2023

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

Madhavi Sunder
Georgetown University Law Center, ms4402@georgetown.edu

Haochen Sun
University of Hong Kong Faculty of Law

Harvard International Law Journal Online.

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

Nov 8, 2023 | Content, Online Scholarship, Perspectives

Madhavi Sunder and Haochen Sun*

Editors' Note: Although HILJ Online: Perspectives *typically publishes short-form scholarship, we occasionally publish exceptional longer pieces such as this one.*

Introduction

Protecting intellectual property (IP) is a question of life and death.[1] 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.[2] However, most of the benefits of this life-saving technology went to high- and upper-middle-income countries.[3] Despite 10 billion vaccines being 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 an 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. IP is implicated in the choked supply of COVID-19 vaccines in low-income countries, particularly during the crucial first year of the vaccines' availability in 2021.[4]

This Article first diagnoses how the IP system bears some blame for a "lost year" of COVID-19 deaths and devastation in 2021. 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. This Article diagnoses a number of causes for the inequitable distribution of life-saving COVID-19 vaccines, from misguided reliance on IP rights and voluntary mechanisms to share knowledge and vaccines, to the rise of vaccine nationalism and vaccine diplomacy, to unequal global IP institutions that disenfranchise low-income countries and continue to reproduce colonial era dependency by poor countries on high-income nations' for life-saving technologies. Ultimately, unequal access to life-saving vaccines during the COVID-19 pandemic wreaked untold havoc on human lives and the global economy. Glaring inequity in global 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.

In response to the diagnosis, this Article develops cures to promote a timely and equitable supply of critical medicines in the next pandemic. As the WHO draft Pandemic Treaty recognizes, there is a critical "need to establish a future pandemic prevention, preparedness and response mechanism that is not based on a charity model."[5] This Article suggests several reforms to prevent such inequity in the next pandemic, including delinking vaccine development that depends on public funding from monopoly rights in technology, enhanced legal requirements to share publicly funded technologies in pandemic times, and investment in technology transfer hubs and local vaccine manufacturing capacity in low- and middle-income countries. We further suggest reforming the IP system to create a robust global technology transfer mechanism and to stimulate faster sharing of patented medicines and vaccines.

I. "The Lost Year" of COVID-19 Deaths

Paradoxically, IP may 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 could not 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 regrettably, however, "[d]ue to vaccine shortfalls, these targets were not achieved by the end of 2021,"[6] and substantial numbers of deaths in the poorest nations were not averted as in rich countries.

What accounts for the COVID-19 vaccine shortfall in the poorest countries during the critical first year of the availability of the 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 hundreds of thousands 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,"[7] 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."[8] IP was hardly the only roadblock to a global vaccination campaign in the pandemic response. *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, IP looms as a central figure.

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.[9] There remains considerable debate about IP's positive and negative role in pandemics. Is IP's role limited to developing 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 IP law.[10] This Article seeks to broaden our understanding of the implications of IP in life-saving technologies, from vaccines to diagnostics and therapeutics, during a global pandemic.

While the development of COVID-19 vaccines is a success story, the distribution of COVID-19 vaccines is not. Of 7 billion vaccines administered globally by late 2021, approximately a year after the vaccines were developed, over 70 percent of shots had gone to high-income countries. Less than 4 percent of people in low-income countries received the shot 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 percent of people in

low-income countries had been vaccinated with at least one dose, starkly contrasting 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, when the critical time came, wealthy country governments instead 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. Vaccine nationalism became the rule. And because the vaccines were protected by IP supply was limited to a few authorized manufacturers, supply could not keep pace with demand, and low-income 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 U.N. Secretary-General António Guterres, "we passed the science test" but received "an F in ethics."[13]

II. 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 like Moderna and Pfizer argue that patents and other IP protections in their groundbreaking mRNA technology were essential 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 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 launched "Operation Warp Speed" in early 2020, a public-private partnership to hasten the development, manufacturing, 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 pandemic. Operation Warp Speed funds, plus additional American taxpayer funding, included $1.5 billion for Johnson & Johnson, $1.2 billion for Oxford-AstraZeneca, and $2.48 billion for Moderna. These funds were for research and development, including costly clinical trials and advance purchase orders.[14] 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.[15] Companies like Moderna also benefited enormously from publicly funded research supported by the National Institutes of Health (NIH).[16]

Public-private partnership is the rule, not the exception, when it comes to vaccine development. As leading public health scholar Lawrence Gostin writes, "[t]he intellectual property system does not generally incentivize companies to produce vaccines or medicines intended for small or uncertain markets."[17] Developing new vaccines can cost billions of dollars and take several years, with no promise of return on investment, especially for diseases primarily afflicting populations in low-income countries.[18] Focusing on cures to the legal innovation infrastructure for pandemics, Gostin makes the case to "overcome market disincentives through targeted financing and partnerships."[19] Decades of experience well before the pandemic teach that we cannot rely on IP alone for vaccine production, 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.[20]

The breakthrough COVID-19 vaccines demonstrate the critical role of public-private partnerships in vaccine development. Patents incentivize pharmaceutical companies to innovate certain drugs that serve those who can afford to pay. But publicly-funded university and government research, alongside public-private partnerships, are key for vaccines that address uncertain diseases and often in low-resource settings. 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, which was critical to the breakthrough COVID-19 vaccines.[21] 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."[22]

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 for this technology. As we explore further, even though companies like Moderna announced they would not enforce their patents on the mRNA vaccine,[23] generic

companies were unable to manufacture the vaccines themselves for fear of violating Moderna's other IP rights and because the generic producers lacked critical "know-how" from Moderna, which still held essential knowledge of how to safely and effectively make the vaccines 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, leading 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. 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. Now, we continue analyzing what went wrong during the COVID-19 pandemic, turning next to the colossal failure to distribute COVID-19 vaccines equitably.

B. Vaccine Distribution: Failure of Philanthropy

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, and Seth Berkley, the head of the Vaccine Alliance, or Gavi, brainstormed and established the COVID-19 Vaccines Global Access (COVAX) facility.[24] COVAX would have rich countries pledge funds to pool vaccine purchases 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 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.

Ultimately, COVAX did not achieve even half its goal,[25] and low-income countries fell tragically behind in vaccinations. Rich countries rushed to make advanced purchases of shots directly from vaccine producers like Moderna and Pfizer, with some countries, like Canada, procuring enough doses to vaccinate their population many times over.[26] The well-planned vaccine diplomacy COVAX leaders imagined gave way instead to vaccine nationalism and hoarding.

Companies like Moderna and Pfizer, which closely held critical knowledge about mRNA vaccine production through patents and tacit knowledge or "know-how," licensed only a handful of manufacturers to produce vaccines. The limited supply raised the prices of the vaccines, and the drug companies catered almost exclusively[27] to wealthy countries and regions such as the United States, the EU, and Israel. These same companies had no market incentive to ramp up manufacturing for shots for low-income

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 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.

Many have opined on why COVAX failed. Public health scholars Matt Kavanagh and Renu Singh have offered a scathing critique of COVAX's "demand-side model" built on private property and market-based tools.[28] Kavanagh and Singh blame COVAX's reliance on the status quo concerning strong IP rights for corporations.[29] This market-based approach ignored the public investment in vaccine development and the critical public interest in equitable vaccine access to end a pandemic where 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,[30] imposing no obligations on companies to share their knowledge and relying instead on the charity of rich countries to pool funds to purchase IP-protected vaccines for the poor, or on private pharmaceutical companies to transfer knowledge voluntarily.

Neither happened. Ultimately, waiting for voluntary funding (by wealthy countries) or voluntary sharing of technology (by pharmaceutical companies) was in vain. Most notably, because COVAX did not alter the status quo rules of IP, 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.

C. Failure of Technology Transfer of Critical Vaccine Production "Know-How"

The pandemic also demonstrated corporate actors' failure to voluntarily share critical trade secrets required to scale up the production of vaccines. Notably, even more than patents, 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 technology at play 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 the production of COVID-19 vaccines by generic producers. Effective and safe production of vaccines, in particular the new mRNA vaccines produced by Pfizer and Moderna, were not easily replicated with the patented formula alone but required affirmative sharing of corporate 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 technology access pool created by the World Health Organization known as C-TAP[31] 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.

In the end, waiting for voluntary funding or donations of doses (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 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. A critical lesson of COVAX and C-TAP is that in the early months of a pandemic, increasing the supply of vaccines is only accomplished by compelling technology transfer by companies holding the secrets to making life-saving vaccines. We discuss proposals for spurring technology transfer of know-how in Part IV.

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

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 now turn to an alternative approach to global public health in pandemic times outside of the IP system. Publicly funded vaccines and other life-saving technologies, such as masks, diagnostic tests, and drug treatments, are necessary goods that must be made widely available in pandemic times to save human lives and to end a pandemic. An alternative approach spearheaded by countries in the Global South rejects monopoly rights on life-saving knowledge during the emergency of a pandemic, focusing on the need to scale up equitable supply and distribution of goods massively. Thus far, this alternative has failed, partly due to structural disempowerment in yet another global governance institution focusing on IP: the World Trade Organization (WTO).

In contrast to the philanthropy approach 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 in 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.[32] They proposed waiving the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part 2[33] of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[34] The waiver proposal was unprecedented in the history of IP protection because it was intended to trigger a moratorium on protecting IP rights, including copyright and related rights, industrial designs, patents, and undisclosed information. Once adopted, the waiver would remain until widespread vaccination was in place globally and most of the world's population had developed COVID-19 immunity.[35]

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.[36] While some countries were in a position to overcome supply issues by manufacturing their 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.[37] 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.[38]

World leaders, policymakers, and scholars had high hopes for the IP waiver proposal, with more than 120 countries supporting it as of May 2021.[39] Most notably, American President Joe Biden issued a statement that month outlining his support for the proposal.[40]

Proponents of the waiver claimed it was a necessary response to the COVID-19 crisis.[41] 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.[42] Since December 2020, when the United States Food and Drug Administration approved the first COVID-19 vaccine, vaccine inequity has prolonged human suffering in many developing countries. While the United States and the United Kingdom had already vaccinated roughly half their populations by early May 2021, vaccination rates in developing economies were significantly lower,[43] 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.[44] Worse still, owing to the extortionate prices charged by pharmaceutical companies, governments worldwide purchased COVID-19 vaccines at prices up to 24 times the estimated cost of production.[45]

Despite the widespread support noted above, the European Union (EU) and Big Pharma vehemently opposed the IP waiver. A much smaller group of high-income countries contested that IP played a significant role in stunting the manufacture and distribution of vaccines in 2021. At a TRIPS Council meeting, the EU asserted that "there is no indication that IPR issues have been a genuine barrier to COVID-19-related medicines and technologies."[46] Pharmaceutical companies acknowledged that IP protection had been important in incentivizing them to develop COVID-19 vaccines. However, they disputed that IP had any role in the failed distribution effort. In expressing his objections to the IP waiver, Pfizer's CEO claimed that while a sizeable company like his would continue to invest in science, he was unsure "if the same is true for the thousands of small biotech innovators that are dependent on accessing capital from investors who invest only on the premise that their intellectual property will be protected."[47]

In June 2021, the EU submitted a counterproposal to the TRIPS Council, insisting that countries take full advantage of the compulsory licensing scheme for patents 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 result was the "Quad" proposal, which adopted the compulsory licensing measures proposed by the EU and limited the waiver effects to vaccines alone, as requested by the United States.[48]

Based on the Quad proposal, the WTO Ministerial Conference adopted the Ministerial Decision on the TRIPS Agreement[49] in June 2022. The Decision clarifies, among other things, three primary existing flexibilities allowing developing countries to invoke compulsory licensing of patented technology under TRIPS Article 31 to contain the COVID-19 pandemic. First, eligible developing countries can expeditiously issue compulsory licensing orders to use patents (including patents on medical ingredients and production processes) necessary for producing COVID-19 vaccines without passing formal laws[50] and without obtaining permission from the patent holders.[51] Second, any eligible developing country can export COVID-19 vaccines produced through compulsory licensing to another eligible developing country. Third, eligible developing countries can also remunerate affected patent holders in lesser amounts because "the humanitarian and not-for-profit purpose" of vaccine production must be considered.[52] The Ministerial Decision also clarifies the ability of countries to access otherwise protected regulatory data under TRIPS 39.3 to promote expeditious vaccine approvals.[53]

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.[54] Lengthy negotiations lasting for nearly one year and eight months resulted only in clarifications of pre-existing TRIPS flexibilities that developing countries were already entitled to capitalize on, even without such clarifications. The waiver was limited to vaccines and did not include diagnostics and treatments, as India and South Africa initially proposed. Notably, the Ministerial Decision is limited to technology covered by patents and 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, as it applies only to the COVID-19 pandemic, the Decision does not proactively deal with public health emergencies caused by future pandemics.

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

It is critically important to go beyond a diagnosis of what went wrong to develop cures

to promote timely and equitable access to critical medicines necessary to save lives in the next pandemic. Given the failure of voluntary mechanisms during the COVID-19 pandemic, reforms proposed and canvassed here focus on mechanisms to spur technology transfer, including critical know-how and show how low- and middle-income country manufacturers can build capacity now so in the event of a future pandemic they may be self-sufficient and ready to produce vaccines and essential medicines themselves.

In particular, we recommend the following:

- *Strengthen technology transfer mechanisms*, including modifying the patent system to require greater disclosure of tacit knowledge and know-how related to the manufacturing of vaccines, diagnostics, and therapeutics; placing knowledge-transfer obligations on patentees receiving significant public funding through *ex-ante* contracts; and strengthening Article 66.2 of the TRIPS Agreement to ensure that developed countries fulfill their obligation to promote technology transfer to least-developed countries;
- *Establish a global mechanism for monitoring* a*nd assessing technology transfer* to measure whether developed countries are effectively incentivizing technology transfer to least-developed countries;
- *Foster local manufacturing capacity*, including facilitating the sharing of tacit knowledge and financing regional technology transfer hubs; and
- *Facilitate faster sharing of medicines and vaccines* protected by patents by amending TRIPS flexibilities to enable the expedited export of medicines and vaccines from countries with manufacturing capacity to those without during public health crises. Amendments must address the complexities and limitations of the existing compulsory licensing system and make it more effective and efficient.

Technology transfer cannot wait until the next pandemic. This process must begin 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.

A. Strengthening Technology Transfer Mechanisms

Enhancing mechanisms of technology transfer is key to equitable access and distribution of vaccines during a pandemic. Peter Lee has described the current 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 American patent rules exclude from protection 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* model 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.[55] Sapna Kumar and Ana Santos Rutschman similarly propose an *ex-ante* approach, arguing that governments and non-governmental funders should integrate pandemic planning into contracts used to fund medical research, for example, through dormant licenses that would be triggered in the event of drug shortages in a pandemic. The licenses would require recipients of public funding to assure that any resulting drug will be made available in sufficient quantity and at accessible prices. Recipients would also agree to share technology and know-how with a qualified third-party manufacturer in exchange for payment of royalties. As Kumar and Rutschman argue, by acting proactively, governments can reduce drug shortages during future pandemics and save lives.[56]

David Levine and Josh Sarnoff 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. Like Kumar and Rutschman, Levine and Sarnoff advocate for reasonable compensation to trade secret holders for compelled disclosure to promote access in some cases. In addition, they propose that sharing trade secrets may be encouraged with legislative nudges and incentives.[57] Others, like Kavanagh and Singh, advocate for internationally binding commitments to share know-how, including mechanisms to encourage compliance with a built-in expectation of national self-interest.[58]

Legal mechanisms to facilitate sharing are critical for vaccine distribution and also for vaccine development. Taking a different tack on the issue of technology transfer, Laura Pedraza-Fariña argues for the creation of legal infrastructure that allows and encourages sharing knowledge among researchers across multiple disciplines to nurture the "boundary-crossing innovation" necessary to cure complex diseases.[59]

B. Establish a Global Mechanism for Monitoring and Assessing Technology Transfer

In addition to these suggestions, 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 to promote and encourage technology transfer to least-developed country Members to enable them to create a sound and viable technological base." The 2001 WTO Ministerial Conference and subsequent Doha Declaration made it clear that this provision imposes a *mandatory* obligation on developed countries.

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 them.[60] However, the system lacks sufficient teeth to ensure developed countries' compliance with their Article 66.2 obligation.[61] 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 annual reports submitted, many of the programs reported by developed countries did not even target LDCs.[62] Therefore, the transfer of technology from developed countries to LDCs has been described as "lackluster" by both least-developed member states and WTO officials.[63]

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 the transfer of technologies that could boost the least-developed countries' capacity to manufacture medical products.[64]

The COVID-19 pandemic has 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 the transfer of soft and hard technologies.[64] The transfer of soft technologies, such as substantial know-how to LDCs, is necessary to boost the production of COVID-19 vaccines because vaccines are complex biological products heavily dependent on specific manufacturing processes and practices often not disclosed in a patent.[66] 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."[67] The cost and effort of reverse-engineering originator firm manufacturing processes have contributed to a history of delays in the entry of biosimilars into the market. In one recent case, Inovio even claimed in a court filing that its plan to expand the manufacturing scale of the experimental COVID-19 vaccine was being blocked by a supplier's refusal to share critical manufacturing information.[68]

C. Fostering and Financing Local Manufacturing Capacity

The reliance of much of the Global South on imports proved deadly. Going forward, we must move from a dependency model to build capacity for local vaccine production in critical regional hubs around the world, including Latin America, Asia, and Africa. William Fisher, Ruth Okediji, and Padmashree Gehl Sampath outline a multi-step strategy to foster local production capacity for vaccines and pharmaceuticals in the Global South, 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.[69]

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 hefty 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.[70] 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,[71] and Nigeria.[72] 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.[73]

The United States and other developed countries must give robust "financial and logistical" support to regional tech transfer hubs in Africa and elsewhere now. As Pedraza-Fariña explains, "know-how transfer, in particular when new technologies are involved, is notoriously tricky" and requires "learning-by-doing … [that] can only happen through immersive training" through, 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.[74] 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.

D. Facilitating Faster Sharing of Medicines and Vaccines through TRIPS

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 cannot 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.[75] 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.[76] Achieving economies of scale in countries with little manufacturing capacity presents further obstacles.[77] Therefore, the Article 31*bis* mechanism remains in limbo because few countries have revised their domestic laws to activate it.[78] Since its introduction in 2003, the mechanism has been used only once.[79] That sole instance involved collaboration between Rwanda as the importing country and Canada as the exporting country for the antiretroviral drug Apo-TriAvir. It took the Canadian generic company Apotex three years to supply this much-needed medicine, which is much too slow in the context of a pandemic.[80]

The COVID-19 pandemic 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.[81] Similarly, in Spring 2022, in the face of vehement opposition from Pfizer, the Dominican Republic declined to grant a compulsory licensing order to manufacture Paxlovid, Pfizer's patented medicine for treating COVID-19 infection.[82]

Although the Ministerial Decision seeks to accelerate the compulsory licensing process to enable developing countries to contain the COVID-19 pandemic, it has not fixed any 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 from being eligible beneficiaries of the Decision, the export permit is infeasible in practice. No other developing country can swiftly manufacture vaccines to meet the public health needs of another developing country.

Moreover, because the Decision applies 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.[83] In the last quarter of 2022, there was an oversupply of COVID-19 vaccines internationally.[84] What is badly needed are testing tools and treatment medicines in the many countries where people are vaccinated yet still become infected with COVID-19.

Against this backdrop, the international community should endeavor to create a global mechanism to facilitate faster sharing of patented medicines and vaccines to deal with the COVID-19 pandemic and any future public health crisis. We must enhance compulsory licensing to achieve the faster export of medicines and vaccines.[84] In the case of chronic diseases such as HIV/AIDS, people could wait years for effective medicines exported by countries that can take advantage of the Article 31*bis* mechanism. However, most public health crises are caused by highly transmissible viruses, creating an urgent need for life-saving medicines and vaccines.

Conclusion

It is time to revisit the toxic marriage between IP and health: in sickness and in health, till death do us part. The tradeoff–breakthrough innovation in exchange for monopoly rights that raise prices and keep critical know-how under lock and key–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 sufficiently 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 boosting vaccine production and promoting equitable access to vaccines in a timely fashion. Developing legal mechanisms for mandatory technology transfer in publicly-financed vaccines is critical now to help build local manufacturing capacity in the Global South so low- and middle-income countries are not again trapped in a state of dependence on the charity of the Global North. In a global pandemic, no one is safe unless everyone is safe. Widespread and equitable vaccine access is a moral imperative because it saves millions of lives. Equitable vaccination is also key to stemming new variants and promoting the global economy's well-being. As late public health experts Paul Farmer and Sister Simone Campbell wrote in May 2021, "Only a people's vaccine that is accessible to all will end the pandemic."[86]

---

* Madhavi Sunder is the Frank Sherry Professor of Intellectual Property Law at the Georgetown University Law Center. Haochen Sun is a Professor of Law at the University of Hong Kong Faculty of Law. The authors are grateful to Bill Alford, Mark Wu, and Peter Yu for comments, as well as to students at Harvard Law School and Texas A&M University Law School. Special thanks to Eva Bishwal for excellent research assistance.

[1] *See* Haochen Sun, Technology and the Public Interest 156-58 (2022).

[2] Oliver J. Watson et al., *Global Impact of the First Year of Covid-19 Vaccination: A Mathematical Modelling Study*, 22 The Lancet Infectious Diseases 1293 (2022).

[3] *Id.*

[4] *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*, 326 JAMA 219 (2021), https://jamanetwork.com/journals/jama/fullarticle/2781756; Matthew M. Kavanagh & Madhavi Sunder, *Biden Must Push Drug Firms To Share Science With the World*, BL (Apr. 23, 2021), https://news.bloomberglaw.com/health-law-and-business/biden-must-push-drug-firms-to-share-science-with-the-world; Matthew M. Kavanagh & Madhavi Sunder, *Poor Countries May Not Be Vaccinated Until 2024. Here's How To Prevent That*, Wash. Post (Mar. 10, 2021), https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-

rights-get-way-global-vaccination/.

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

[6] Watson et al., *supra* note 2.

[7] *Id.* at 1300.

[8] *Id.* at 1300-01.

[9] *See* Sheryl G. Stolberg et al., *Pressure Mounts to Lift Patent Protections on Coronavirus Vaccines*, N.Y. Times (May 17, 2021), https://www.nytimes.com/2021/05/03/us/politics/biden-coronavirus-vaccine-patents.html.

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

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

[12] Ali Sawafta & Rami Ayyub, *Palestinians Cancel Deal for Near-Expired COVID Vaccines from Israel*, Reuters (June 18, 2021), https://www.reuters.com/world/middle-east/israel-give-palestinians-1-million-covid-vaccine-doses-israeli-statement-2021-06-18/#:~:text=TEL%20AVIV%2C%20June%2018%20(Reuters,the%20PA%20health%20minister%20said.

[13] Michelle Nichols, *U.N. Chief Grades World on Vaccine Rollout: 'F In Ethics'*, The Guardian (Sept. 21, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/un-chief-grades-world-vaccine-rollout-f-ethics-2021-09-21/.

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

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

[16] Arthur Allen, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork,* Scientific American (Nov. 18, 2020), https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-

government-funded-science-laid-the-groundwork/.

[17] Lawrence O. Gostin, Global Health Security: A Blueprint for the Future 193 (2021).

[18] *Id.* at 194.

[19] *Id.*

[20] Sharon LaFraniere et al., *Politics, Science and the Remarkable Race for a Coronavirus Vaccine*, N.Y. Times (Nov. 21, 2020), https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html ("Moderna got nearly $2.5 billion to develop, manufacture and sell its vaccine to the federal government and teamed up with the National Institutes of Health on the scientific work, a highly successful partnership that managed to sidestep the political meddling by Mr. Trump and his aides that had bedeviled other efforts to confront the virus.").

[21] Anthony E. Kiszewski et al., *NIH Funding for Vaccine Readiness Before The COVID-19 Pandemic*, 39 Vaccine 2458 (2021).

[22] Samuel Cross et al., *Who Funded The Research Behind The Oxford–Astrazeneca COVID-19 Vaccine*?, BMJ Global Health (Nov. 17, 2021), https://gh.bmj.com/content/bmjgh/6/12/e007321.full.pdf.

[23] Press Release, *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.

[24] Adam Taylor, *Why Covax, the Best Hope for Vaccinating the World, Was Doomed to Fall Short*, Wash. Post (Mar. 22, 2022), https://www.washingtonpost.com/world/2022/03/22/covax-problems-coronavirus-vaccines-next-pandemic/.

[25] Adam Taylor, *Covax Promised 2 Billion Vaccine Doses to Help the World's Neediest in 2021. It Won't Deliver Even Half That*, Wash. Post (Dec. 10, 2021), https://www.washingtonpost.com/world/2021/12/10/covax-doses-delivered/.

[26] Sandrine Rastello & Kait Bolongaro, *Canada Has Reserved More Vaccine Doses Per Person Than Anywhere*, Bloomberg (Dec. 7, 2020), https://www.bloomberg.com/news/articles/2020-12-07/canada-has-reserved-more-vaccine-doses-per-person-than-anywhere#xj4y7vzkg.

[27] Amnesty International, *Covid-19: Pharmaceutical Companies' Failure on Equal Vaccine Access Contributed to Human Rights Catastrophe In 2021* (Feb. 14, 2022), https://www.amnesty.org/en/latest/news/2022/02/covid-19-pharmaceutical-companies-

failure-on-equal-vaccine-access-contributed-human-rights-catastrophe-in-2021/ (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").

[28] Matthew M. Kavanagh & Renu Singh, *Legal Paradigms and the Politics of Global COVID-19 Vaccine Access*, in Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures (Haochen Sun & Madhavi Sunder eds., forthcoming 2024).

[29] *Id*.

[30] Erin Banco et al., *How Bill Gates and Partners Used Their Clout To Control the Global Covid Response — With Little Oversight*, Politico (Sept. 14, 2022), https://www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969 ("During the pandemic, the foundation pushed back publicly on pressuring pharmaceutical companies to share its intellectual property, saying doing so would do little to spur rigorous vaccine development in the short term").

[31] Michael Safi, *WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began*, The Guardian (Jan. 22, 2021).

[32] 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).

[33] *See id.*

[34] 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.

[35] *See supra* note 32.

[36] *Id.*

[37] *See id.*

[38] *Id.*

[39] *See Over 120 Countries back IP Rights Waiver on Covid-19 Vaccines*, Pharm. Tech. (May 7, 2021), https://www.pharmaceutical-technology.com/news/ip-waiver-covid-19-vaccines/.

[40] *See* Andrea Shalal et al., *U.S. Reverses Stance, Backs Giving Poorer Countries Access to COVID Vaccine Patents*, Reuters (May 5, 2021), https://www.reuters.com/business

/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/.

[41] *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*, SSRN Electronic Journal (May 24, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737#.

[42] *See* Kavanagh & Sunder, *Poor Countries May Not Be Vaccinated Until 2024. Here's How To Prevent That*, *supra* note 4.

[43] *See* Farasat Bokhari, *US-Backed Vaccine Patent Waiver: Pros and Cons Explained*, The Conversation (May 6, 2021), https://theconversation.com/us-backed-vaccine-patent-waiver-pros-and-cons-explained-160480.

[44] *See id.*

[45] *See* Anna Marriott and Alex Maitland, *The Great Vaccine Robbery*, The People's Vaccine (Jul. 29, 2021), https://webassets.oxfamamerica.org/media/documents/The_Great_Vaccine_Robbery_Policy_Brief.pdf.

[46] Thiru Balasubramaniam, *WTO Trips Council: European Union Dismisses Concerns that IPRs Are a Barrier to COVID-19 Medicines and Technologies,* Knowledge Ecology International (Oct. 20, 2020), https://www.keionline.org/34275.

[47] See Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC (May 7, 2021), https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html.

[48] Thiru Balasubramaniam, *TRIPS Waiver Negotiations Go Down to the Wire in the Run-Up to MC12*, IISD (June 7, 2022), https://www.iisd.org/articles/policy-analysis/trips-waiver-negotiations-mc12.

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

[50] *See id.* ¶ 2.

[51] *See id.* ¶ 3(a).

[52] *See id*. ¶ 3(d).

[53] Ana S. Rutschman, *Introductory Note to Ministerial Decision on the TRIPS Agreement (WTO),* 62 Int'l Legal Materials 289 (2023).

[54] *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.").

[55] Peter Lee, *New and Heightened Public-Private Quid Pro Quos: Leveraging Public Support to Enhance Private Technical Disclosure*, in Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures (Haochen Sun & Madhavi Sunder eds., forthcoming 2024).

[56] Sapna Kumar & Ana Santos Rutschman, *New Licensing Avenues to Promote Public Health*, in Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures (Haochen Sun & Madhavi Sunder eds., forthcoming 2024).

[57] David S. Levine & Joshua D. Sarnoff, *Compelling Trade Secret Sharing*, in Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures (Haochen Sun & Madhavi Sunder eds., forthcoming 2024).

[58] Kavanagh & Singh, *Legal Paradigms and the Politics of Global COVID-19 Vaccine Access, supra* note 28.

[59] Laura Pedraza-Fariña, *COVID-19 as a Complex Disease: The Case for a Non-Traditional Team Approach*, in Intellectual Property, COVID-19, and the Next Pandemic: Diagnosing Problems, Developing Cures (Haochen Sun & Madhavi Sunder eds., forthcoming 2024).

[60] Jayashree Watal & Leticia Caminero, *Least-Developed Countries, Transfer of Technology and the TRIPS Agreement*, WTO Staff Working Paper ERSD-2018-01 (Feb. 22, 2018), https://www.wto.org/english/res_e/reser_e/ersd201801_e.pdf.

[61] *See* Suerie Moon, *Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999–2007)*, ICTSD (Dec. 2008), https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf.

[62] *See id.* ("Many of the policies and programmes reported either barely targeted or did not at all target LDCs.").

[63] 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).

[64] William Fisher, Ruth Okediji, & Padmashree Gehl Sampath, , *Fostering Production of Pharmaceutical Products in Developing Countries*, 43 Mich. J. Int'l L. 1, 14 (2022).

[65] Hard technology encompasses physical and tangible assets, including machinery, equipment, and hardware designed for practical applications.

[66] *See* Ana S. Rutschman & Julia Barnes-Weise, *The COVID-19 Vaccine Patent Waiver: The*

Wrong Tool for the Right Goal, Bill of Health (May 5, 2021), https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/.

[67] 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, 135–36 (2011).

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

[69] Fisher *et al., supra* note 64.

[70] Stephanie Nolen, *Can Africa Get Close to Vaccine Independence? Here's What It Will Take*, N.Y. Times (April 25, 2023).

[71] *See* Swati Bharadwaj, *WHO to Set Up mRNA Vaccine Hub in Hyderabad As Part of Global Plan*, Times of India (February 22, 2023).

[72] See Adam Taylor, Plan to make mRNA vaccines in developing countries needs U.S. funding, backers say, N.Y. Times (March 14, 2023).

[72] *Id.*

[74] Pedraza-Fariña, *supra* note 59.

[75] *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).

[76] *Id.* at 1211.

[77] *See* Prabhash Ranjan, *The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines*, 456 Observer Rsch. Found. (2021).

[78] *See* William A. Reinsch, *Compulsory Licensing: A Cure for Distributing the Cure?*, Center for Strategic & International Studies (May 8, 2020), https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure.

[79] *See* Halajian, *supra* note 75, at 1204.

[80] *See* Laura Chung, *Use of Paragraph 6 Systems for Access to Medicine*, 36 n.c. j. int'l l. 137, 170 (2010).

[81] *See* Kerry Cullinan, *Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine Intellectual Property*, Health Policy Watch (Nov. 15, 2021), https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-

for-johnson-johnson-covid-19-vaccine/.

[82] *See* Sheryl G. Stolberg, *As Poor Nations Seek Covid Pills, Officials Fear Repeat of AIDS Crisis*, N.Y. Times (May 11, 2022), https://www.nytimes.com/2022/05/08/us/politics/covid-pills-global-aids-hiv.html.

[83] Ministerial Decision, *supra* note 49, at ¶ 8.

[84] Francesco Guarascio & Jennifer Rigby, *COVID Vaccine Supply for Global Programme Outstrips Demand for First Time*, Reuters (Feb. 2, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/covax-vaccine-supply-outstrips-demand-first-time-2022-02-23/.

[85] *See* Sun, *supra* note 1, at 189.

[86] Paul Farmer & Simone Campbell, *To Save Lives, We Must Scrap Patent Protections on Coronavirus Vaccines*, National Catholic Reporter (May 5, 2021), https://www.ncronline.org/news/coronavirus/save-lives-we-must-scrap-patent-protections-coronavirus-vaccines.

Cover image credit