**Intellectual Property, COVID-19, and the Next Pandemic:**

**Diagnosing Problems, Developing Cures**

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The protection of intellectual property (IP) is a question of life and death. Vaccines, partially incentivized by intellectual property, are estimated to have saved nearly 20 million lives worldwide during the first year of their availability in 2021.[[3]](#footnote-3) The vast majority of the benefit of this life-saving technology, however, went to high and upper-middle income countries.[[4]](#footnote-4) Paradoxically, intellectual property may also be partly responsible for millions 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% of deaths in low-income countries could have been averted if just 20% 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 regrettably notes, however, “[d]ue to vaccine shortfalls, these targets were not achieved by the end of 2021”[[5]](#footnote-5) and substantial numbers of deaths in the poorest nations were not averted as they were in rich countries.

What accounts for the COVID-19 vaccine shortfall in the poorest countries during the critical first year of the availability of COVID-19 vaccine? Despite the benefits of vaccine development and distribution to high and middle-income countries, 2021 proved to be “the lost year” during which millions of lives in low-income countries could have been saved, virulent variants of COVID-19 could have been stemmed, and the length of the global pandemic could have been shortened. The *Lancet* study, while acknowledging “the considerable uncertainty inherent in estimating vaccine impact,”[[6]](#footnote-6) 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.”[[7]](#footnote-7) 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 and for worse, in the world’s response to the COVID-19 pandemic, intellectual property looms as a central figure.

This volume begins to diagnose the role of intellectual property during the COVID-19 pandemic. The analyses in the volume make plain: while the promise of monopoly rights in breakthrough technology helps incentive 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 inequity 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”[[8]](#footnote-8) in early 2020 when the U.S. failed to contain the coronavirus’ spread. This volume demonstrates that the global intellectual property system bears some of the blame for a “lost year” of COVID-19 deaths and devastation.

The role of intellectual property 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.[[9]](#footnote-9) There remains considerable debate about the positive as well as negative role of intellectual property in pandemics. Is IP’s role limited to development of breakthrough drugs, but not their distribution? We readily accept IP’s goal to promote efficiency, but does IP also have an obligation to promote equity? We should pay attention to issues of distributional justice in intellectual property law.[[10]](#footnote-10) This volume seeks to broaden our understanding of the implications of intellectual property in life-saving technologies, from vaccines to diagnostics and therapeutics, during a global pandemic.

The volume first takes up diagnosis: what role did intellectual property play during the COVID-19 pandemic? We celebrate the role of intellectual property 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 patents 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.”[[11]](#footnote-11)

While the development of COVID-19 vaccines is a success story, the distribution of COVID-19 vaccines is not. Of seven 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. Less than four percent of people in low-income countries received the jab by the end of 2021. 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% of people in low-income countries had been vaccinated with at least one dose, in stark contrast to 60% vaccinated in high-income countries.[[12]](#footnote-12) 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 intellectual property, and supply was limited to a few authorized manufacturers, supply could not keep pace with demand and poor 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.[[13]](#footnote-13) The result was vaccine apartheid. In the words of U.N. Secretary General António Guterres, “we passed the science test” but received “an F in ethics.”[[14]](#footnote-14)

 Intellectual property is implicated in the choked supply of COVID-19 vaccines, particularly during the crucial first year of the vaccines’ availability in 2021.[[15]](#footnote-15) It was not the only constraint. A few factors help explain the inequitable access to the poorest countries in the world during that time. This book identifies several converging practices, including vaccine nationalism and vaccine diplomacy, and “colonial hangovers”[[16]](#footnote-16) of poor health infrastructure in low-income countries, to use Funmi Arewa’s phrase in this volume. This volume illuminates the complex factors that contributed to the inequitable distribution of COVID-19 vaccines. But unquestionably, the refusal 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, who were at the back of line waiting in vain for doses to be donated and delivered during much of 2021.

This volume critically assesses the role of intellectual property in pandemic times through lessons learned from the COVID-19 pandemic. 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-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 intellectual property be reformed now to prepare for a future pandemic?  The volume chronicles the history and lessons learned with respect to intellectual property during the COVID-19 pandemic and makes recommendations for how retooling intellectual property may offer a cure as the world prepares for the next pandemic.

The volume builds on a virtual [conference](http://www.covidip.hku.hk) 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 intellectual property alone incentivize timely development of life-saving vaccines? Will donations and philanthropy without significant reform to international intellectual property 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) intellectual property 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-intellectual property protections over vaccine technology?[[17]](#footnote-17) What are the future opportunities and challenges for local vaccine manufacturing in Africa and other low-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 misguided reliance on intellectual property rights and 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 & development. Going further, the volume offers concrete suggestions for reform, including delinking vaccine development from monopoly rights in technology, enhanced legal requirements under national and international law for sharing publicly funded technologies in pandemic times, and funding by rich nations to former colonies to build local vaccine manufacturing capacity in low and middle-income countries, including in Africa.

1. The Diagnosis: Intellectual Property’s Role in the Covid-19 Pandemic
2. Vaccine development: fruits of public-private partnership, but who calls the shots?

The development of revolutionary COVID-19 vaccines has been hailed as an intellectual property success story. Pharmaceutical companies like Moderna and Pfizer argue that patents and other intellectual property protections in their groundbreaking mRNA technology were the essential 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 & 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 to the pandemic. Operation Warp Speed funds, plus additional U.S. 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 & development, including costly clinical trials, and advance-purchase orders.[[18]](#footnote-18) While 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.[[19]](#footnote-19)

Companies like Moderna also benefited enormously from publicly funded research supported by the National Institutes of Health (NIH).[[20]](#footnote-20) Dr. Barney Graham’s team at NIH rapidly redeployed technology they were working on after China published SARS-cov-2 genetic data in January 2020, and quickly shared their work with their partners at Moderna to manufacture a vaccine ready to submit for government-funded clinical trials. The Moderna vaccine research was almost entirely funded by the U.S. government. The U.S. 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.[[21]](#footnote-21) India’s first homegrown COVID-19 vaccine, Covaxin, was the result of public-private partnership between Bharat Biotech and the taxpayer-funded Indian Council of Medical Research.[[22]](#footnote-22)

In fact, the singular reliance on intellectual property may be more to 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 surprising for vaccine manufacturers. As leading public health scholar and global activist Lawrence Gostin writes in this volume, “The intellectual property system does not generally incentivize companies to produce vaccines or medicines intended for small or uncertain markets.”[[23]](#footnote-23) 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.[[24]](#footnote-24) In his contribution to this volume, focusing on cures to the legal innovation infrastructure for pandemics, Gostin makes the case to “overcome market disincentives through targeted financing and partnerships.”[[25]](#footnote-25) Decades of experience well before the pandemic teach that for vaccine production, we cannot rely on intellectual property 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.

Thus, the breakthrough COVID-19 vaccines are, in fact, a poster child for public-private partnerships in areas critical to public health, such as 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 National Institutes of Health had invested over $17 billion on vaccine research between 2000 and 2019 that served as critical to the breakthrough COVID-19 vaccines.[[26]](#footnote-26) 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.”[[27]](#footnote-27) The authors of the study recognize that following the money is key to understanding 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 understanding 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 like Moderna announced they would not enforce their patents on the mRNA vaccine,[[28]](#footnote-28) generic companies were unable to manufacture the vaccines themselves for fear of violating Moderna’s other intellectual property rights and without critical “know-how” from Moderna, which still held essential knowledge under lock and key in the form of tacit knowledge and trade secrets. Companies like 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 shot to compel companies to share technology with more manufacturers to ramp up production of life-saving shots. Several authors in this volume describe the failure of the U.S. government to have either required technology transfer as a precondition of receiving public funds, 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. These authors recommend reforms that would more effectively foster technology transfer that is critical to increase supply of life-saving technologies. We turn to the colossal failure to equitably distribute COVID-19 vaccines next.

1. 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 world health organizations imagined a way out of this dilemma. 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 COVID-19 Vaccines Global Access (COVAX) facility.[[29]](#footnote-29) COVAX would have rich countries pledge funds to pool vaccine purchases that would be targeted to low-income countries. The goal was for COVAX to pool funds from rich countries to enable COVAX 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% 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,[[30]](#footnote-30) and low-income countries fell tragically behind in vaccinations. Rich countries rushed to make advanced purchases of jabs directly from vaccine producers like Moderna and Pfizer, with some countries, like Canada, procuring enough doses to vaccinate their population many times over.[[31]](#footnote-31) The well-planned, equitable approach COVAX leaders imagined gave way instead to vaccine nationalism and hoarding. Rather than honor their pledges to fund COVAX and help ensure that the most vulnerable patients around the world would be vaccinated first, vaccine nationalism ruled the day, with rich countries buying enough doses to vaccinate their entire adult populations with two and even third “booster” shots. Companies like Moderna and Pfizer, which closely 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 first to wealthy countries and regions such as the U.S., EU nations, and Israel, which paid $20 to $30 per dose. These same companies had no market incentive to ramp up manufacture for shots for poor countries who 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, 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.

Many have opined on why COVAX failed. Public health scholars Matt Kavanagh and Renu Singh in this volume offer a scathing critique of COVAX’s “demand-side model” built on private property and market-based tools.[[32]](#footnote-32) Kavanagh and Singh lay the blame on COVAX’s reliance on the status quo with respect to strong intellectual property rights for corporations.[[33]](#footnote-33) 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 intellectual property rights in vaccines, imposing no obligations on companies to share their knowledge and relying instead on the largess 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 World Health Organization (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.[[34]](#footnote-34)

In the end, waiting for voluntary funding (by wealthy countries) or voluntary sharing of technology (by pharmaceutical companies) was in vain. Kavanagh and Singh argue that the COVAX approach premised on intellectual property and philanthropy was flawed from the start, given underlying political and market pressures. As Kavanagh and Singh write, “failure of the demand-focused/voluntary paradigm to secure equity was foreseeable and foreseen.”[[35]](#footnote-35)

Most notably, because COVAX did not alter the status quo rules of intellectual property, companies like Moderna and Pfizer had no market incentive nor were they legally compelled to license their technologies to more manufacturers to increase global vaccine supply. Going forward, Kavanagh and Singh advocate instead for a “supply-side model” that would legally compel the sharing of knowledge and the pooling of intellectual property in life-saving vaccines that are critical to ending a pandemic, including internationally binding commitments to share know-how. A critical lesson of COVAX 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.

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.”[[36]](#footnote-36) Had they been at the table, representatives from low-income countries may have pushed back on the intellectual property-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 intellectual property 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.[[37]](#footnote-37) 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.”[[38]](#footnote-38) Botswana’s President Mokgweetsi Masisi judged Covax as “just a scam” that had “overpromised and underdelivered.” “Covax has disappointed Africa,” Winnie Byanyima, executive director of UNAIDS, concluded.[[39]](#footnote-39) Arewa in this volume characterizes the absence or marginalization of low-income country representation in global governance institutions as a continuing form of colonialism. The COVAX property-philanthropy model forced low-income countries into a state of dependence upon rich countries and property-owning corporations.

Yet equitable access to medicines in a pandemic is both a human rights issue and a pragmatic one: no one is safe unless everyone is safe. We turn now to alternative approaches to global intellectual property and public health in pandemic times advocated by low and middle-income countries. Most of these countries prefer a global public goods approach that sees publicly funded vaccines, and other life-saving technologies, such as masks, diagnostic tests, and drug treatments, as necessary goods that must be made widely available in pandemic times to save human life and to end a pandemic. This approach rejects monopoly rights on life-saving knowledge during the emergency of a pandemic, focusing on the need to massively scale up equitable supply and distribution of goods. Thus far, this alternative voice has failed, partly due to structural disempowerment in yet another global governance institution focusing on intellectual property: the World Trade Organization.

C. The Failure of Institutions: The Rise and Demise of the WTO IP Waiver

In contrast to the donation/philanthropy approach of COVAX that would leave intellectual property protections in place, in the World Trade Organization (WTO), low- and middle-income countries led an alternate effort to waive intellectual property 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.[[40]](#footnote-40) They proposed waiving the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part 2[[41]](#footnote-41) of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[[42]](#footnote-42) The 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 waiver, once adopted, would remain in place until widespread vaccination was in place globally and a majority of the world’s population had developed COVID-19 immunity.[[43]](#footnote-43)

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.[[44]](#footnote-44) 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.[[45]](#footnote-45) 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.[[46]](#footnote-46)

World leaders, policymakers, and scholars had high hopes for the IP waiver proposal, with more than 120 countries supporting it as of May 2021.[[47]](#footnote-47) Most notably, U.S. President Joe Biden issued a statement that month outlining his support for the proposal.[[48]](#footnote-48)

Proponents of the waiver claimed that it was a necessary response to the COVID-19 crisis.[[49]](#footnote-49) 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.[[50]](#footnote-50) Since December 2020 when the first COVID-19 vaccine was approved by the U.S. Food and Drug Administration, vaccine inequity had prolonged human suffering in many developing countries. While the U.S. and U.K. had already vaccinated roughly half their populations by early May 2021, vaccination rates in developing economies were significantly lower,[[51]](#footnote-51) with India having vaccinated just 9.4% of its population, and Asia and Africa’s overall vaccination levels standing at just 4.4% and below 1%, respectively.[[52]](#footnote-52) Worse still, owing to the extortionate prices charged by pharmaceutical companies, governments around the world have been paying 4 to 24 times more than they should for COVID-19 vaccines.[[53]](#footnote-53)

Despite the widespread support noted above, the European Union (EU) and Big Pharma vehemently opposed the IP waiver. These parties contested that intellectual property 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 issues have been a genuine barrier in relation to COVID-19-related medicines and technologies.”[[54]](#footnote-54) For their part, pharmaceutical companies alleged that IP protection had played an important role in incentivizing them to develop COVID-19 vaccines but disputed that IP had any role in the failed distribution effort. For example, 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.”[[55]](#footnote-55)

In June 2021, the EU submitted a counterproposal to the TRIPS Council, insisting that countries should take full advantage of the 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 EU, India, South Africa, and the US 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 waiver effects to vaccines alone, as requested by the U.S. [[56]](#footnote-56)

Based on the Quad proposal, the WTO Ministerial Conference adopted the Ministerial Decision on the TRIPS Agreement[[57]](#footnote-57) in June 2022. The Decision clarifies, among other things, three main existing flexibilities allowing developing countries to invoke compulsory licensing 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[[58]](#footnote-58) and without obtaining permission from the patent holders.[[59]](#footnote-59) 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.[[60]](#footnote-60)

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.[[61]](#footnote-61) 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. Worse still, as it is applicable only to the COVID-19 pandemic, the Decision does not deal proactively with public health emergencies caused by any future pandemics.

 D. India, the World’s Pharmacy, Fails to Deliver

At the start of the pandemic, India, long a model in designing intellectual property 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”[[62]](#footnote-62) in the race to vaccinate the world against COVID-19. One of the world’s largest suppliers of generic drugs[[63]](#footnote-63) and the largest supplier of generic drugs to Africa,[[64]](#footnote-64) the world was relying on India to play a critical role in COVID-19 vaccine production, especially for doses targeted for low- and middle-income countries. Before the pandemic, India was considered a “vaccine powerhouse”[[65]](#footnote-65) as a critical supplier of 60 percent of the world’s vaccines, targeted especially to low and middle-income countries.[[66]](#footnote-66) Experts estimated India had the capacity to produce 3 billion COVID-19 vaccines annually[[67]](#footnote-67)–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.[[68]](#footnote-68) Oxford-AstraZeneca licensed the Serum Institute of India, the world’s largest vaccine manufacturer by volume,[[69]](#footnote-69) 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.[[70]](#footnote-70) In addition to cosponsoring the IP waiver with South Africa at the World Trade Organization in October 2020, India embarked on a diplomatic strategy named “Vaccine Maitri” (maitri means friendship in Hindi) to donate COVID-19 vaccines to 44 low-income countries. India exported close to 60 million doses to 70 countries in the early months of 2021.[[71]](#footnote-71) Indian researchers and companies also developed a homegrown vaccine: Bharat Biotech in collaboration with the publicly-funded [Indian Council of Medical Research](https://en.wikipedia.org/wiki/Indian_Council_of_Medical_Research) developed India’s first indigenous COVID-19 vaccine, Covaxin.[[72]](#footnote-72) In early January 2021 Indian Prime Minister proudly boasted that “India is ready to save humanity.”[[73]](#footnote-73)

Within weeks of laying these plans, however, Indian pharmaceutical companies were struggling. The very week Modi declared India a hero, his government began placing export bans on Serum Institute, redirecting jabs to Indian citizens.[[74]](#footnote-74) 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.[[75]](#footnote-75) 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.[[76]](#footnote-76) Serum’s manufacturing was further slowed by export bans by the U.S. 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.[[77]](#footnote-77)

In the end, a confluence of factors were to blame for the stunning failure of the pharmacy to the developing world to deliver during the critical months of 2021.[[78]](#footnote-78) To begin with, the Indian government failed to purchase sufficient doses for its own population in advance (as the U.S. and EU had done nearly a year before effective vaccines were developed), leaving the country’s 1 billion-plus population woefully unprepared when it was suddenly hit with a deadly second wave in May 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, as well. Advanced purchase contracts and additional public funding to domestic manufacturers like 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 intellectual property and philanthropy rather than a shared knowledge approach that understood publicly funded vaccines as a global public good. Kavanagh and Singh argue in their chapter 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 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, who could then also drive-up vaccine price, the Indian government severely jeopardized access to 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, Serum Institute was unable to deliver to poor countries outside of India as promised, and no other manufacturers were given the recipe to do so instead.[[79]](#footnote-79) 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.”[[80]](#footnote-80) A central question is why India did not exploit all intellectual property flexibilities at its disposal to confront the COVID-19 pandemic. This is surprising given that India has long taken an aggressive approach to intellectual property and public health, walking a fine line between being TRIPS-compliant and promoting as widespread access as possible to life-saving technology through generics.

Intellectual property is critical to understanding what went wrong in India in 2021. At the same time, intellectual property 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 intellectual property 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 develop 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. 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. [[81]](#footnote-81)

The crucial fact is that under international intellectual property 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. Indian pharmaceutical companies produce over 90% 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 World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Agreement (TRIPS) in 1995. For the first time, intellectual property became tethered to the world trade system, which gave teeth to enforcement of international intellectual property 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 at 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. Notably, the Indian Patent Act of 2005 included the now famous Section 3(d), aimed at preventing abuses by patent holders who 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.[[82]](#footnote-82) The Supreme Court of India upheld this provision in the landmark judgment, *Novartis v. Union of Indi*a (2013).[[83]](#footnote-83) 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.[[84]](#footnote-84) The Indian Supreme Court has protected indigenous generic drug production and access to medicines in a number of other important rulings, as well.[[85]](#footnote-85)

The WTO IP 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 intellectual property 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 Asia-Pacific trade agreement that would have included India, China, South Korea, Japan, Australia, New Zealand, and the Association of Southeast Asian Nations (ASEAN)[[86]](#footnote-86) and reset the rules of intellectual property for Asia in the 21st 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.[[87]](#footnote-87) 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 intellectual property infrastructure to promote life over property for half a century, tragically did not exercise all the flexibilities at its disposal when it mattered most.

 E. China Affirms Intellectual Property + Philanthropy

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

In his chapter in this volume, 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”[[88]](#footnote-88) 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 U.S., the EU, Japan, and South Korea) on one side, and low and middle-income countries on the other.[[89]](#footnote-89) Notably, China’s role in the TRIPS Waiver debate remains consistent with the role it has played in earlier transnational negotiations involving intellectual property and public health. In 2018, China and India were among key powers negotiating the Regional Comprehensive Economic Partnership Agreement (RCEP), a trade agreement for the Asia-Pacific region that, with both countries involved, would have governed intellectual property rules for half the world’s population. As Anupam Chander and Madhavi Sunder argued in 2018, China remained neutral during contentious negotiations involving public health and intellectual property provisions in the RCEP, letting India go toe-to-toe with pharmaceutical powerhouses South Korea and Japan over public health provisions.[[90]](#footnote-90) China did not veer from this steady position during the COVID-19 pandemic. China neither threw its weight behind India and South Africa’s proposed IP Waiver, nor did it openly oppose the waiver.

As Yu describes in his contribution to this volume, China’s neutral approach to the waiver advanced several China’s long term and short-term goals. Yu explains China’s neutral stance on several factors, from China’s ambition to become a powerhouse of indigenous innovation, to its growth into a leading developer of pharmaceutical intellectual property, to the soft power benefits to China from vaccine diplomacy with its poor neighbors. Yu predicts these factors will lead China to continue to pave a middle road in ongoing debates around intellectual property and public health that does not upset the foundations of international intellectual property regimes.

Yu identifies China’s “growing ambition to become an intellectual property power” as a primary reason why China 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.”[[91]](#footnote-91) 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 for regulatory delays and data exclusivity that would push off the entry of generic drugs. As Yu concludes, China’s “ambition in the intellectual property 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.”[[92]](#footnote-92)

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 U.S.[[93]](#footnote-93) Most notably, China successfully manufactured homegrown COVID-19 vaccines, CoronaVac and Sinopharm, and had the capacity to manufacture enough for domestic as well as export markets.[[94]](#footnote-94)

China’s primary means of promoting public health for the global poor has been through pandemic diplomacy, including significant donations of “masks, ventilators, vaccines, and other supplies.”[[95]](#footnote-95) 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.”[[96]](#footnote-96) China’s pandemic diplomacy efforts are consistent with its Belt and Road Initiative to ambitiously expand global infrastructure trade belts affecting some 150 countries.[[97]](#footnote-97) 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.”[[98]](#footnote-98) 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.”[[99]](#footnote-99) 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.”[[100]](#footnote-100) 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”[[101]](#footnote-101) initiative might include more robust 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 intellectual property rules. That China’s intellectual property 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 like 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 intellectual property position would align more closely with that of the global South.”[[102]](#footnote-102) As Yu concludes, “China now takes policy positions that align more closely with those of developed countries than those of developing countries.”[[103]](#footnote-103)

1. The Cure: Spurring Technology Transfer to Promote Supply, Access, and Agency

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. Primarily, reforms focus on legally mandated mechanisms to spur technology transfer to low and middle-income vaccine manufacturers, given the failure of voluntary mechanisms during the COVID-19 pandemic. 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.

Perhaps one of the most disappointing results of the much-awaited WTO Ministerial Decision regarding an IP waiver in June 2022 was the missed precious opportunity to adopt a long-term approach to reforming two major structural problems with the international IP protection system. Taking full advantage of the problems exposed by the COVID-19 pandemic, the WTO should have called for the establishment of new global mechanisms to expedite the export of medicines and vaccines from a country with manufacturing capacities to another without such capacities and to gradually boost developing countries’ innovation and manufacturing capacities through the robust transfer of technologies. We outline here a host of strategies considered in this volume that national governments and international institutions must collaborate on together in the coming years to be better prepared 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 – continues to be the key to both equitable access and distribution of vaccines during a pandemic, and broader equity in public health for low- and middle-income countries. Many of the contributors to this volume propose important, and practicable, reforms for enhancing mechanisms of technology transfer. Peter Lee 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 U.S. patent 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.[[104]](#footnote-104)

Sapna Kumar and Ana Santos Rutschmanpropose an *ex-ante* approach to tackling drug scarcity and argue that governments should integrate pandemic planning into contracts used to fund medical research. Governments should require pandemic funding recipients to assure that any resulting drug will be made available in sufficient quantity. 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.[[105]](#footnote-105)

Kavanagh and Singh advocate internationally binding commitments to the sharing of know-how, including mechanisms to encourage compliance with a built-in expectation of national self-interest.[[106]](#footnote-106)

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.[[107]](#footnote-107) 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 set up an Article 66.2 reporting system that requires developed countries to submit detailed reports every three years and annual reports updating their detailed reports.[[108]](#footnote-108) To date, however, the system has proved itself to lack sufficient teeth to ensure developed countries’ compliance with their Article 66.2 obligation.[[109]](#footnote-109) The mere act of submitting a report does not necessarily mean that a developed country’s self-assessment has rendered it compliant with the 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.[[110]](#footnote-110) Therefore, the transfer of technology from developed countries to LDCs has been described as “lackluster” by both least-developed country members and WTO officials.[[111]](#footnote-111)

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 least-developed countries’ capacity in manufacturing medical products.[[112]](#footnote-112)

The COVID-19 pandemic has clearly demonstrated the urgent need to establish such a global mechanism, thereby providing the international community with a 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 LDCs 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.[[113]](#footnote-113) 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.”[[114]](#footnote-114) 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.[[115]](#footnote-115)

Taking a different tack on the issue of technology transfer, Laura Pedraza-Fariña argues in this volume 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.[[116]](#footnote-116)

1. 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 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 its undertaking process, but also because of the burdensome requirements, challenge of recovering expenditures, and resulting lack of incentives for generic manufacturers.[[117]](#footnote-117) 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.[[118]](#footnote-118) The challenge of achieving economies of scale in countries with little manufacturing capacity presents further obstacles, as these countries are usually small in size.[[119]](#footnote-119) Therefore, the Article 31*bis* mechanism remains in limbo because few countries have revised their domestic laws to activate it.[[120]](#footnote-120) Since its introduction in 2003, the mechanism has been used only once.[[121]](#footnote-121) That sole instance involved collaboration between Rwanda as the importing country and Canada as the exporting country for the antiretroviral drug Apo-TriAvir.[[122]](#footnote-122) It took the Canadian generic company Apotex *three* years to supply this much-needed medicine.[[123]](#footnote-123)

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% 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.[[124]](#footnote-124) 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 for treating a COVID-19 infection.[[125]](#footnote-125) 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 the 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.[[126]](#footnote-126) In the last quarter of 2022, there is an oversupply of COVID-19 vaccines internationally.[[127]](#footnote-127) 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 the COVID-19 pandemic and any future public health crisis. We must render compulsory licensing more capable of achieving the swift export of medicines and vaccines. In the case of chronic diseases such as HIV/AIDS, people waited years for the arrival of effective medicines, which is why the Article 31*bis* mechanism still offers some hope. However, most public health crises are caused by highly transmissible viruses for which effective medicines and vaccines are lacking. Too many people have died during the COVID-19 pandemic because of a lack of medicines and/or vaccines.

1. Fostering local manufacturing capacity.

William Fisher and Ruth Okediji in this volume demonstrate the critical need for boosting developing countries’ local manufacturing capacity, and outline a strategy to achieve this goal, from building a domestic legal infrastructure to regulate and support local drug production, to government purchasing of medicines and vaccines, technology transfer through apprenticeship, robust quality-control, and capitalizing on the economic and political power of regional economic communities in Africa, Latin America, and Asia.[[128]](#footnote-128)

D. Reforming International Institutions.

Acknowledging the failures of the best laid plans to avoid vaccine inequity in the Covid-19 pandemic, Jayashree Watal argues in this volume for an effective implementing agency to reduce vaccine inequity through the procurement and distribution of existing and projected manufacturing output.[[129]](#footnote-129) Calvin Ho in this volume suggests means of strengthening cooperation among key international organizations (particularly the World Health Organization, the World Trade Organization and the World Intellectual Property Organization), and influential private actors operating at the coalface through initiatives like ACT-A.[[130]](#footnote-130)

1. ESG and human rights obligations of pharmaceutical companies.

Haochen Sun proposes 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% 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 of medical products, construction of facilities, training of professionals, and facilitating public health education.

1. Colonial Hangovers: From Dependency to Capacity Building

Funmi Arewa in her contribution in this volume 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 the result of extractive colonial policies, absence from decision making 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.

**Conclusion**

It is time to revisit the toxic marriage between intellectual property and health: in sickness and in health, till death do us part. The patent tradeoff–breakthrough innovation in exchange for a twenty-year monopoly that raises prices and decreases access–does not work in pandemic times. Vaccines, the workhorse 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 promote equitable access to vaccines in a timely fashion. In a global pandemic, no one is safe unless everyone is safe. Widespread and equitable access to vaccines is a moral imperative because it saves millions of lives. Equitable vaccination is also key to stemming new variants and to the wellbeing of the global economy. As late public health expert Paul Farmer and Sister Simone Campbell wrote in May 2021, “Only a people’s vaccine that is accessible to all will end the pandemic.”[[131]](#footnote-131)

1. Frank Sherry Professor of Intellectual Property Law and Associate Dean for Graduate and International Programs, Georgetown University Law Center. [↑](#footnote-ref-1)
2. Professor of Law, University of Hong Kong Faculty of Law. [↑](#footnote-ref-2)
3. Oliver J. Watson, et al., Global Impact of the First Year of Covid-19 Vaccination: a Mathematical Modelling Study, *The Lancet* 1293 (Sept. 2022) (published online June 23, 2022). [↑](#footnote-ref-3)
4. *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). [↑](#footnote-ref-4)
5. *Id*. [↑](#footnote-ref-5)
6. *Id.* at 1300. [↑](#footnote-ref-6)
7. *Id.* at 1300-1301. [↑](#footnote-ref-7)
8. Grant Hindsley, The Lost Month: How the Failure to Test Blinded the U.S. to Covid, NY Times, March 2022. [↑](#footnote-ref-8)
9. *See* Sheryl Gay Stolberg et al., Pressure Mounts to Lift Patent Protections on Coronavirus Vaccines, N.Y. Times, May 17, 2021. [↑](#footnote-ref-9)
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11. Yasmeen Abutalub et. al., How the ‘Deep State’ Scientists Vilified By Trump Helped Him Deliver an Unprecedented Achievement, Washington Post, Dec. 14, 2002. [↑](#footnote-ref-11)
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