in low-income countries could have been averted if just 20 percent of the most high-risk patients in those countries had been vaccinated in 2021 – the goal initially set in April 2020 by the COVID-19 Vaccines Global Access (COVAX) facility to ensure equitable access to vaccines upon vaccine availability. As *The Lancet* study notes, however, "[d]ue to vaccine shortfalls, these targets were not achieved by the end of 2021"[3] and substantial numbers of deaths in the poorest nations were not averted as they were in rich countries. Despite the benefits of vaccine development and distribution to high- and middle-income countries, 2021 proved to be "the lost year," during which hundreds of thousands of lives in low-income countries could have been saved, virulent variants of COVID-19 could

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[1] Oliver J. Watson et al., *Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study*, The Lancet 1293 (Sep. 2022).

[2] *Id.* (estimating that 12.1 million lives were saved by vaccines in high- and upper-middle-income countries between December 8, 2020, and December 8, 2021).

[3] *Id.*

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have been stemmed, and the duration of the global pandemic could have been shortened.

What accounts for the COVID-19 vaccine shortfall in the poorest countries during the critical first year of the availability of COVID-19 vaccines? *The Lancet* study, while acknowledging "the considerable uncertainty inherent in estimating vaccine impact,"[4] concludes that "more lives could have been saved if vaccines had been distributed more rapidly to many parts of the world," which, going forward, requires that "[i]ntellectual property . . . be shared more quickly in the future, with more open technology and knowledge transfer surrounding vaccine production and allocation."[5] Intellectual property was hardly the only roadblock to a global vaccination campaign in the pandemic response. To be sure, *The Lancet* study identifies other critical factors that contributed to the inequitable distribution of vaccines, including misinformation, vaccine hesitancy, insufficient vaccine donations, and poor distribution and delivery infrastructure. But make no mistake, for better or for worse, in the world's response to the COVID-19 pandemic, IP looms as a central figure.

This volume begins to diagnose the role of IP during the COVID-19 pandemic. The analyses in the book make plain that, while the promise of monopoly rights through intellectual property in breakthrough technology helps incentivize life-saving innovation, holding life-saving knowledge hostage in corporate monopolies to maximize private profit has tragic consequences. Unequal access to life-saving vaccines during the COVID-19 pandemic wreaked untold havoc on human lives and on the global economy. Glaring inequities in access affected rich countries as well, as variants emerged in poorly vaccinated parts of the world and spread worldwide, prolonging the health and economic effects of the pandemic. Leadership failures, among other factors, have been blamed for "the lost month"[6] in early 2020 when the United States failed to contain the spread of the virus.[7] This volume demonstrates that the global IP system bears some of the blame for a "lost year" of COVID-19 deaths and devastation in 2021.

The role of IP in this crisis is hotly debated. Pharmaceutical companies highlight the role IP played in incentivizing the development of COVID-19 vaccines, while downplaying IP's role in mediating manufacture, access, and distribution.[8] There remains considerable debate about the positive as well as negative role of IP in pandemics. Is IP's role limited to development of breakthrough drugs, but not their

[4] *Id.*, at 1300.
[5] *Id.*, at 1300–1301.
[6] Grant Hindsley, *The Lost Month: How the Failure to Test Blinded the U.S. to COVID-19*, N.Y. Times (Mar. 2022).
[7] *See also* Paul Farmer, Fevers, Fueds, and Diamonds: Ebola and the Ravages of History 523 (2020).
[8] *See* Sheryl Gay Stolberg et al., *Pressure Mounts to Lift Patent Protections on Coronavirus Vaccines*, N.Y. Times (May 17, 2021).

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distribution? We readily accept IP's goal to promote efficiency, but does it also have an obligation to promote equity? We should pay attention to issues of distributional justice in IP law.[9] This volume seeks to broaden our understanding of the implications of IP in life-saving technologies, from vaccines to diagnostics and therapeutics, during a global pandemic.

The volume first takes up diagnosis: what role did IP play during the COVID-19 pandemic? We celebrate the role of IP in the development of life-saving vaccines at breakneck speed, with highly effective vaccines developed by December 2020, a record nine months compared to the normal course of several years for vaccine development. As several chapters in this volume elaborate, however, the historic development of these vaccines, including the revolutionary new mRNA vaccines by Moderna and Pfizer, were not the product of private companies going it alone, but rather the result of significant public investment in innovation, through critical publicly funded research, public funding for clinical trials, and advance-purchase contracts to procure hundreds of millions of doses. Revolutionary COVID-19 vaccines are not the poster child for IP rights as pharmaceutical companies suggest. Rather, these vaccines are the fruits of taxpayer-funded government investment around the world. The governments of the United States, Germany, and India, to name just a few countries, spent billions of dollars to produce effective vaccines at "warp speed."[10]

While the development of COVID-19 vaccines is a success story, the distribution of the vaccines is not. Of 7 billion vaccines administered globally by late 2021, approximately one year after the vaccines were developed, over 70 percent of jabs had gone to high-income countries. In low-income African countries, including Nigeria, Mali, and Uganda, a mere 1 percent of the population had been vaccinated a year after the vaccines were rolled out. Even by early January 2022, a mere 8.5 percent of people in low-income countries had been vaccinated with at least one dose, in stark contrast to 60 percent vaccinated in high-income countries.[11] What happened? Despite the best laid plans in 2020 to equitably distribute vaccines to first inoculate the most at-risk patients around the world in all countries, namely medical providers and the elderly, through pre-pledged donations by rich countries, wealthy country governments cut to the front of the line, buying up doses from vaccine producers such as Moderna and Pfizer, often enough to inoculate their populations many times over. Because the vaccines were protected by IP, and limited to a few authorized manufacturers, supply could not keep pace with demand and poor

[9] *See generally* Anupam Chander & Madhavi Sunder, *The Romance of the Public Domain*, 92 Cal. L. Rev. 1331 (2004); Madhavi Sunder, *The Invention of Traditional Knowledge*, 70 Law & Contemp. Probs. 95 (Spring 2007).

[10] Yasmeen Abutaleb et al., *How the "Deep State" Scientists Vilified by Trump Helped Him Deliver an Unprecedented Achievement*, Wash. Post (Dec. 14, 2002).

[11] *See* Coronavirus (COVID-19) Vaccinations, https://ourworldindata.org/covid-vaccinations (last visited Jan. 4, 2022).

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countries were left empty-handed. Rich countries pledged donations but often the donations failed to materialize or arrived just as the donated vaccines were set to expire.[12] The result was vaccine apartheid. In the words of UN Secretary General António Guterres, "we passed the science test" but received "an F in ethics."[13]

Intellectual property is implicated in the choked supply of COVID-19 vaccines, particularly during the crucial first year of the vaccines' availability in 2021.[14] It was not the only constraint. A few factors help explain the inequitable access for the poorest countries in the world during that time. This book identifies several converging practices, including vaccine nationalism and vaccine diplomacy, and "colonial hangovers" of poor health infrastructure in low-income countries, to use Olufunmilayo Arewa's phrase.[15] This book illuminates the complex factors that contributed to the inequitable distribution of COVID-19 vaccines. But unquestionably, the refusal to share or to legally mandate sharing of knowledge underlying the COVID-19 vaccines to scale up manufacture at accessible prices impeded the ability to meet the needs of poor countries, which were at the back of the line, waiting in vain for doses to be donated and delivered during much of 2021.

This volume critically assesses the role of IP in pandemic times through lessons learned from COVID-19. It aims to broaden our understanding of the implications of IP protection for both development and distribution of essential technologies such as vaccines. Is IP the exclusive driver of breakthrough innovation in the context of COVID-19 vaccines, or is the success the result of a more complex public–private partnership of government-backed research and up-front government investment in R&D, clinical trials, and procurement contracts? Should life-saving technologies developed with public funds be considered public goods to be used and shared at state direction, or as purely private property with pharmaceutical companies calling all the shots about price, manufacture, distribution, and technology transfer? Most importantly, how may IP law be reformed now to prepare for a future pandemic? The volume chronicles the history and lessons learned with respect to IP during the COVID-19 pandemic and makes recommendations for how to retool IP as the world prepares for the next pandemic.

[12] Ali Sawafta & Rami Ayyub, *Palestinians Cancel Deal for Near-Expired COVID Vaccines from Israel*, Reuters (Jun. 18, 2021), www.reuters.com/world/middle-east/israel-give-palestinians-1-million-covid-vaccine-doses-israeli-statement-2021-06-18/ (last visited Dec. 30, 2022).

[13] Michelle Nichols, *U.N. Chief Grades World on Vaccine Rollout: "F in Ethics,"* Reuters (Sep. 21, 2021), www.reuters.com/business/healthcare-pharmaceuticals/un-chief-grades-world-vaccine-rollout-f-ethics-2021-09-21/ (last visited Dec. 30, 2022).

[14] *See generally* Matthew M. Kavanagh, Lawrence O. Gostin & Madhavi Sunder, *Sharing Technology and Vaccine Doses to Address Global Vaccine Inequity and End the COVID-19 Pandemic*, JAMA (Jul. 1, 2021); Matthew M. Kavanagh & Madhavi Sunder, *Biden Must Push Drug Firms to Share Science with the World*, Bloomberg Law (Apr. 23, 2021); Matthew Kavanagh & Madhavi Sunder, *Poor Countries May Not Be Vaccinated until 2024. Here's How to Prevent That*, Wash. Post (Mar. 10, 2021).

[15] Olufunmilayo B. Arewa, *COVID-19 Exclusion and Colonial Hangovers in Africa*, Chapter 14 this volume.

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The volume builds on a virtual conference co-organized by Georgetown University Law Center and the University of Hong Kong Faculty of Law on November 5 and 6, 2021. Conference speakers, including legal academics, public health scholars, and leaders from global institutions such as the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), explored a host of questions: Will IP alone incentivize timely development of life-saving vaccines? Will donations and philanthropy without significant reform to international IP laws spur equitable distribution of vaccines? If voluntary mechanisms for sharing doses and vaccine technology are not working, what are the key legal levers for expanding access to COVID-19 vaccine technology so global manufacturers can produce these life-saving technologies on their own? Is a waiver of World Trade Organization (WTO) IP rules necessary? Beyond compulsory licenses for patents, what are the prospects for technology transfer of trade secrets and know-how by vaccine manufacturers to local manufacturers in Latin America, Asia, and Africa? Can governments force companies to share their knowledge with global manufacturers to scale up production to end the pandemic? How do regulatory barriers outside of traditional IP, including data exclusivity and patent linkage, function as para-IP protections over vaccine technology?[16] What are the future opportunities and challenges for local vaccine manufacturing in Africa and other low- and middle-income regions? The contributors to this volume address these and related questions that are critical to understanding what went well and what went wrong during the COVID-19 pandemic, so we can be better prepared for the next one.

The volume diagnoses a number of causes for the inequitable distribution of life-saving COVID-19 vaccines, from private companies holding exclusive monopoly rights in publicly funded technology, to misguided reliance on voluntary mechanisms to share knowledge and vaccines rather than legally mandated sharing of publicly funded technology, to the rise of vaccine nationalism and vaccine diplomacy, to unequal global intellectual property institutions that disenfranchise low-income countries and continue to reproduce colonial-era dependency by poor countries on high-income nations for life-saving technologies, knowledge, and funding for research and development.

Going further, the volume elaborates the recognition of the Zero Draft of the WHO pandemic treaty of "the need to establish a future pandemic prevention, preparedness and response mechanism that is not based on a charity model."[17] The WHO draft pandemic treaty recognizes "that publicly funded research and development plays an important role in the development of pandemic-related products and, as such, requires conditionalities."[18] The contributors to this volume

[16] Cynthia Ho, *Beyond Traditional IP: Addressing Regulatory Barriers*, Chapter 7 this volume.

[17] *Zero Draft of The WHO CA+ for The Consideration of The Intergovernmental Negotiating Body at its Fourth Meeting*, 7 World Health Organization, https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf (last visited Aug. 12, 2023).

[18] *Id.*, at 8.

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offer concrete suggestions for reform to this end, including delinking vaccine development from monopoly rights in technology, enhanced legal requirements under national and international law to share publicly funded technologies in pandemic times, and funding by rich nations to build technology transfer hubs and local vaccine manufacturing capacity in low- and middle-income countries, including in Africa.

We turn first to the diagnosis – what went well and what went wrong with the development and distribution of vaccines during the COVID-19 pandemic and what was IP's role? We then turn to cures, considering how IP and vaccine innovation infrastructure may be reformed to equitably meet the needs of all of the world's people in the next pandemic.

1 THE DIAGNOSIS: INTELLECTUAL PROPERTY'S ROLE IN THE COVID-19 PANDEMIC

A *Vaccine Development: Fruits of Public–Private Partnership, But Who Calls the Shots?*

The development of revolutionary COVID-19 vaccines has been hailed as an IP success story. Pharmaceutical companies such as Moderna and Pfizer argue that patents and other IP protections in their groundbreaking mRNA technology were the keys to their success. The real story of the successful development of COVID-19 vaccines is more complex. The timely development of the vaccines was not the result of private companies going it alone, but instead the fruit of critical public–private partnerships between governments and pharmaceutical companies, with governments investing billions of dollars in research and development, clinical trials, and through advanced purchase contracts promising to buy hundreds of millions of doses. These investments significantly de-risked COVID-19 vaccine development by private companies, thus qualifying the usual claim by private corporations to monopoly control in their patented inventions.

In the United States, the Trump Administration in early 2020 launched "Operation Warp Speed," a public–private partnership to hasten the development, manufacture, and distribution of effective COVID-19 vaccines. Operation Warp Speed paid $14 billion in taxpayer dollars to several private companies racing to develop a cure for the virus. Operation Warp Speed funds, plus additional US taxpayer funding, included a total of $1.5 billion for Johnson & Johnson, $1.2 billion to Oxford University–AstraZeneca, and $2.48 billion to Moderna. These funds were for research and development, including costly clinical trials, and advance-purchase orders.[19] While

[19] Congressional Research Service (CRS), Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Materials (Mar. 1, 2021), https://crsreports.congress.gov/product/pdf/IN/IN11560 (last visited Dec. 30, 2022).

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Pfizer did not receive Operation Warp Speed funding for research and development, it did receive $2 billion from the Operation Warp Speed budget for an advance-purchase order to manufacture 100 million doses of a COVID-19 vaccine for use in the United States when the vaccine was shown to be safe and authorized for use by the FDA.[20]

Companies such as Moderna also benefitted enormously from publicly funded research supported by the National Institutes of Health (NIH).[21] After China published SARS-CoV-2 genetic data in January 2020, Dr. Barney Graham's team at NIH rapidly redeployed technology they were working on, and quickly shared their work with their partners at Moderna to manufacture a vaccine ready to submit for government-funded clinical trials. In the end, the Moderna vaccine research was almost entirely funded by the US government. The United States was not alone in investing significant public monies into COVID-19 vaccine development. The German government invested half a billion dollars in the Pfizer–BioNTech vaccine.[22] India's first homegrown COVID-19 vaccine, Covaxin, was the result of a public–private partnership between Bharat Biotech and the taxpayer-funded Indian Council of Medical Research.[23]

In fact, the singular reliance on IP may be subject to more blame than praise in Moderna's long history. For years, Moderna's mRNA technology languished as it failed to develop a single product and struggled to attract investors. This is not unusual for vaccine manufacturers. As leading public health law scholar Lawrence Gostin writes in this volume, "[t]he intellectual property system does not generally incentivize companies to produce vaccines or medicines intended for small or uncertain markets."[24] Developing new vaccines can cost billions of dollars and take several years, with no promise of return on the investment, especially for diseases primarily afflicting populations in low-income countries.[25] In his contribution to this volume (Chapter 2), focusing on cures to the legal innovation infrastructure for

[20] Sydney Lupkin, *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NPR (Nov. 24, 2021), www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections (last visited Dec. 30, 2022).

[21] Arthur Allen, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, Scientific American (Nov. 18, 2020), www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/ (last visited Dec. 30, 2022).

[22] Riley Griffin & Drew Armstrong, *Pfizer Vaccine's Funding Came from Berlin, Not Washington*, Bloomberg (Nov. 9, 2020), www.bloomberg.com/news/articles/2020-11-09/pfizer-vaccine-s-funding-came-from-berlin-not-washington?leadSource=uverify%20wall (last visited Dec. 30, 2022).

[23] Press Release, Press Information Bureau Government of India Ministry of Health and Family Welfare, Phase 3 Clinical Trial of COVAXIN, Developed by ICMR & Bharat Biotech, Shows 81% Efficacy (Mar. 3, 2021), https://pib.gov.in/Pressreleaseshare.aspx?PRID=1702293 (last visited Dec. 30, 2022).

[24] Lawrence O. Gostin, *Global Medical War Chest*, Chapter 2 this volume. *See generally* Lawrence O. Gostin, Global Health Security: A Blueprint for the Future 193 (2021).

[25] Gostin, *Global Medical War Chest*, supra note 24. Gostin describes other factors that impede vaccine development, including the unpredictability of outbreaks and pathogen mutations,

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pandemics, Gostin makes the case to "overcome market disincentives through targeted financing and partnerships."[26] Decades of experience well before the pandemic teach that for vaccine production, we cannot rely on IP alone, which only incentivizes market-driven innovation. It is no surprise that in the context of COVID-19, it was ultimately government funding that got Moderna over the finish line.

Intellectual property rights spur development but can also create significant hurdles – what Laura Pedraza-Fariña in Chapter 3 calls the "anti-innovation" norms of IP. Her chapter contrasts Operation Warp Speed and the Accelerating COVID-19 Therapeutic Interventions and Vaccine (ACTIV) initiative. Pedraza-Fariña concludes that it was not strong IP rights and secret bilateral contracts but rather Operation Warp Speed's "vast funding" that "allowed for simultaneous, as opposed to sequential, clinical trials, process development, and manufacturing scale-up," among other things, that were critical to success. She concludes that "rapid information sharing across collaboration networks, rather than secrecy, holds the key to an effective and fast response."[27]

The breakthrough COVID-19 vaccines demonstrate the critical role of public–private partnership in vaccine development. Patents incentivize pharmaceutical companies to innovate certain drugs that serve those who can afford to pay. But for vaccines that address uncertain diseases and often in low-resource settings, publicly funded university and government research, alongside public–private partnerships, are key. Just as private companies like Moderna had invested large sums in their research for years before the pandemic, the NIH had invested over $17 billion in vaccine research between 2000 and 2019 that was critical to the breakthrough COVID-19 vaccines.[28] Similarly, a study of the funding for the Oxford–AstraZeneca vaccine, which committed to manufacture 1.3 billion doses for low-income countries, concluded that "public and charitable funders provided the majority of identifiable funding to the University of Oxford towards the R&D of the Oxford–AstraZeneca vaccine … which may have significant implications for the global discourse around vaccine nationalism and COVID-19 health technology access."[29] The authors of the study recognize that following the money is key to understanding

uncertainty about the amount of vaccines needed to curb an outbreak, and the high likelihood that outbreaks will occur in low and middle-income countries. As Gostin concludes, "Consequently, industry lacks financial incentives to develop products for many novel diseases." *Id.*

[26] Gostin, Global Health Security: A Blueprint for the Future, *supra* note 24, at 193.

[27] Laura G. Pedraza-Fariña, *COVID-19 and Boundary-Crossing Collaboration*, Chapter 3 this volume.

[28] AE Kiszewski et al. *NIH Funding for Vaccine Readiness before the COVID-19 Pandemic*, 39 Vaccine, 2458–66 (2021).

[29] Samuel Cross et al., *Who Funded the Research behind the Oxford–AstraZeneca COVID-19 Vaccine?*, BMJ Glob. Health. (Nov. 17, 2021).

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opportunities to use publicly funded technologies openly to rapidly copy and deploy technologies to meet public health needs in low-resourced settings.

Recognizing the critical role of public funding is a first step to understand the need for increased governmental authority over how these technologies are shared, licensed, and ultimately distributed. A critical problem, however, is that though COVID-19 vaccines were the fruit of significant public investment, this taxpayer-funded innovation is trapped in corporate monopolies that allow private companies to call all the shots with respect to this technology. As we explore further, even though companies such as Moderna announced they would not enforce their *patents* on the mRNA vaccine,[30] generic companies were unable to manufacture the vaccines themselves for fear of violating Moderna's *other IP rights*, including critical "know-how" from Moderna, which still held essential knowledge of how to make the mRNA vaccines effectively and safely. Companies such as Moderna and Pfizer refused to share this critical knowledge beyond a handful of licensed manufacturers, which led to an undersupply of vaccines during critical months in 2021 when billions more doses were needed to vaccinate vulnerable populations in rich and poor countries alike. Worse, governments seem to have thrown away their opportunity to compel companies to share technology with more manufacturers to ramp up production of life-saving shots. Authors in this volume describe the failure of the US government to require technology transfer as a precondition of receiving public funds[31] or to exercise government power under the Defense Production Act and other levers to force technology sharing to boost vaccine supply during critical months in 2021.[32] We review these authors' recommended reforms to more effectively foster technology transfer critical to increase supply of life-saving technologies in Section 2. Now, we continue the analysis of what went wrong during the COVID-19 pandemic, turning to the colossal failure to equitably distribute COVID-19 vaccines.

B *Vaccine Distribution: Failure of the Intellectual Property + Philanthropy Model*

Even before effective COVID-19 vaccines were developed in late 2020, global health experts predicted a frenzied global race to procure a limited supply of vaccines that would leave low- and middle-income countries waiting at the back of the line. Two Western leaders of global health organizations imagined a way out of this dilemma.

[30] Press Release, Moderna, Statement by Moderna on Intellectual Property Matters during the Covid-19 Pandemic (Oct. 8, 2020), https://investors.modernatx.com/Statements–Perspectives/Statements–Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx (last visited Dec. 30, 2022).

[31] *See* Sapna Kumar & Ana Santos Rutschman, *Planning for Pandemic and Epidemic-Related Drug Scarcity*, Chapter 9 this volume.

[32] *See* David Levine & Joshua Sarnoff, *Compelling Trade Secret Sharing*, Chapter 11 this volume.

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In early 2020, Richard Hatchett, director of the Coalition for Epidemic Preparedness Innovations (CEPI), and Seth Berkley, the head of the Vaccine Alliance, or Gavi, brainstormed and established the COVAX facility.[33] Rich countries would pledge funds for vaccine purchases that would be targeted to low-income countries. The goal was for COVAX to pool funds from rich countries to purchase 2 billion vaccine doses to deliver to low- and middle-income countries. If all went according to plan, COVAX would procure enough vaccines to ensure that 20 percent of the most vulnerable citizens in all countries, namely medical workers and the elderly, were vaccinated by the end of 2021, regardless of a country's wealth.

In the end, COVAX did not deliver on even half of its goal,[34] and low-income countries fell tragically behind in vaccinations. Rich countries rushed to make advanced purchases of jabs directly from vaccine producers such as Moderna and Pfizer, with some countries, including Canada, procuring enough doses to vaccinate their populations many times over.[35] The well-planned, equitable approach COVAX leaders had imagined gave way instead to vaccine nationalism, with rich countries rushing to buy up and hoard expensive doses for their own populations. Rather than honor their pledges to fund COVAX and help ensure that the most vulnerable patients around the world would be vaccinated first, rich countries bought enough doses to vaccinate their entire adult populations with two and even three "booster" shots. Companies such as Moderna and Pfizer, which held critical knowledge about the mRNA vaccine production in the form of patents and tacit knowledge or "know-how," licensed only a handful of manufacturers to produce vaccines. The limited supply raised prices on the vaccines, and the drug companies catered almost exclusively[36] to wealthy countries and regions such as the United States, the European Union, and Israel. These same companies had no market incentive to ramp up manufacture for shots for poor countries that could not afford to pay much more than the manufacturing price. There was little left over from a limited supply of vaccines for COVAX to purchase on behalf of low-income countries. High-income countries did not donate to COVAX as promised. Left underfunded and undersupplied, COVAX could not compete to secure vaccines. Worse still, leaders of African and other low-income countries were told they could not seek to procure doses directly from developers, but that they had to go through COVAX.

[33] Adam Taylor, *Why Covax, the Best Hope for Vaccinating the World, Was Doomed to Fall Short*, Wash. Post (Mar. 22, 2022).

[34] Adam Taylor, *Covax Promised 2 Billion Vaccine Doses to Help the World's Neediest in 2021. It Won't Deliver even Half That*, Wash. Post (Dec. 10, 2021).

[35] Sandrine Rastello & Kait Bolongaro, *Canada Has Reserved More Vaccine Doses per Person than Anywhere*, Bloomberg (Dec. 7, 2020).

[36] Amnesty International reported that in 2021, Pfizer and Moderna "projected revenues of up to US $54 billion, yet supplied less than 2% of their vaccines to low-income countries." Amnesty International, COVID-19: Pharmaceutical companies' failure on equal vaccine access contributed to human rights catastrophe in 2021 (Feb. 14, 2022).

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Many have opined on why COVAX failed. In Chapter 4, public health scholars Matt Kavanagh and Renu Singh offer a scathing critique of COVAX's "demand-side model" built on private property and market-based tools.[37] Kavanagh and Singh lay the blame on COVAX's reliance on the status quo with respect to strong IP rights for corporations.[38] This market-based approach ignored the public investment in vaccine development and the critical public interest in equitable access to vaccines to end a pandemic in which no one is safe unless everyone is safe. From the start, the parties at the table leading the COVAX initiative, including the Bill and Melinda Gates Foundation, insisted that pharmaceutical companies should retain strong IP rights in vaccines, imposing no obligations on companies to share their knowledge and relying instead on the largesse of rich countries to pool funds to purchase IP-protected vaccines for the poor, or on private pharmaceutical companies to voluntarily transfer knowledge.

Neither happened. Indeed, in May 2020, the WHO created another mechanism to facilitate technology transfer: the COVID-19 Technology Access Pool (C-TAP). The goal of C-TAP was for companies to pool critical vaccine technology, which could be used by the WHO and potential global manufacturers to scale up vaccine production to meet demand. But no corporation voluntarily contributed technology to the pool.[39]

Kavanagh and Singh argue that the COVAX approach premised on IP and philanthropy was flawed from the start, given underlying political and market pressures. As they write, "failure of the demand-focused/voluntary paradigm to secure equity was foreseeable and foreseen." They argue that "vaccine nationalism and hoarding by wealthy nations was entirely predictable to observers of the politics of 2020–2021 – characterized by rising populism, growing international rivalries, and a retreat from multilateralism." They conclude that, "[l]ooking ahead, far more attention is needed to deploying law in ways designed to succeed in the real-world political context."[40]

Another critical problem with COVAX was the lack of representation of leaders from low-income countries in developing the plan from the beginning. COVAX was the brainchild of leaders from philanthropic organizations largely based in high-income countries. A report by Doctors Without Borders found that key early meetings of COVAX "excluded officials from the developing world, but included McKinsey & Co., a U.S. consulting firm with close ties to pharmaceutical companies."[41] Had they been at the table, representatives from low-income countries

[37] Matthew M. Kavanagh & Renu Singh, *Legal Paradigms and the Politics of Global COVID-19 Vaccine Access*, Chapter 4 this volume.
[38] *Id.*
[39] Michael Safi, *WHO Platform for Pharmaceutical Firms Unused since Pandemic Began*, The Guardian (Jan. 22, 2021).
[40] Kavanagh & Singh, *supra* note 37.
[41] Taylor, *supra* note 33.

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may have pushed back on the IP–philanthropy model on which the effort was based. In the end, this approach left poor countries in a deadly state of dependence, unable to make vaccines themselves for lack of critical IP underlying the technology, or to import vaccines because too few companies were licensed for production. Furthermore, these countries were forced to depend only on COVAX as the singular provider of vaccines to poor countries.[42] Ghanaian Vice President Mahamudu Bawumia said he was unable to enter deals on behalf of his country to secure doses. "[W]e're told no, developing countries have to go through this special facility called COVAX."[43] Botswana's President Mokgweetsi Masisi judged COVAX "just a scam" that had "overpromised and underdelivered." "COVAX has disappointed Africa," concluded Winnie Byanyima, executive director of UNAIDS, a leading public health charity seeking to end AIDS globally.[44] In Chapter 14, Professor Arewa characterizes the absence of representation and marginalization of low-income countries in global governance institutions as a continuing form of colonialism. The COVAX IP–philanthropy model forced low-income countries into a state of dependence on the charity of rich countries and property-owning corporations.

C *Failure of Technology Transfer of "Know-How" and "Show-How" Critical to Vaccine Production*

A recurring theme in this volume is the failure of voluntary mechanisms to promote sharing of critically needed funding and technology for vaccine production during the COVID-19 pandemic. COVAX illustrated the failure of high-income countries to donate funds and doses of vaccines to low-income countries. The pandemic also demonstrated corporate actors' failure to voluntarily share critical IP required to scale up production of vaccines. Numerous contributors to the volume make clear that compulsory licensing of only patents may not be sufficient to assure competitive R&D, testing, regulatory approval, and manufacturing at scale. As David Levine and Josh Sarnoff write in Chapter 11, "[s]haring trade secret knowledge may also be necessary, and where patent holders also possess relevant trade secret rights the compelled sharing of those trade secrets also may be needed."[45]

Notably, even more than patents, tacit knowledge and trade secrets in the form of corporate "know-how" and "show-how" with respect to how to make safe and effective vaccines proved to be critical during the COVID-19 pandemic. Unlike in earlier public health crises, such as the AIDS epidemic of the late 1990s and early 2000s, compulsory licensing of patents was not enough to facilitate production of COVID-19 vaccines by generic producers. Effective and safe production of vaccines,

[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] Levine & Sarnoff, *supra* note 32.

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in particular the new mRNA vaccines produced by Pfizer and Moderna, were not easily replicated with the patented formula alone, but required sharing know-how and show-how in order to make the vaccines safely and effectively. But companies such as Pfizer and Moderna did not voluntarily share this IP with the WHO's C-TAP or with potential vaccine manufacturers in low- and middle-income countries. The failure of companies to voluntarily share this know-how, and of governments to mandate sharing, proved deadly.

Peter Lee (Chapter 1) details how elusive tacit knowledge can undermine the patent bargain of exclusive rights in exchange for teaching the patented technology.[46] Jorge Contreras (Chapter 12) describes historic and novel voluntary pledges of IP during the COVID-19 pandemic. Under the Open Covid Pledge, an astonishing 500,000 patents were promised![47] As Contreras explains, however, the pledge was more successful in some technology segments than in others. While substantial IP rights were pledged with respect to copyright in research and patents in personal protective equipment and digital innovation, he observes that "few pledges were made with respect to biopharmaceutical products such as vaccines and treatments." As he notes, despite its promising beginnings, "little or no technology has been contributed to the C-TAP to date."[48] Contreras' chapter also demonstrates the limits of voluntary mechanisms of technology transfer with respect to critical technologies such as vaccines, and with respect to trade secrets held in the form of know-how. He concludes that "[i]n this area, more direct governmental intervention may be required to encourage IP holders to make their IP more broadly available to expand access to lifesaving vaccines and therapies."[49] In Section 2, we highlight suggested reforms by contributors to this volume to spur, nudge, or in some cases legally compel knowledge sharing and pooling of know-how and show-how related to life-saving vaccines, which are critical to ending a pandemic.

In the end, waiting for voluntary funding (by wealthy countries) or voluntary sharing of technology (by pharmaceutical companies) was in vain. Notably, COVAX and C-TAP, premised on voluntary sharing, did not alter the status quo rules of IP. Companies such as Moderna and Pfizer had no market incentive and were not legally compelled to license their technologies to more manufacturers to increase global vaccine supply. A critical lesson of COVAX and C-TAP is that in the early months of a pandemic, increasing supply of vaccines is only accomplished by compelling technology transfer by companies holding the secrets to making life-saving vaccines. We turn now to an alternative approach spearheaded by countries in the Global South that rejects monopoly rights on life-saving knowledge during

[46] Peter Lee, *New and Heightened Public–Private Quid Pro Quos: Leveraging Public Support to Enhance Private Technical Disclosure*, Chapter 1 this volume.

[47] Jorge L. Contreras, *Voluntary Intellectual Property Pledges and COVID-19*, Chapter 12 this volume.

[48] *Id. See also* Pedraza-Fariña, *supra* note 27.

[49] Contreras, *supra* note 47.

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the emergency of a pandemic, focusing on the need to massively scale up equitable supply and distribution of goods. Thus far this alternative has failed, partly due to structural disempowerment in yet another global governance institution focusing on IP: the World Trade Organization.

D *The Failure of Institutions: The Rise and Demise of the WTO IP Waiver*

In contrast to the charity model of COVAX that would leave IP protections in place, in the WTO, low- and middle-income countries led an alternate effort to waive IP rights to enable global manufacturers to scale up vaccine production to get desperately needed vaccines into Africa and other poor regions. In response to the exceptional circumstances of the COVID-19 pandemic, South Africa and India submitted an IP waiver request to the WTO in October 2020.[50] They proposed waiving the implementation, application, and enforcement of sections 1, 4, 5, and 7 of Part 2[51] of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which governs international IP rules for WTO members.[52] The IP waiver proposal was unprecedented in the history of IP protection because it was intended to trigger a moratorium on the protection of IP rights, which include copyright and related rights, industrial designs, patents, and undisclosed information. The IP waiver, once adopted, would remain in place until widespread vaccination was available globally and a majority of the world's population had developed COVID-19 immunity.[53]

In their submission, South Africa and India further asserted that IP rights were a major cause of the manufacturing and supply problems with diagnostic kits, personal protective equipment, ventilators, medicine, and vaccines.[54] While some countries were in a position to overcome supply issues by manufacturing their own medical products, many developing or least-developed countries (LDCs) were not, and therefore would remain extremely vulnerable without the rapid scaling up of global production. Therefore, they argued that an unprecedented solution was needed to address the impact of a pandemic that could not be effectively contained without expeditious access to affordable medicines and vaccines.[55]

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

[51] *See Id.*

[52] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31 (Apr. 15, 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 213999.

[53] *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention and Containment and Treatment of COVID-19*, *supra* note 50.

[54] *Id.*

[55] *Id.*

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World leaders, policymakers, and scholars had high hopes for the IP waiver proposal, with more than 120 countries supporting it as of May 2021.[56] Most notably, US President Joe Biden issued a statement that month outlining his support for the proposal.[57]

Proponents of the IP waiver claimed that it was a necessary response to the COVID-19 crisis.[58] Just as the AIDS crisis prompted the Doha Declaration on the TRIPS Agreement and Public Health in 2001, the scale of the COVID-19 pandemic necessitated an immediate and substantive response.[59] Since December 2020 when the first COVID-19 vaccine was approved by the US Food and Drug Administration, vaccine inequity had prolonged human suffering in many developing countries. While the United States and United Kingdom had already vaccinated roughly half their populations by early May 2021, vaccination rates in developing economies were significantly lower,[60] with India having vaccinated just 9.4 percent of its population, and Asia and Africa's overall vaccination levels standing at just 4.4 percent and below 1 percent, respectively.[61] Worse still, owing to the extortionate prices charged by pharmaceutical companies, governments worldwide purchased COVID-19 vaccines at prices up to twenty-four times the estimated cost of production.[62]

Despite the widespread support noted above, the European Union and Big Pharma vehemently opposed the IP waiver. This much smaller group of high-income countries contested that IP played any significant role in stunting the manufacture and distribution of the vaccines in 2021. The EU asserted at a TRIPS Council meeting that "there is no indication that IPR [IP rights] issues have been a genuine barrier in relation to COVID-19-related medicines and technologies."[63] For their part, pharmaceutical companies alleged that IP protection had played an

[56] *See Over 120 Countries Back IP Rights Waiver on COVID-19 Vaccines*, PHARM. TECH. (May 7, 2021), www.pharmaceutical-technology.com/news/ip-waiver-covid-19-vaccines/ (last visited Dec. 30, 2022).

[57] *See* Andrea Shalal, Jeff Mason & David Lawder, *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, REUTERS (May 5, 2021), www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/ (last visited Dec. 30, 2022).

[58] *See, e.g.*, Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic* 3 (LSE Legal Studies Working Paper No. 06/2021) (May 24, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737 (last visited Dec. 30, 2022).

[59] *See* Matthew Kavanagh & Madhavi Sunder, *Opinion: Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That*, WASH. POST (Mar. 10, 2021).

[60] *See* Farasat Bokhari, *US-Backed Vaccine Patent Waiver: Pros and Cons Explained*, THE CONVERSATION (May 6, 2021).

[61] *See Id.*

[62] *See* Anna Marriott & Alex Maitland, *The Great Vaccine Robbery* 1 (Jul. 29, 2021), https://webassets.oxfamamerica.org/media/documents/The_Great_Vaccine_Robbery_Policy_Brief.pdf (last visited Dec. 30, 2022).

[63] Knowledge Ecology International, *European Union Dismisses Concerns that IPRs Are a Barrier to COVID-19 Medicines and Technologies* (Oct. 20, 2020), www.keionline.org/34275 (last visited Dec. 30, 2022).

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important role in incentivizing them to develop COVID-19 vaccines but disputed that IP had any role in the failed distribution effort. Big Pharma representatives held fast to the argument that strong IP rights were the critical incentive to invest in innovating vaccines. In expressing his objections to the IP waiver, the CEO of Pfizer claimed that while a big company like his would continue to invest in science, he was not sure "if the same is true for the thousands of small biotech innovators that are totally dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected."[64]

In June 2021, the EU submitted a counterproposal to the TRIPS Council, insisting that countries should take full advantage of the patent-related compulsory licensing scheme allowed for under the TRIPS Agreement. One month after the postponement of its Twelfth Ministerial Conference in November 2021, the WTO held a series of informal negotiations with the European Union, India, South Africa, and the United States at the ministerial and technical levels. The end result was the so-called Quad proposal, which adopted the compulsory licensing measures proposed by the EU and limited the IP waiver effects to vaccines alone, as requested by the United States.[65]

Based on the Quad proposal, the WTO Ministerial Conference adopted the Ministerial Decision on the TRIPS Agreement[66] in June 2022. The Decision clarifies, among other things, three main existing flexibilities allowing developing countries to invoke compulsory licensing of patented technology under TRIPS article 31 to contain the COVID-19 pandemic. Under the Decision, eligible developing countries can expeditiously issue compulsory licensing orders to use any patents (including patents on medical ingredients and production processes) that are necessary only for the production of COVID-19 vaccines without passing any formal laws[67] and without obtaining permission from the patent holders.[68] Any eligible developing country can further export COVID-19 vaccines produced through compulsory licensing to another eligible developing country. An eligible developing country can also remunerate affected patent holders in lesser amounts because "the humanitarian and not-for-profit purpose" of vaccine production must be considered.[69] The Ministerial Decision also clarifies the ability of countries to access otherwise protected regulatory data under TRIPS 39.3 in order to promote expeditious vaccine approvals.[70]

[64] See Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive COVID Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (May 7, 2021).

[65] Thiru Balasubramaniam, *TRIPS Waiver Negotiations Go Down to the Wire in the Run-Up to MC12*, 2022, IISD (Jun. 7, 2022), www.iisd.org/articles/policy-analysis/trips-waiver-negotiations-mc12 (last visited Dec. 30, 2022).

[66] Ministerial Conference of the World Trade Organization, Ministerial Decision on the TRIPS Agreement adopted on Jun. 17, 2022 (Jun. 22, 2022), WT/MIN(22)/30, WT/L/1141.

[67] *See Id.*, ¶ 2.

[68] *See Id.*, ¶ 3 (a).

[69] *See Id.*, ¶ 3 (d).

[70] Ana Santos Rutschman, *Introductory Note to Ministerial Decision on the TRIPS Agreement (WTO)*, 62 International Legal Materials 289 (Jun. 17, 2022).

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The Ministerial Decision officially tolled the death knell of the IP waiver proposal because it does not waive the implementation of any IP protection provision under the TRIPS Agreement.[71] Lengthy negotiations lasting for nearly one year and eight months resulted only in clarifications of the TRIPS flexibilities that developing countries were already entitled to capitalize on even in the absence of such clarifications. The IP waiver was limited to vaccines and did not include diagnostics and treatments, as India and South Africa initially proposed. Notably, the Ministerial Decision does nothing to address the most difficult technology transfer challenges to scaling up vaccine production, which requires access to know-how and show-how not covered by patents. Finally, applicable only to the COVID-19 pandemic, the Decision does not deal proactively with public health emergencies caused by any future pandemics.

E *India, the World's Pharmacy, Fails to Deliver*

At the start of the pandemic, India, long a model in designing IP laws to promote public health and equitable access to medicines, was positioned to take a leading role during the pandemic well beyond the IP waiver. Known as the "pharmacy to the developing world," India was poised to be "the absolute star in the story"[72] in the race to vaccinate the world against COVID-19. One of the world's largest suppliers of generic drugs[73] and the largest supplier of generic drugs to Africa,[74] the world was relying on India to play a critical role in COVID-19 vaccine production, especially doses for low- and middle-income countries. Before the pandemic, India was considered a "vaccine powerhouse"[75] as a critical supplier of 60 percent of the world's vaccines, targeted especially to low- and middle-income countries.[76] Experts estimated India had the capacity to produce 3 billion COVID-19 vaccines

[71] *See* Reto M. Hilty et al., Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement adopted on 17 June 2022 ("While the Decision refers to 'clarifications and waiver', it does not in fact waive any intellectual property (IP) rights as such under the TRIPS Agreement").

[72] Joanna Slater, *Who Will Make Coronavirus Vaccines for the Developing World? India Holds the Key*, Wash. Post (Nov. 11, 2020) (quoting Andrea Taylor of the Duke Global Health Innovation Center).

[73] In 2020, India supplied "20% of the global supply of generics." See Phillippe J. Guerin et al., *The Consequence of COVID-19 on the Global Supply of Medical Products: Why Indian Generics Matter for the World?*, National Library of Medicine (Apr. 1, 2020), www.ncbi.nlm.nih.gov/pmc/articles/PMC7284150/#ref-3 (last visited Dec. 30, 2022).

[74] *Id.*

[75] Slater, *supra* note 72.

[76] Khan Sharun & Kuldeep Dhama, *COVID-19 Vaccine Diplomacy and Equitable Access to Vaccines Amid Ongoing Pandemic*, Elsevier Public Health Emergency Collection (Apr. 2023), www.ncbi.nlm.nih.gov/pmc/articles/PMC8062433/ (last visited Dec. 30, 2022). India contributes 60 percent of the global vaccine supply and acts as the major vaccine manufacturing hub.

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annually[77] – enough to meet the needs of its own population of 1.3 billion, as well as those of low-income countries in neighboring Asia and in Africa.

In late 2020, while promising vaccine candidates were reaching their final stage, India was gearing up for a mass vaccine production effort to meet the moment. AstraZeneca signed an agreement with Oxford University to provide 1.3 billion doses of its vaccine on a not-for-profit basis for the duration of the pandemic across the world, and "in perpetuity" to low- and middle-income countries to ensure a supply to poor countries that could not be hoarded by rich nations.[78] Oxford–AstraZeneca licensed the Serum Institute of India, the world's largest vaccine manufacturer by volume,[79] as its sole manufacturer, and Serum agreed to provide vaccine doses to meet 10 percent of COVAX's goal to vaccinate 2 billion people by the end of 2021, with an option for the Serum Institute to later provide hundreds of millions more doses.[80] In addition to cosponsoring the IP waiver with South Africa at the WTO in October 2020, India embarked on a diplomatic strategy named "Vaccine Maitri" (*maitri* means friendship in Hindi) to donate COVID-19 vaccines to forty-four low-income countries. India exported close to 60 million doses to seventy countries in the early months of 2021.[81] Indian researchers and companies also developed a homegrown vaccine: Bharat Biotech, in collaboration with the publicly funded Indian Council of Medical Research, developed India's first indigenous COVID-19 vaccine, Covaxin.[82] In early January 2021 the Indian Prime Minister Narendra Modi proudly boasted that "India is ready to save humanity."[83]

Within days of the pronouncement, however, Indian pharmaceutical companies were struggling. The very week Modi declared India a hero, his government began placing export bans on the Serum Institute, redirecting jabs to Indian citizens.[84] The breaking point came in late April and early May 2021, when a deadly second-wave COVID-19 outbreak in India led to a horrific number of illnesses and deaths.[85]

[77] Khan Sharun & Kuldeep Dhama, *India's Role in COVID-19 Vaccine Diplomacy*, Journal of Travel Med. (Apr. 2021).

[78] Peter Beaumont, *Oxford-AstraZeneca Vaccine to Be Sold to Developing Countries at Cost Price*, The Guardian (Nov. 23, 2020).

[79] Slater, *supra* note 72.

[80] *Id.*

[81] AJ Vinayak, *50 Days of Vaccine Diplomacy with 60 mn Doses to 70 Countries*, The Hindu (Mar. 12, 2021). *See generally* Sharun & Dhama, *supra* note 77.

[82] Press Release, Press Information Bureau Government of India Ministry of Health and Family Welfare, Phase 3 Clinical Trial of COVAXIN, Developed by ICMR & Bharat Biotech, Shows 81% Efficacy (Mar. 3 2021), https://pib.gov.in/Pressreleaseshare.aspx?PRID=1702293 (last visited Dec. 30, 2022).

[83] Suhasini Haidar, *India Ready to Save Humanity with Two Vaccines, Says Modi*, The Hindu (Jan. 9, 2021).

[84] Joe Wallen & Sarah Newey, *'The Pharmacy of the Developing World Shuts Its Doors': India Stockpiles Oxford-AstraZeneca Vaccine*, The Telegraph (Jan. 4. 2021).

[85] Udani Samarasekera, *India Grapples with Second Wave of COVID-19*, The Lancet (Jun. 1, 2021) (on May 1, 2021, India was reporting 400,000 new cases of COVID-19 in a single day).

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Facing a public health tragedy at home, the Indian government quickly pivoted from vaccine diplomacy to vaccine nationalism, mandating that doses made in India stay in India.[86] Serum's manufacturing was further slowed by export bans by the US government on raw materials. By mid-2021, India's pharmacy to the world closed its doors. The Serum Institute was slammed for not honoring its contracts with COVAX and many low-income country governments. Between June and October 2021, COVAX was not able to deliver any doses made by Serum.[87]

In the end, a confluence of factors was to blame for the stunning failure of the pharmacy to the developing world to deliver during the critical months of 2021.[88] To begin with, the Indian government failed to purchase sufficient doses for its own population in advance (as the United States and European Union had done nearly a year before effective vaccines were developed), leaving the country's 1.4 billion-plus population woefully unprepared when it was suddenly hit with a deadly second wave in March and April 2021. In hindsight, India's vaccine diplomacy was premature, promising donations to others before the country had secured vaccines for its own population. The Indian government made several other missteps. Advanced purchase contracts and additional public funding to domestic manufacturers such as the Serum Institute and Bharat Biotech came too late; earlier funding would have helped to boost manufacture of desperately needed doses.

Going further, the Indian government and other players, from Oxford–AstraZeneca to Bharat Biotech, made the same mistake as COVAX: reliance on IP and philanthropy rather than a shared knowledge approach that understood publicly funded vaccines as a global public good. Kavanagh and Singh argue in Chapter 4 that the flaw in the plan between Serum Institute and Oxford–AstraZeneca is that even this licensing deal focused on promoting access to poorer countries was premised on the proprietary paradigm of closely held IP, rather than open sharing. In fact, both the Oxford–AstraZeneca vaccine and India's homegrown Covaxin vaccine were the result of significant public funding. These technologies could have been shared more widely with ready and able vaccine manufacturers rather than closely held and licensed to just two producers. Relying on just two domestic producers of vaccines, which could then also drive up the vaccine price, the Indian government severely jeopardized access for its own citizens and much of the developing world. Observers criticized the Indian government for not stepping in to more aggressively repurpose existing Indian drug companies for the manufacture of vaccines. In the end, the Serum Institute was unable to deliver to poor countries outside of India as had been promised, and no other manufacturers were

[86] Anuttama Banerji, *India's Flawed Vaccine Diplomacy*, Stimson (Jun. 25, 2021).
[87] Taylor, *supra* note 33.
[88] Nikhil Inamdar & Aparna Alluri, *How India's Vaccine Drive Went Horribly Wrong*, BBC News (May 14, 2021).

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given the recipe and know-how to do so.[89] Critics noted the inconsistency between India's position at home and abroad: "While India has supported waiving the patents on foreign-made vaccines, it has made no move to suspend it for Covaxin."[90] A central question is why India did not exploit all IP flexibilities at its disposal to confront the COVID-19 pandemic. This is surprising given that India has long taken an aggressive approach to IP and public health, walking a fine line between being TRIPS-compliant and promoting as widespread as possible access to life-saving technology through generics.

Intellectual property is critical to understanding what went wrong in India in 2021. At the same time, IP and its careful design is also critical for understanding why India was in the pivotal position to serve as the pharmacy to the developing world in the first place. India's position as a leading manufacturer of generic drugs for the developing world is the result of half a century of intentional IP law-making in the country. The key to the development of India's robust generic drug industry was a conscious move by the country in the 1970s to abandon colonial-era patent laws that favored foreigners over Indian inventors and patients. Recognizing that India lacked research and development capacity to produce patentable inventions, and that foreign patents drove up prices that threatened access to life-saving medicines for India's large, poor population, India consciously rewrote its patent law to promote indigenous industry and access to medicines.[91] The most notable element of India's Patent Act of 1970 was that it did not recognize patents in breakthrough drug *products* but only in inventive *processes* to create the drugs. This approach allowed Indian pharmaceutical companies to reverse engineer patented drugs. So long as an Indian drug company could make the same medicine in a novel way, they would not violate patents and could build their own store of knowledge and know-how at the same time.[92]

The crucial fact is that under international IP rules existing at the time, India was fully able to tailor its patent law to promote its own national interests. The result of the Indian Patent Act of 1970 was the growth of India's pharmaceutical sector into one of the most powerful, lucrative, and impactful in the world. Within three decades, India was producing most of the drugs and vaccines used in Africa.

[89] Kavanagh & Singh, *supra* note 37 ("COVAX at this point was largely dependent on [the Serum Institute] – which was to produce a majority of its planned supplies for the first half of 2021 – and had no alternative in a context of constrained supplies and monopoly production").

[90] Inamdar & Alluri, *supra* note 88.

[91] On the development of Indian patent law during colonial rule of the British Raj, see Rajesh Sagar, *Patent Policy in India under the British Raj: A Bittersweet Story of Empire and Innovation*, *in* Patent Cultures: Diversity and Harmonization in Historical Perspective (Graeme Gooday & Steven Wilf eds., 2020), at 273–301. For a more contemporary look at the development of patent law in India, see Tania Sebastian, *The India Twist to Patent Culture: Investigating Its History*, in Patent Cultures: Diversity and Harmonization in Historical Perspective (Graeme Gooday & Steven Wilf eds., 2020), at 302–318.

[92] *See generally* Madhavi Sunder, From Goods to a Good Life: Intellectual Property and Global Justice 173–199 (2012).

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Indian pharmaceutical companies produce over 90 percent of the antiretroviral medicines used in low-income countries and two-thirds of the medicines used by Doctors Without Borders in the treatment of HIV, tuberculosis, and malaria. India's Patent Act of 1970 provided the legal infrastructure for India to become the "pharmacy to the developing world."

However, India's ability to deliver drugs to the world's poor was significantly threatened with the establishment of the WTO and TRIPS in 1995. For the first time, IP became tethered to the world trade system, which gave teeth to enforcement of international IP rules, with violators facing trade sanctions. Further, TRIPS required all WTO members to recognize patents in drug products and processes – a change that could strike a lethal blow to India's generic drug industry. Notably, in amending India's patent laws to be TRIPS-compliant, the Indian Parliament sought to create a law that would provide maximum flexibility for generic drug production under the strict confines of TRIPS. The Indian Patent Act of 2005 included the now famous Section 3(d), aimed at preventing abuses by patent holders that sought to extend monopolies on patented drugs by obtaining a new patent on a mere tweak or modification of a drug – a process known as "evergreening." Section 3(d) is an anti-evergreening provision, which restricts the patenting of incremental innovations of patented pharmaceuticals after patent expiry that would simply serve to delay generic entrants.[93] In 2013, the Supreme Court of India upheld this provision in the landmark judgment of Novartis v. Union of India.[94] In so doing the Indian Supreme Court expressly acknowledged that the ability of India to continue to serve as the "pharmacy to the developing world" hung in the balance.[95] The Court has protected indigenous generic drug production and access to medicines in a number of other important rulings as well.[96]

The WTO Intellectual Property Waiver proposal with South Africa in response to the COVID-19 pandemic was not the first time India has taken a leading global role advocating for IP policies that promote access to medicines. India advocated for a combination of legal levers to promote access to medicines during negotiations for the Regional Comprehensive Economic Partnership Agreement (RCEP), a regional

[93] Setting a high bar on patentability, the Act excludes "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy" of a drug. Indian Patent Act (2005) s. 3(d).

[94] Novartis v. Union of India, AIR 2013 SC 1311 (2013) (India).

[95] Madhavi Sunder, *Novartis v. Myriad: The Indian and U.S. Supreme Courts on Patents and Public Health*, Eur. Intell. Prop. Rev. (Nov. 2013).

[96] *See, e.g.*, Bayer Corporation v. Union of India, 2019 (78) PTC 521 (Del) (2019) (India); Bajaj Auto Ltd. v. TVS Motor Company Ltd., 2009 (41) PTC 398 (SC) (2009) (India) (holding that matters involving intellectual property rights should be quickly and expeditiously resolved, so as not to delay generic market entry); Indoco Remedies Ltd. v. Bristol-Myers-Squibb Holdings, decision of the Delhi High Court dated Sep. 18, 2020, in FAO(OS) (COMM) 3/2020 (2020) (India), upheld by the Supreme Court of India in decision dated Jun. 29, 2021 in SLP (C) 7213/2021 (affirming public interest as a factor to be weighed in case involving generic COVID-19 treatment).

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Asia-Pacific trade agreement that would have included India, China, South Korea, Japan, Australia, New Zealand, and the Association of Southeast Asian Nations (ASEAN)[97] and reset the rules of IP for Asia in the twenty-first century. Leaked drafts of the negotiations demonstrate that India sought to include provisions that would protect its status as the pharmacy to the developing world, including high patentability standards and affirmation of TRIPS flexibilities regarding compulsory licenses. Additionally, India argued against data exclusivity and patent extensions to compensate for regulatory delays, both of which delay market entry for generic drugs.[98] India ultimately dropped out of the RCEP alliance in 2020, perhaps to preserve its ability to produce generic drugs for two-thirds of humanity. Without a doubt, India's consistent efforts to protect its role as pharmacy to the developing world are critical to the survival of the 1.3 billion people in India but also for millions in low-income countries. Yet India, which had prepared its IP infrastructure to promote life over property for half a century, tragically did not exercise all the flexibilities at its disposal when it mattered most.

F *China Affirms Intellectual Property + Philanthropy*

China, too, played a critical role in promoting access to COVID-19 vaccines during the pandemic. China's role, focused on indigenous innovation of homegrown vaccines and vaccine diplomacy – donating vaccines to enhance its geopolitical influence – has affirmed traditional IP rules rather than challenging or remaking them.

In Chapter 13, legal scholar Peter Yu argues that China's role in the WTO IP waiver debate was consistent with China's usual "middle-of-the-road"[99] approach to IP and public health. Nearly a decade ago Yu described China and India as the "Middle Intellectual Property Powers" between high-income regions (including the United States, the EU, Japan, and South Korea) on one side, and low- and middle-income countries on the other.[100] Notably, China's role in the TRIPS IP waiver debate remains consistent with the role it has played in earlier transnational negotiations involving IP and public health. In 2018, China and India were among key powers negotiating the RCEP, a trade agreement for the Asia-Pacific region that, with both countries involved, would have governed IP rules for half the world's population. As Anupam Chander and Madhavi Sunder argued in 2018, China

[97] Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam.

[98] *See* Chander and Sunder, *supra* note 98.

[99] Peter Yu, *China, the TRIPS Waiver, and the Global Pandemic Response*, Chapter 13 this volume.

[100] Peter K. Yu, *The Middle Intellectual Property Powers*, in Law and Development of Middle-income Countries 84, 89–91 (Randall Peerenboom & Tom Ginsburg eds., 2014).

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remained neutral during contentious negotiations involving public health and IP provisions in the RCEP, letting India go toe-to-toe with pharmaceutical powerhouses South Korea and Japan over public health provisions.[101] China did not veer from this steady position during the COVID-19 pandemic. It did not throw its weight behind India and South Africa's proposed IP waiver, nor did it openly oppose the IP waiver.

Yu notes that China's neutral approach to the IP waiver advanced several of China's long-term and short-term goals. He explains China's neutral stance by several factors, from its ambition to become a powerhouse of indigenous innovation, to its growth into a leading developer of pharmaceutical IP, to the soft power benefits to China from vaccine diplomacy with its poor neighbors. Yu predicts these factors will lead China to continue to follow a middle road in ongoing debates around IP and public health that does not upset the foundations of international IP regimes.

Yu identifies China's "growing ambition to become an intellectual property power" as a primary reason why it did not openly support India and South Africa's IP waiver proposal. Yu recounts China's "innovative turn" in the 2000s, including the adoption of a National Intellectual Property Strategy in 2008, which "provided a comprehensive plan to improve the creation, utilization, protection, and administration of intellectual property rights."[102] More recently, the Made in China 2025 strategic plan of 2015 identified biomedicine and high-performance medical devices as one of the ten priority sectors, specifically identifying "biologic-based therapeutics" and vaccines, among other drugs, for domestic manufacture. Yu notes that consistent with these ambitions, China has adopted maximalist protections for drug patents beyond those required by TRIPS, including patent extensions to accommodate regulatory delays and data exclusivity that would prevent the entry of generic drugs. As Yu concludes, China's "ambition in the IP and pharmaceutical arenas is loud and clear" and "a TRIPS waiver that would suspend close to half of the provisions in the TRIPS Agreement ... did not sit very well with the country's current policy position."[103]

China's long-term planning has succeeded. China has surpassed all its targets for domestic patents per year and the country now has the world's second largest pharmaceutical market, behind the United States.[104] Most notably, China successfully manufactured homegrown COVID-19 vaccines, CoronaVac and Sinopharm,

[101] Anupam Chander & Madhavi Sunder, *The Battle to Define Asia's Intellectual Property Law: From TPP to RCEP*, 8 UC Irvine L. Rev. 331, 344 (2018). *Compare* Peter K. Yu, *The RCEP Negotiations and Asian Intellectual Property Norm Setters*, in The Future of Asian Trade Deals and IP 85, 103–05 (Liu Kung-Chung & Julien Chaisse eds., 2019).

[102] *See generally* Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 Am. U. L. Rev. 1045, 1079–87 (2018); Peter K. Yu, *China's Innovative Turn and the Changing Pharmaceutical Landscape*, 51 U. Pac. L. Rev. 593, 599–608 (2020).

[103] Yu, *supra* note 99.

[104] *Id.*

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and had the capacity to manufacture enough for domestic as well as export markets.[105]

China's primary means of promoting public health for the global poor has been through what Yu calls "pandemic diplomacy," including significant donations of "masks, ventilators, vaccines, and other supplies."[106] Yu writes that by mid-2022, China had "delivered more than a billion doses of COVID-19 vaccines to over 100 countries, out of which at least tens of millions were donations."[107] China's pandemic diplomacy efforts are consistent with its Belt and Road Initiative to ambitiously expand global infrastructure trade belts affecting some 150 countries.[108] As Yu explains, "A key goal of pandemic diplomacy is to gain soft power and goodwill through the donation or delivery of health products and technologies to other countries."[109] In addition, China has made substantial profits from selling its vaccines, including to COVAX. Yu concludes that "the proposed waiver would have undermined these commercial activities."[110] All told, China had more to gain from holding onto its IP and making donations and sales to developing countries than it did by supporting a developing country IP waiver initiative.

China's vaccine diplomacy, while recognized for its critical delivery of life-saving technology to countries in need, has been criticized. Like the critique of the COVAX donation model, poor countries are still left dependent on donor countries, lacking the knowledge and manufacturing capacity to make vaccines themselves, now or in the future. Further, vaccine diplomacy may come with strings attached.

Chinese officials talked of COVID-19 vaccines as "global public goods."[111] But in its actions thus far, China does not walk the walk. It remains an open question to what extent China's "Health Silk Road"[112] initiative might include more robust

[105] Smriti Mallapaty, *China's COVID Vaccines Have Been Crucial – Now Immunity Is Waning*, Nature (Oct. 14, 2021) ("China's CoronaVac and Sinopharm vaccines account for almost half of the 7.3 billion COVID-19 vaccine doses delivered globally, and have been enormously important in fighting the pandemic, particularly in less wealthy nations").

[106] Yu, *supra* note 99.

[107] *Id*.

[108] See Peter K. Yu, *Building Intellectual Property Infrastructure Along China's Belt and Road*, 14 U. Pa. Asian L. Rev. 275 (2019).

[109] Yu, *supra* note 99. *See also* China Power Team, *Is China's COVID-19 Diplomacy Succeeding?*, Center for Strategic & International Studies (Mar. 17, 2022); Denny Roy, *China's Pandemic Diplomacy*, East–West Center, Asia Pacific, Issue No. 144 (2020); William Wang & Holly Snape, *Why a Coronavirus Vaccine Is Politically Valuable to China*, The Conversation (Oct. 20, 2020).

[110] Yu, *supra* note 99.

[111] Sarah Wheaton, *Chinese Vaccines Would Be "Global Public Good," Xi Says*, Politico (Mar. 18, 2020); Ministry of Foreign Affairs of the People's Republic of China, Wang Yi: China-Aided Vaccines to Africa Will Cross Mountains and Rivers and Outpace the Virus (Dec. 1, 2021), www.fmprc.gov.cn/mfa_eng/zxxx_662805/202112/t20211201_10460739.html (last visitied Dec. 30, 2022); *China Walks the Talk in Making COVID-19 Vaccines Global Public Goods*, Xinuanet (Jul. 22, 2021).

[112] Yanzhong Huang, *The Health Silk Road: How China Adapts the Belt and Road Initiative to the COVID-19 Pandemic*, Am. J. of Pub. Health (Apr. 2022).

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technology transfer, especially regarding helping to scale up local manufacturing capacity in low-income countries. Overall, however, at least with respect to patents and public health, going forward China is more likely to align with developed countries than developing countries, without upsetting current international IP rules. That China's IP approach in this sphere does not represent any essentialist "Asian values" should not come as a surprise. First, the stereotype of Chinese piracy of the last century is not in line with China's contemporary ambition or reality. Indeed, Yu cautions against cultural stereotypes that would lead observers to align China with other Asian countries such as India, observing that "many observers remain fixated on the old narrative on China's piracy and counterfeiting problems," leading them "to mistakenly assume that the country's IP position would align more closely with that of the global South."[113] As Yu concludes, with respect to IP, "China now takes policy positions that align more closely with those of developed countries than those of developing countries."[114]

2 THE CURE: SPURRING TECHNOLOGY TRANSFER TO PROMOTE SUPPLY, ACCESS, AND CAPABILITY

The contributors to this volume go beyond diagnosis to developing cures for the failure to promote timely and adequate supply of and equitable access to critical medicines necessary to save lives and end a pandemic. Many argue for a paradigm shift away from the sole reliance on a market-based, IP model toward a human capability approach focused on sharing technology and promoting local innovation capacity. As Calvin Ho writes (Chapter 8), "It does not auger well for global health justice if the majority of health systems should rely on the goodwill of a few health systems, or worse, a few corporations and private organizations that are accountable only to their shareholders or sponsors." He advocates for a new paradigm for pandemic governance focused on the capability approach developed by philosophers Amartya Sen and Martha Nussbaum. Several contributors in this volume agree with Ho's assessment that "[t]he world will remain unprepared for the next pandemic unless we depart from the status quo."[115]

Reforms proposed here focus on mechanisms to spur technology transfer to low- and middle-income vaccine manufacturers, given the failure of voluntary mechanisms during the COVID-19 pandemic. In particular, proposals for reform include the following:

- Enhancing legal requirements for technology transfer in pandemic emergencies;
- Addressing barriers beyond IP, such as data exclusivity and patent linkages;

[113] Yu, *supra* note 99.
[114] *Id.*
[115] *See, e.g.*, Ho, *supra* note 16.

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- Facilitating faster sharing of global medicines and vaccines;
- Fostering local manufacturing capacity in low- and middle-income countries;
- Enhancing pandemic financing and global governance;
- Adopting human rights and environmental, social, and governance (ESG) obligations for pharmaceutical companies; and
- Addressing colonial hangovers and moving from dependency to capacity building in low- and middle-income countries.

Technology transfer cannot wait until the next pandemic. This process must begin now to help scale up local production capacity in Africa and other low- and middle-income regions, through funding and knowledge sharing with regional technology transfer hubs, including mRNA technology transfer hubs. We outline here a host of strategies considered in this volume that national governments and international institutions must collaborate on in the coming years to better prepare for the next pandemic.

A *Enhanced Legal Requirements for Technology Transfer in Pandemic Emergencies*

Technology transfer – the very promise upon which the TRIPS bargain was founded[116] – continues to be the key to equitable access and distribution of vaccines during a pandemic. Many of the contributors to this volume propose important, and practicable, reforms for enhancing mechanisms of technology transfer. Peter Lee (Chapter 1) illuminates a paradox: though patents are premised on a quid pro quo in which inventors receive exclusive rights in exchange for disclosing a novel invention, disclosure rules under current US patents exclude tacit knowledge and critical know-how that is necessary for those skilled in the art to manufacture the vaccines. Lee suggests modifying the patent quid pro quo to require greater tacit knowledge disclosure from patentees, for instance by resurrecting the best-mode requirement and imposing an ongoing requirement to disclose information related to commercializing technologies, particularly for vaccines, diagnostics, and therapeutics. Lee also suggests that public institutions should place knowledge-transfer obligations on patentees receiving significant public funding, such as biopharmaceutical firms holding patents on COVID-19 vaccines.[117]

Sapna Kumar and Ana Santos Rutschman (Chapter 9) propose an ex ante approach to tackling drug scarcity and argue that governments and

[116] For a critical history of the TRIPS agreements and its aftermath, see Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights 121–162 (2003); Christopher May & Susan K. Sell, Intellectual Property Rights: A Critical History 162–218 (2006).

[117] Lee, *supra* note 46.

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nongovernmental funders should integrate pandemic planning into contracts used to fund medical research. Funders should require pandemic funding recipients to assure that any resulting drug will be made available in sufficient quantity and at accessible prices. In the event of a future drug shortage, the recipient would agree to share its technology and know-how to a qualified third-party manufacturer in exchange for payment of royalties. Alternatively, when governments fund medical research, they could utilize dormant licenses that activate in the event of an outbreak to require rights holders to license out technology and know-how. By acting proactively, governments can reduce drug shortages during future pandemics and save lives.[118]

Kavanagh and Singh (Chapter 4) advocate internationally binding commitments to the sharing of know-how, including mechanisms to encourage compliance with a built-in expectation of national self-interest.[119]

Levine and Sarnoff (Chapter 11) argue that many mechanisms already exist to allow governments to compel trade secret holders to share know-how in public health emergencies, including the Defense Production Act under existing federal law in the United States. Levine and Sarnoff argue that the primary obstacle to mandatory disclosure of trade secrets is not law – even TRIPS "does not prohibit governments from compelling trade secret rights," they write – but rather, political will. In some cases, Levine and Sarnoff advocate reasonable compensation to trade secret holders for compelled disclosure to promote access. In addition, they propose that sharing trade secrets may be encouraged with legislative nudges and incentives.

Taking a different tack on the issue of technology transfer, Pedraza-Fariña (Chapter 3) argues for the need to create a legal infrastructure that allows and encourages sharing knowledge among researchers across multiple disciplines, to nurture the "boundary-crossing innovation" necessary to cure complex diseases.[120]

Finally, we urge that the technology transfer mechanism in the TRIPS Agreement itself also be strengthened. Article 66.2 of the TRIPS Agreement states that "[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." Both the 2001 WTO Ministerial Conference and subsequent Doha Declaration made it clear that this provision imposes a *mandatory* obligation on developed countries.[121] Nevertheless, the WTO has yet to establish a mechanism for monitoring and assessing whether and how developed countries have fulfilled this treaty obligation. In 2003, the TRIPS Council

[118] Kumar & Rutschman, *supra* note 31.
[119] Kavanagh & Singh, *supra* note 37.
[120] Pedraza-Fariña, *supra* note 27.
[121] Carlos Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, in Int'l Pub. Goods and Transfer of Tech. under a Globalized Intell. Prop. Regime 253 (2005).

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set up an article 66.2 reporting system that requires developed countries to submit detailed reports every three years and annual reports updating them.[122] To date, however, the system has proved itself to lack sufficient teeth to ensure developed countries' compliance with their article 66.2 obligations.[123] The mere act of submitting a report does not necessarily mean that a developed country's self-assessment has rendered it compliant with article 66.2. For instance, despite the increase in the number of annual reports submitted, many of the programs reported by developed countries did not even target LDCs.[124] Therefore, the transfer of technology from developed countries to LDCs has been described as "lackluster" by both least-developed country members and WTO officials.[125]

What is still lacking is a global mechanism that can evaluate two critical aspects of the article 66.2 obligation: first, whether a developed country has taken effective actions to incentivize technology transfer to an LDC and, second, whether such actions have contributed to the growth of a technological base in the LDC concerned. It is incumbent upon the WTO to reshape the reporting system operated by the TRIPS Council into a global mechanism capable of monitoring and critically assessing whether developed countries have met these two aspects of their obligation and of making recommendations on any necessary follow-up actions. A major focus of this mechanism would be transfer of technologies that could boost LDCs' capacity to manufacture medical products.[126]

The COVID-19 pandemic has clearly demonstrated the urgent need to establish such a global mechanism, thereby providing the international community with a

[122] Jayashree Watal & Leticia Caminero, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, WTO Staff Working Paper ERSD-2018-01 (Feb. 22, 2018).

[123] *See* Suerie Moon, *Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999–2007)*, Policy Brief Number 2 (Dec. 2008), UNCTAD – ICTSD Project on IPRs and Sustainable Dev., https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf (last visited Dec. 30, 2022) ("However, eight years later in 2011, no such review has taken place. This analysis suggests that not only is such a review long overdue, the existing reporting mechanism also clearly falls short of an effective monitoring system"); Cameron Hutchison, *Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?*, 3 U. Ottawa L. & Tech. J. 517, n. 29 (2006) ("LDCs have repeatedly complained that little or no action has been taken under [article 66.2]").

[124] Hutchison, *Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?*, *supra* note 123 ("Many of the policies and programmes reported either barely targeted or did not at all target LDCs").

[125] David M. Fox, *Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting Their End of the Bargain?*, 10 Hastings Sci. & Tech. L.J. 1, 20 (2019).

[126] William Fisher et al., *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 Mich. J. Int'l L. 1, 14 (2022) ("Technology-transfer arrangements associated with [pharmaceutical manufacturing] not only helped the local firms establish manufacturing capacity for formulations, but also supported the expansion of product portfolios over time and helped local companies meet the quality standards needed for export markets"); World Health Organization, Increasing Access to Vaccines through Technology Transfer and Local Production (2011), https://apps.who.int/iris/handle/10665/44714 (last visited Dec. 30, 2022).

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prime opportunity to pressure the WTO and developed countries to adopt reform measures and accept the mechanism to stimulate transfer of soft and hard technologies. The transfer of soft technologies such as substantial know-how to low-income countries is necessary to boost production of COVID-19 vaccines because vaccines are complex biological products that are heavily dependent on specific manufacturing processes and practices, which are often not disclosed in a patent.[127] For instance, it is very difficult to replicate biological processes involving recombinant proteins from the information contained in patents alone, as "the high degree of process dependence in the cell-mediated synthesis of biologics" makes it "quite possible that an attempt to make the patented protein by a different method will yield a product that lacks the asserted utility of the claimed invention."[128] The cost and effort of reverse-engineering originator firm manufacturing processes have contributed to a history of delays in the entry of biosimilars to the market. In one recent case, Inovio even claimed in a court filing that its own experimental COVID-19 vaccine was being held hostage by a contract manufacturer's refusal to share its manufacturing details.[129]

B *Addressing Barriers beyond Intellectual Property*

Cynthia Ho (Chapter 7) describes emergent barriers to vaccine access beyond traditional IP rights. One barrier is data exclusivity, which prohibits generic drug developers from relying on earlier clinical data of the original drug maker – essentially treating clinical data as a form of property, if not formally as IP. In addition, Ho describes the practice of "patent linkages" in some countries, which can stymie regulatory approval of generics "solely due to alleged infringement of patent(s) associated with making that drug."[130] The continuing presence of these barriers highlights that there are many challenges to developing generic medicines and vaccines, beyond traditional IP rights such as patents and trade secrets.

C *Facilitating Faster Sharing of Medicines and Vaccines*

The TRIPS Agreement should create a new global mechanism that can effectively facilitate faster export of patented medicines and vaccines from a country with adequate manufacturing capacity to another without such capacity when a public

[127] *See* Ana Santos Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*, Bill of Health (2021).

[128] Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 Hastings Sci. & Tech. L.J. 109, 135–136 (2011).

[129] *See* W. Nicholson Price II et al., *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 Sci. 912 (2020).

[130] Ho, *supra* note 16.

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health crisis occurs. Article 31*bis* of the TRIPS Agreement was designed to meet this goal. It allows a member state that lacks the capacity to manufacture patented medicines or vaccines under compulsory licensing to import them from another member state. However, the compulsory licensing system has proved to be fatally ineffective, not only because of the complexity, length, and cost of undertaking this process, but also because of the burdensome requirements, challenge of recovering expenditures, and resulting lack of incentives for generic manufacturers.[131] For example, the exporting country must ensure that generic drugs are exported only to the importing country, are easily identifiable in color or shape as generic drugs, and are manufactured only in the specific amount necessary to meet the importing country's requirements.[132] The challenge of achieving economies of scale in countries with little manufacturing capacity presents further obstacles, as these countries are usually small in size.[133] Therefore, the article 31*bis* mechanism remains in limbo because few countries have revised their domestic laws to activate it.[134] Since its introduction in 2003, the mechanism has been used only once.[135] That sole instance involved collaboration between Rwanda as the importing country and Canada as the exporting country for the antiretroviral drug Apo-TriAvir.[136] It took the Canadian generic company Apotex three years to supply this much-needed medicine.[137]

The COVID-19 pandemic has also highlighted serious problems with the article 31*bis* mechanism. In spring 2021, Biolyse, a Canadian pharmaceutical company, attempted to take advantage of compulsory licensing to provide 15 million doses of the Johnson & Johnson COVID-19 vaccine to Bolivia, where only around 5 percent of the population had thus far been vaccinated. However, the Canadian government refused to grant a compulsory license to allow Biolyse to manufacture the vaccine using Johnson & Johnson's patent.[138] Similarly, in spring 2022, in the face of vehement opposition from Pfizer, the Dominican Republic did not venture to grant a compulsory licensing order to manufacture Paxlovid, Pfizer's patented medicine

[131] *See* Dina Halajian, *Inadequacy of Trips & the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Program*, 38 Brook. J. Int'l L. 1191, 1203 (2013); Sapna Kumar, *Compulsory Licensing of Patents during Pandemics*, 54 Conn. L. Rev. 57, 59–60 (2022); Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicines Tool*, 102 Minn. L.R. 2463, 2464–68 (2018).

[132] Halajian, *supra* note 131, at 1211.

[133] *See* Prabhash Ranjan, *The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines*, 456 Observer Rsch Found. Issue Brief 1, 9 (2021).

[134] See William Alan Reinsch, *Compulsory Licensing: A Cure for Distributing the Cure?*, Ctr. for Strategic and Int'l Studies (May 8, 2020).

[135] *See, e.g.*, Halajian, *supra* note 131, at 1204.

[136] *See* Yahong Li, *Intellectual Property and Public Health: Two Sides of the Same Coin*, 6 Asian J. WTO & Int'l Health 389, 409–410 (2011).

[137] *See Id.*, at 411.

[138] *See* Kerry Cullinan, *Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine Intellectual Property*, Health Policy Watch (Nov. 15, 2021).

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for treating COVID-19 infections.[139] Although the Ministerial Decision seeks to speed up the compulsory licensing process to enable developing countries to contain the COVID-19 pandemic, it has not fixed any of these major problems with the article 31*bis* mechanism. The export permit that the Decision has introduced is virtually meaningless. It allows an eligible developing country to export vaccines that it produces to another eligible country. However, because China and India, the two developing countries with the greatest vaccine manufacturing capacity, are excluded as ineligible beneficiaries of the Decision, the export permit is infeasible in practice. No other developing countries can swiftly manufacture vaccines to meet the public health needs of another developing country. Moreover, because the Decision is applicable only to the production of COVID-19 vaccines, no eligible developing country can avail itself of compulsory licensing to offer COVID-19 diagnostics and therapeutics, such as Paxlovid.[140] In the last quarter of 2022, there was an oversupply of COVID-19 vaccines internationally.[141] What is badly needed are testing tools and treatment medicines in the many countries where people are vaccinated but still become infected with COVID-19. Against this backdrop, the international community should endeavor to create a global mechanism that can facilitate faster sharing of patented medicines and vaccines to deal with both COVID-19 and any future public health crisis. We must render compulsory licensing more capable of achieving the swift export of medicines and vaccines.

D *Fostering Local Manufacturing Capacity*

The reliance of much of the Global South on imports proved deadly – what Ken Shadlen in Chapter 15 calls the "Achilles heel" that needs to be addressed before the next pandemic. Focusing on Latin America, Shadlen writes that this region accounts for one-tenth of the world but suffered one-third of global COVID-19-related deaths. Like other contributors to this volume, Shadlen points out that the technology transfer issues with respect to COVID-19 vaccines are distinct from past experiences with AIDS medicines, which did not require active participation on the part of patent holders to facilitate transfer of know-how. Shadlen and others in this volume argue that the focus going forward must be on boosting local vaccine production capability, a significant challenge because vaccine producers, especially mRNA vaccine manufacturers Moderna and Pfizer, have been unwilling to share know-how and show-how. This need not be the case. In contrast to Moderna and Pfizer, Shadlen notes that the partnership between Astrazeneca and the Brazilian

[139] *See* Sheryl Gay Stolberg, *As Poor Nations Seek COVID Pills, Officials Fear Repeat of AIDS Crisis*, N.Y. Times (May 11, 2022).

[140] Ministerial Decision, *supra* note 66, at ¶ 8.

[141] Francesco Guarascio & Jennifer Rigby, *COVID Vaccine Supply for Global Programme Outstrips Demand for First Time*, Reuters, www.reuters.com/business/healthcare-pharmaceuticals/covax-vaccine-supply-outstrips-demand-first-time-2022-02-23/ (last visited Dec. 30, 2022).

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government was exemplary, because it provided significant technology transfer commitments that would eventually allow Brazilian vaccine manufacturers to make vaccines on their own. At times, Shadlen explains, Astrazeneca vaccines "accounted for half of the vaccines used in Brazil." He notes that neither Pfizer nor Moderna provided for mRNA vaccine production in Latin America in 2021, an absence he calls "curious, as the appropriate production capabilities are present."[142]

William Fisher, Ruth Okediji, and Padmashree Gehl Sampath (Chapter 5) highlight the convergence of three developments that makes fostering local production of pharmaceuticals, including vaccines, imperative: "the emergence of novel diseases that pose severe threats to the health of the residents of developing countries; the rise of healthcare nationalism; and revelation of the scale of the transnational trade in substandard medicines." They outline a multi-step strategy to achieve this goal of fostering local production capacity for vaccines and pharmaceuticals in the Global South. The authors lay a blueprint for the future, which includes building domestic legal infrastructure to regulate and support local drug production, government purchasing of medicines and vaccines, technology transfer through apprenticeships, robust quality control, and capitalizing on the economic and political power of regional economic communities in Africa, Latin America, and Asia.[143]

Efforts have begun to establish WHO-supported technology transfer hubs in key locations in Latin America, Asia, and Africa. The African Union has set a goal to build capacity to locally produce 60 percent of the continent's vaccine needs by 2040. This is a challenging goal, as Africa currently imports 99 percent of its vaccines. The WHO is supporting an mRNA technology transfer hub at Afrigen in Cape Town, South Africa, and the hub has had significant initial successes.[144] However, securing financing for the hubs presents a significant hurdle. The WHO is struggling to raise the significant finances necessary to establish other planned hubs in countries such as Brazil, India,[145] and Nigeria.[146] In the meantime, access to critical mRNA know-how, held by Moderna and Pfizer, continues to be elusive, as these firms have thus far failed to offer significant support to the initiatives.[147]

[142] Kenneth C. Shadlen, *Technology Transfer for Production of COVID-19 Vaccines in Latin America*, Chapter 15 this volume.
[143] William Fisher, Ruth Okediji & Padmashree Gehl Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, Chapter 5 this volume.
[144] Stephanie Nolen, *Can Africa Get Close to Vaccine Independence? Here's What It Will Take*, N.Y. Times (Apr. 25, 2023).
[145] *See* Swati Bharadwaj, *WHO to Set Up mRNA Vaccine Hub in Hyderabad as Part of Global Plan*, Times of India (Feb. 22, 2023).
[146] *See* Adam Taylor, *Plan to Make mRNA Vaccines in Developing Countries Needs U.S. Funding, Backers Say*, N.Y. Times (Mar. 14, 2023).
[147] *Id.*

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E *Enhancing Pandemic Financing and Global Governance*

Pedraza-Fariña (Chapter 3) urges the United States and other developed countries to give robust "financial and logistical" support to regional tech transfer hubs in Africa and elsewhere now. Acknowledging that "know-how transfer, in particular when new technologies are involved, is notoriously tricky," she emphasizes that the required "learning-by-doing … can only happen through immersive training" by, for example, regional tech transfer hubs. Countries such as Indonesia, Thailand, and Vietnam are "some of the only lower-income countries that are now producing COVID-19 vaccines," she writes, because of the positive spillovers of having participated in an influenza vaccine technology transfer program spearheaded by the WHO in 2005.[148] Critical investment in technology transfer hubs in diverse regions in the Global South is needed so countries can build their knowledge and capacity now for success in future pandemics.

Financing and enhanced global governance structures are key in other ways. In the absence of significant change from the status quo IP approach, Jayashree Watal (Chapter 10) proposes establishing an 'International Pandemic Fund," prefinanced by the European Union and the United States, which would allow for procuring vaccines for poor countries, as well as a global governing authority with speedy decision-making capability to equitably distribute vaccines. Acknowledging the failures of the best laid plans to avoid vaccine inequity in the COVID-19 pandemic, Watal argues for an effective implementing agency to reduce vaccine inequity through the procurement and distribution of existing and projected manufacturing output.[149] Calvin Ho (Chapter 8) suggests means of strengthening cooperation among key international organizations (particularly the WHO, the WTO, and the WIPO), and influential private actors operating at the coalface through initiatives such as ACT-A.[150]

F *Human Rights and ESG Obligations of Pharmaceutical Companies*

Haochen Sun (Chapter 6) takes yet another tack, proposing a philanthropy requirement for companies receiving patents in life-saving technologies. He would build into the patent quid pro quo an obligation on these patentees to donate 1 percent of their annual post-tax profits accrued from their patented medicines. Such financial contributions would then be deployed by pharmaceutical companies to promote public health in the United States and abroad through knowledge transfer, donation

[148] Pedraza-Fariña, *supra* note 27.
[149] Jayashree Watal, *Improving Global Governance of Pandemic Response: Lessons from COVID-19*, Chapter 10 this volume.
[150] Calvin Ho, *Capability Approach to Developing Global Health Initiatives for Equitable Access to Vaccines*, Chapter 8 this volume.

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of medical products, construction of facilities, training of professionals, and facilitating public health education.[151]

G *Colonial Hangovers: From Dependency to Capacity Building*

Olufunmilayo Arewa (Chapter 14) offers a powerful call to look beneath vaccine apartheid at deeper levels of "colonial hangover" and "double marginalization" that create and perpetuate poverty, dependency, and restricted capacity for knowledge production in Africa. Among the colonial hangovers that Arewa identifies are poor health systems as a result of extractive colonial policies, absence from decision-making fora where rules are made by others for others and at Africa's expense, and further victimization from loss of tourism revenues due to racially discriminatory travel bans.[152]

Arewa's contribution to this volume is part of a growing recognition of the "coloniality of global public health," to use Eugene T. Richardson's phrase in his recent book, *Epidemic Illusions*.[153] Richardson's book, like Arewa's chapter, situates global public health within a framework of structural racism from colonial to postcolonial times. In the introduction to that book, the late public health expert Paul Farmer acknowledges the role that "Northern institutions play . . . in perpetuating global health inequalities,"[154] writing that "global health inequality – and the noxious ideologies that have been the blueprint for it – have marred most colonial and postcolonial efforts to address epidemic disease."[155] Richardson writes that only "breaking up the Global North's monopoly on truth will transform global health by transforming its representations."[156] In the case of IP and COVID-19, the authors in this volume powerfully demonstrate how the status quo ideology of strong IP protections prevented critical sharing of knowledge during the first year of vaccine rollout, and that going forward, alternative paradigms must be adopted.

3 CONCLUSION

It is time to revisit the toxic marriage between IP and public health: in sickness and in health, till death do us part. The IP tradeoff – breakthrough innovation in exchange for monopoly rights that raise prices and decreases access – does not work in pandemic times. In a global pandemic, no one is safe unless everyone is safe.

[151] Haochen Sun, *Patent Philanthropy*, Chapter 6 this volume. *See also* HAOCHEN SUN, TECHNOLOGY AND THE PUBLIC INTEREST (2022).
[152] Arewa, *supra* note 15.
[153] EUGENE T. RICHARDSON, EPIDEMIC ILLUSIONS: ON THE CORONIALITY OF GLOBAL PUBLIC HEALTH (2020).
[154] *Id.*, at xviii.
[155] *Id.*, at xi.
[156] *Id.*, at 10.

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Widespread and equitable access to vaccines and the technology underlying them is a moral imperative because it saves millions of lives, and it is a public health and economic necessity. Moreover, vaccines, the tool for saving lives and ending a pandemic, are often the result of public–private partnerships, as markets alone do not incentivize these investments. Given significant public investments in vaccines, it is not appropriate that the know-how underlying these technologies should be trapped in private monopolies with pharmaceutical companies calling all the shots. Sharing life-saving technologies underlying pandemic vaccines is critical to boost vaccine production and to promote equitable access to vaccines in a timely fashion.

This volume offers a blueprint for a path forward to avert the tragic and entirely foreseeable inequity of vaccine distribution in the next pandemic. Doing better in the future will require sharing privately held know-how and making financial investments in technology transfer hubs to build knowledge and technical capacity for vaccine production in the Global South, including in Latin America, Asia, and Africa. Low- and middle-income countries must be able to stand on their own two feet and make vaccines for their own populations, rather than rely on an outdated charity model. Knowledge capacity building also requires retooling IP rules to spur and at times mandate technology transfer of know-how critical to vaccine production. This volume demonstrates that a cure to the ills of pandemics, and pandemic inequality, is possible and within reach.

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