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COVID-19 Vaccines and Intellectual Property



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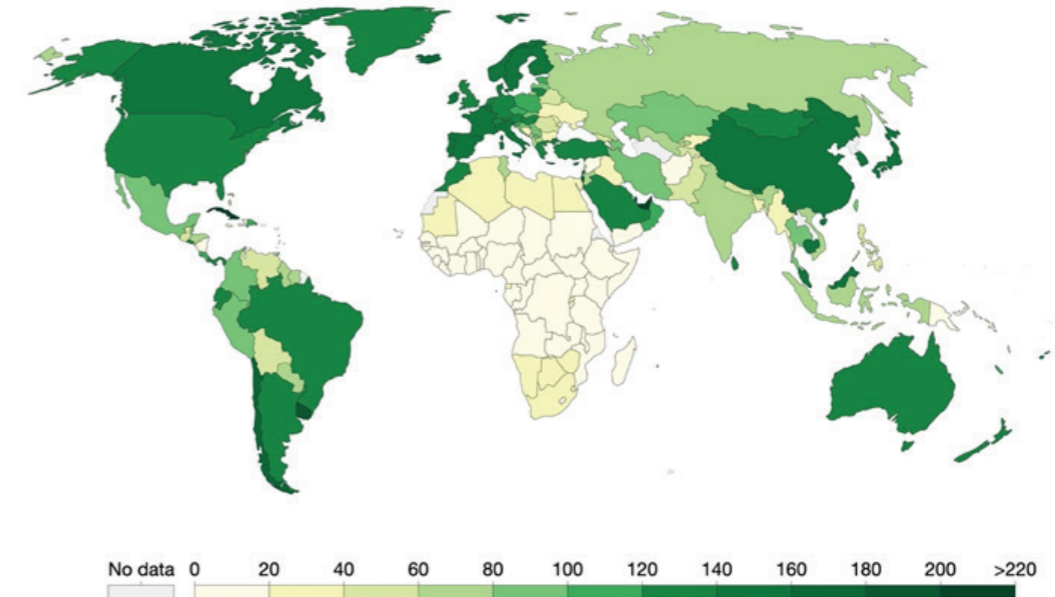
Executive Summary

Inequitable access and distribution of COVID-19 vaccines constitutes the most important challenge facing the global COVID-19 response. Low- and middle-income countries asked to coordinate with wealthier countries and international organizations have lost trust in international legal instruments and actors as the investments they made in the International Health Regulations (2005) core capacities still did not result in access to the most important medical intervention. Although both governments and public health professionals have confirmed that the world cannot fully reopen until the global population reaches herd immunity, wealthy countries continue to hoard vaccines and related technology. COVID-19 vaccines, especially the most efficacious of them produced in Europe and North America, are protected by a range of intellectual property protections: patents, trade secrets, and proprietary know-how essential to low-cost manufacturing elsewhere. Although the United States, long a defender of strong intellectual property protections worldwide, assented to the idea of a TRIPS waiver for COVID-19 vaccines, European Union (EU) member states, the UK, and Switzerland, among others, maintained resistance, and the disagreements mean that no firm decision will be taken until late 2021 at the earliest. This report identifies the most significant intellectual property barriers and proposes near- and long-term solutions toward reducing those barriers.

More than 95% of the global population lacks access to the first dose of life-saving COVID-19 vaccines while governments in wealthy countries are considering booster vaccines for those already inoculated.

COVID-19 vaccine doses administered per 100 people

All doses, including boosters, are counted individually. As the same person may receive more than one dose, the number of doses per 100 people can be higher than 100.



Source: Official data collated by Our World in Data – Last updated 22 October 2021, 10:40 (London time)
OurWorldInData.org/coronavirus • CC BY

Our World In Data. Used with permission under a Creative Commons license. <https://ourworldindata.org/grapher/covid-vaccination-doses-per-capita?tab=map&time=latest>

One possibility to address this inequity is for wealthy countries that have stockpiled COVID-19 vaccine doses, and maintain contracts to further hoard, to facilitate their donation, sale, and transfer. Another, longer-term possibility, is for those governments to 1) fully support waivers of intellectual property protection for technologies required to address potentially pandemic diseases and 2) make bilateral and regional investments in the manufacturing capacity of low- and middle-income countries, along the lines of what has been accomplished in the context of influenza vaccines. Moreover, wealthy governments could commit to both know-how and supply chain guarantees vital for manufacturing capacity to develop in regional hubs across the world. Those kinds of measures and investments could help the world prevent and prepare for future pandemics caused by increasing human encroachment on habitats where pandemic viruses circulate.



Recommendations

1. The World Trade Organization should immediately commit to a broad vaccine waiver for diseases with pandemic potential, those listed on the WHO Blueprint, and those listed in Annex 2 of the International Health Regulations (2005).
2. OECD Governments, in concert with private sector researchers, should work with vaccine manufacturers and research universities in low- and middle-income countries to transfer know-how and manufacturing inputs to regional manufacturing hubs that build on facilities already committed to influenza vaccine production. Such leveraging would rationalize access to sufficiently pure water, human resources, and other vaccine inputs to manufacture vaccines that combat current and future pandemic viruses.
3. The Pandemic Influenza Preparedness Framework should be converted to an all-pathogens agreement that combines private sector support and contracting with WHO-administered access to end-product diagnostics, antivirals, and vaccines and transfer of relevant technology.
4. Under WHO and UNESCO leadership, a global scientific corps should be developed that could respond and assist countries aiming to build vaccine manufacturing capacity. Because middle-income countries not only lack access to know-how but also to scientists themselves, governments should agree to adequately support an international capacity building service built along the lines of extension and outreach agents in the U.S. landgrant university context or the CGIAR in the global agricultural context.
5. Governments, in their procurement and joint development agreements with manufacturers, should include fair provisions for the transfer of technology.
6. Civil society organizations and professional associations should mobilize their membership networks to target both governments and vaccine manufacturers to fulfill ethical and moral obligations to share technology and know-how.

Introduction

The availability of diagnostics, therapeutics and, especially, vaccines has defined the inequality in the global response to the COVID-19 pandemic. Before the availability of the latter, wealthy countries developed systems for mass testing, implemented vast contact tracing systems, and invested billions of dollars in accelerating the processes leading to safe and effective vaccines. After those vaccines were available, they immunized their populations at a galloping pace. In the United States, approximately 75% of adults have received at least one vaccine dose, and a little more than half are fully immunized.¹ In the EU, problems with vaccine development and procurement caused some delays, but rates of people in the 27-member EU with at least one dose have climbed from less than 4% in mid-February to 60%, while rates in the United States rose from nearly 12% to less than 58%.²

Worldwide herd immunity is the only feasible way to the pandemic's end, but less than 95% of the global population has access to a first vaccine dose, even while populations in rich countries are considering booster jabs.³

The ACT Accelerator – the world's best effort at facilitating access to COVID-19 diagnostics, therapeutics, and vaccines for low- and middle-income countries – brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), FIND, Gavi, the Vaccine Alliance (Gavi), The Global Fund, Unitaid, The Wellcome Trust, the WHO, and the World Bank). COVAX, the vaccine pillar of the ACT Accelerator, is co-led by CEPI, Gavi and WHO, alongside key delivery partner UNICEF. In the Americas, the PAHO Revolving Fund is the recognized procurement agent for COVAX. It aimed to supply approximately 2 billion doses in 2021 to the world's poorest countries but by late October had distributed only 371 million. Many governments including the U.S., Japan, and the EU are circumventing COVAX in favor of bilateral deals and donations tainted by politics and geopolitical preferences.



Scope:

This report examines some of the key challenges and implications of intellectual property protections for various aspects of COVID-19 vaccines. Drawing on evidence from the vaccines for which information is most available – AstraZeneca’s AZD 1222 (Vaxzevria), Johnson & Johnson’s JNJ-78436735 (Janssen Covid-19), Moderna’s mRNA-1273 (Spikevax), and Pfizer-BioNTech’s BNT162b2 (Comirnaty) - this report is intended to provide a roadmap to the barriers intellectual property erected to global vaccine access, how those barriers may be equitably addressed to prevent and respond to future pandemics, and to propose specific near- and long-term measures toward that end. The United States, the EU, and the UK are the primary governments of analysis, as they presided over most of the upstream development of the aforementioned vaccines, and have, similarly, championed strong intellectual property protections worldwide, especially for pharmaceuticals. However, the challenges examined here are not limited to those governments, and will likely manifest in various countries to varying degrees. Some dynamics and narratives detailed herein involve the highly consolidated structure of global vaccine development and production, and thus the reach of antitrust and competition law and regulation. Thus, the intellectual property challenges articulated in this report should be explored with a view towards multifaceted policy approaches toward vaccine access, pandemic and routine.

Box 1—Terminology explainer: vaccines are produced in three main steps: (1) raw material manufacturing; (2) drug-substance manufacturing; and (3) fill and finish.⁴ The supply chains of raw materials needed for COVID-19 vaccines are global and came under stress during the initial phases of the pandemic. Drug substance manufacturing is the most technically complex step of the process and for mRNA vaccines it is concentrated in a few high-income countries. The fill and finish stage packages, inspects and labels the drug substance ahead of final distribution.

As a regulatory matter, medicines may be divided into two categories: small-molecule compounds generated through chemical synthesis and biologics, and larger molecule therapies and vaccines derived from living organisms.⁵ The former are far easier to copy than the latter which explains, in part, why intellectual property protections for vaccines are so controversial. Vaccines are vital for the protection of individual and public health, but they require vast financial resources to develop, and intellectual property rights offer incentives to do so, although how well-tailored those incentives are remains the subject of heated debate.

Key terminology:

- **Patents:** Government-provided legal monopolies given to inventors of new, useful, and non-obvious products, including vaccines and incorporated technologies, in exchange for disclosing the technology
- **Market Exclusivity:** Government-provided legal monopolies given to companies that invest in clinical trials, data generation, and manufacturing to bring new medicines and vaccines to market
- **Trade secrets:** Legal protection for something used in a company’s business that is not known or readily accessible by competitors, has commercial value or that provides a competitive advantage in the marketplace, and the owner of the information protects from disclosure through reasonable efforts to maintain its secrecy.

Patents

The patent is the fundamental form of intellectual property that governments offer to vaccine developers (and all other inventors who meet criteria for novelty, usefulness, and non-obviousness). By international accord, the Agreement on Trade-Related Aspects of Intellectual Property, or TRIPS, that is analyzed further below, a patent granted to an applicant after meeting legal criteria must be for a minimum of 20 years. The patent represents a bargain. The successful applicant is legally entitled to prevent others from using the invention without its (often compensated) permission, while society benefits from the full disclosure of the new and useful technology.⁶ The promise of such compensation, the argument goes, provides an important incentive for research and development into medical products that are costly to develop, frequently fail to meet standards for safety and therapeutic efficacy, and, even when finally allowed onto market, subject the manufacturer to significant liability for injuries or deaths attributable to the medicine or vaccine.

Because patents cover products, processes, and methods, more than one, and for vaccines, many more than one, patent may cover a single vaccine. In the case of mRNA vaccines like Pfizer-BioNTech's and Moderna's for example, patents cover the lipid nanoparticle technology that allows the mRNA to be effectively and safely delivered into human cells as well as the modified mRNA technology itself which instructs cellular production to generate proteins that will elicit a protective biological response. Dozens of patents protect these vaccine features, each with a 20-year life. "Vaccine patent holders have the ability to refuse licensing their technology to others, even against a backdrop of vaccine scarcity".⁷ Although patents are generally regarded as the foundational and most important protection, they are of limited duration, may be costly to enforce and, *ex ante*, are expensive to obtain.⁸

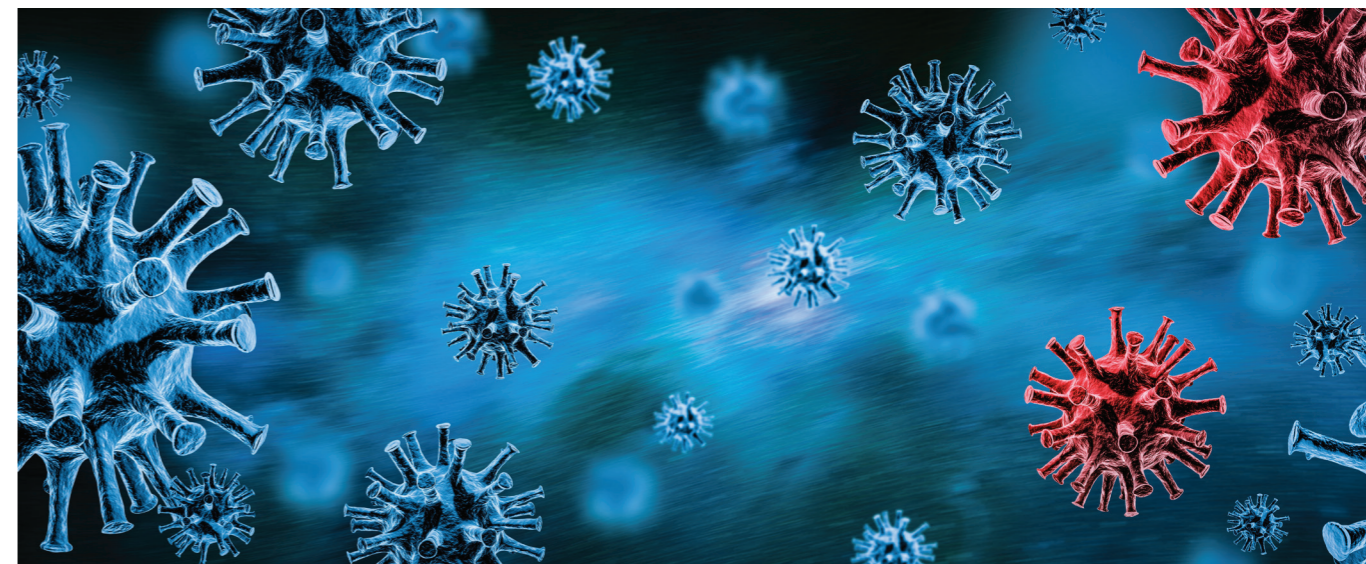
Regulatory Market Exclusivity

Beyond the role of patents, intellectual property protections cover the investments companies make in producing the data necessary to obtain regulatory approval, including information relevant to manufacture of the compound. Some of these protections take the form of legal protections, codified in statutes, specific to the compound itself. For example, in the United States new biologics- including vaccines- receive 12 years of market exclusivity. Similarly, exclusivity periods granted by government agencies such as the Food and Drug Administration (FDA) or European Medicines Authority (EMA) allow pharmaceutical manufacturers to market drugs without competition.⁹ Knowledge related to manufacturing processes may be protected by trade secrets and other contractual restraints that may be of indefinite duration.

Trade Secrets

Trade secrets are protected by law when they represent knowledge used in a company's business that is not known or readily accessible by competitors, has commercial value or that provides a competitive advantage in the marketplace, and the owner of the information protects from disclosure through reasonable efforts to maintain its secrecy. Trade secret information can be almost any aspect of business that provides an economic or competitive advantage over a company's competitors. Trade secret law protects a wide range of valuable information, including information that would not be eligible for protection under patent law or the law protecting new vaccines from market competition.

"... [Trade secrets] could include formulae and recipes, proprietary databases, business processes and methods, information about costs, pricing, margins, overhead, manufacturing processes, proprietary computer software programs, customer lists, and strategic plans and marketing programs. Often the owners of these trade secrets may not even know that this type of information is protectable by trade secret laws. Such overlooked trade secrets may include customer lists, supply chain information, or even business development and financial plans."¹⁰



This array of intellectual property protections explains why establishing COVID-19 manufacturing centers in low- and middle-income countries has proven so difficult.¹¹ Moderna, for example, promised in October 2020 that it would not enforce patents related to its COVID-19 vaccine, after which the World Health Organization initiated an effort to establish a "vaccine hub" in South Africa to help supply the vaccine to the African continent where only 3% of people have received COVID-19 immunizations.¹² But efforts by WHO to negotiate with Moderna as to other relevant aspects of its vaccine protected by trade secrets have not resulted in Moderna's sharing or support.

"In practice, though, it is hard to replicate a vaccine without the information on how it is made, and the World Health Organization-backed tech transfer hub in South Africa - set up in June to give poorer nations the know-how to produce COVID-19 vaccines - has so far not reached a deal with the company." -- Wendell Roelf, Reuters¹³

These incentives, the companies and many scholars argue, encourage pharmaceutical companies to continually innovate to develop medicines and vaccines to fight common and rare diseases, identify promising new medicines researched in the academy and small biotechnology companies, and facilitate the later entry of less expensive generics that use the information disclosed by the patent and the regulatory process.¹⁴ Conversely, a significant number of critics argue that the incentives do precisely the opposite: they encourage investment in incremental changes that just barely qualify for costly patent protection, keep drug prices high and out of the reach of many who need them most, and impose significant barriers to entry for other manufacturers.¹⁵

And those protections, in turn, all precede just the pure inputs of money and people. Pfizer-BioNTech, for example, estimates that it cost \$1 billion to develop their COVID-19 vaccine. It requires dozens of scientists, industrial engineers, and other skilled and semi-skilled workers to ensure that vaccine inputs are of sufficient quality and purity, are processed correctly, and are finished, including bottling, packaging, and labeling. Each of these steps requires intensive capital and human resources.



The global response's key biomedical technologies that have been built with:

- (1) advanced research infrastructure;
- (2) significant pools of capital resources from both private and public sector sources—needed to invest in often risky and failed clinical trials for medicines and vaccines;
- (3) highly trained personnel to guide the scientific process from hypothesis– to finished products, which includes navigating strict regulatory requirements and composing information on safe and effective use to accompany these products.

From March 2021 onwards, a robust debate emerged as to one aspect of this complex constellation of infrastructure, capital, and regulation that leads to most biomedical products: intellectual property.

How Intellectual Property has Limited Access to COVID-19 Vaccines in Low- and Middle-Income Countries

Companies carefully plan intellectual property protections for their products to preserve the revenues from them. The major developers of vaccines worldwide are legally reportable to investors, who pressure the companies to maximize returns, even under the circumstances of an international public health emergency. The companies are therefore unlikely to share life-saving technologies, even if the capacity to apply that technology effectively and to manufacture vaccines existed worldwide. Of course, it does not.

“I’ll sign an executive order to ensure that the United States government prioritizes the getting out of the vaccine to American citizens before sending it to other nations.”— U.S. President Donald Trump, December 8, 2020¹⁶

Vaccine research, development, and manufacturing capacity is overwhelmingly concentrated in just a handful of wealthier countries.¹⁷ The governments in those countries quickly acted to ensure that even if the companies were inclined to share technology or finished doses with others, they would be prevented from doing so. While making Operation Warp Speed, a USD\$ 18 billion interagency effort to coordinate government activities including Biomedical Advanced Research and Development Authority (BARDA), Department of Defense (DOD), and the National Institute for Health (NIH) funding for the development and manufacturing of COVID-19 vaccines (and the right to lay exclusive claim to them), the U.S. government also sought to diversify its vaccine candidate portfolio during the earlier stages of the pandemic.¹⁸ In March 2020, the German press reported that the White House approached German biotech company CureVac in an attempt to guarantee exclusive access to its vaccine. The German government warded off this effort by a foreign government to lay claims to

CureVac’s vaccine candidate,¹⁹ noting that “Germany is not for sale” and noting that “if a vaccine is developed in Germany, then it is for Germany and the world”.²⁰ A few months later, the German government invested €300 million (roughly US\$337 million) to guarantee a 23% stake in CureVac.²¹

“We also have an obligation towards our own citizens, ... There has to be a balance, ... not a single German vaccination appointment will be endangered.” – German Chancellor Angela Merkel, February 20, 2021²²

The French government also intervened to halt negotiations between the French pharmaceutical company Sanofi and foreign governments, after the CEO of Sanofi publicly announced that the U.S. had “the right to the largest pre-order”.²³ A day after the announcement, on the heels of mounting criticism, both the French government and Sanofi announced that the deal would not move forward. Several other countries acted according to nationalistic paradigms. India’s Serum Institute (SII)—the world’s largest vaccine manufacturer—initially announced that it was committed to “equitable” distribution of COVID-19 vaccines globally, but soon thereafter narrowed that commitment by reserving the majority of initial doses of COVID-19 vaccines for its domestic population.^{24 25}

“We’re not talking about billions of doses immediately, or billions and billions of euros. It’s about much more rapidly allocating 4-5 per cent of the doses we have. ... It won’t change our vaccination campaigns, but each country should set aside a small number of the doses ...” – French President Emmanuel Macron, February 18, 2021²⁶

Over the course of 2020, some governments exercised extreme forms of ‘vaccine nationalism’, refusing to share, or contemplate sharing, COVID-19 vaccines or related knowledge with any populations but their own. According to Rutschman:

As some governments began narrowing down the roster of projects receiving priority status in late spring, the first hints of ‘vaccine nationalism’ appeared. The expression is linked to agreements that reserve the bulk of emerging vaccines for a limited number of countries, traditionally in the developed world. While these strategies are not new, they have become a recent hallmark of negotiations during large-scale outbreaks of vaccine-preventable diseases. If left unaddressed, vaccine nationalism can have serious consequences for equitable access to the first COVID-19 vaccines to come to market.²⁷

Over the course of the pandemic, two important, related exceptions to this general rule of non-sharing arose. The first was AstraZeneca’s licensure of its technology to Serum Institute of India, the world’s largest vaccine-manufacturing company. The second was the establishment of the COVAX Facility, an international partnership that was to facilitate access to finished doses for low- and middle-income countries.

AstraZeneca early on made a commitment to sell its vaccine doses at cost, and it licensed manufacturing know-how to SII in June 2020 with an aim to supply 1 billion doses for global supply.²⁸ Over the same period, the COVAX Facility originated within a broader international collaboration known as the ACT (Access to COVID-19 Tools) Accelerator,²⁹ identified above.³⁰ The ACT Accelerator, launched in April 2020, is broader than COVAX and includes four “pillars”: the Diagnostic Pillar supported by the Foundation for Innovative New Diagnostics (FIND) and the Global Fund to Fight Aids, Tuberculosis, and Malaria (Global Fund), the Therapeutics Pillar supported by Unitaid and Wellcome Trust, the Health Systems Pillar supported by the World Bank, Global Fund, and WHO, and the Vaccine Pillar supported by Gavi, CEPI, and the World Health Organization.³¹

At its origin, COVAX envisioned supplying 2 billion doses of COVID-19 vaccines, largely through its relationship with SII. The AstraZeneca vaccine was to be supplied by SII at an affordable price so that COVAX could match shipments with countries that had made adequate financial and other commitments, and shown evidence that they could effectively deploy the vaccine.

But as the delta variant of COVID-19 devastated India over the early months of 2021, the government-imposed export controls and the supply of vaccines to COVAX was temporarily disrupted. Pfizer-BioNTech never committed more than a limited number of doses, while manufacturing problems for Johnson & Johnson’s vaccine have meant that COVAX, as of the time of writing, has only successfully managed to deliver approximately 370 million doses since it was established in June 2020. The effect of the disruption was to devastate COVAX’s aim to deliver 2 billion doses by the end of 2021.

The combination of intellectual property protections, rich-world hoarding, and manufacturing limitations have left much of the world without access to a single dose. Fatally for vaccine equity, the COVAX Facility was by design reliant on international solidarity and aimed at ensuring a fair distribution of doses manufactured in a handful of countries, it was never intended to share technology or expand local manufacturing capability, at least not directly.

There have been some partnerships developed, but those have resulted in few actual vaccine doses. The aforementioned partnership between AstraZeneca and SII is the most productive. The Pan-American Health Organization has identified the Bio-Manguinhos Institute of Technology on Immunobiologicals at the Oswaldo Cruz Foundation (FIOCRUZ) as an mRNA vaccine manufacturing center in Brazil and Sinergium Biotech, a private sector biopharmaceutical company, was selected as a similar center in Argentina. Sinergium will partner with mAbxience to develop and manufacture active vaccine ingredients. The two companies have extensive experience in the production and development of vaccines and biotechnological medicines.³² The WHO has endeavored to establish a similar center in South Africa, but progress has been slow for precisely the intellectual property barriers identified above. Moderna, for example, has promised not to enforce patents, but it is the related input and manufacturing technology that is needed.

CanSinoBio, Sinopharm, and Sinovac, the major Chinese vaccine developers, have licensed vaccine production in Turkey, Indonesia, Brazil, Malaysia, Mexico, Pakistan, Egypt, and the UAE, but production from any these locations is significantly constrained.³³ Similarly, the Russian Sputnik V vaccine was licensed for production in Argentina, but has resulted in only 5 million doses as at the time of writing.³⁴

The Solution: Securing Intellectual Property Transfers and Local Production of COVID-19 Vaccine

Although it is considered next generation technology, as a platform, mRNA has inherent benefits for manufacturers over other platforms. First, mRNA vaccines are more affordable and simpler to manufacture than traditional vaccines.³⁵ Second, the same manufacturing capacity used for mRNA vaccines can potentially play a role in the manufacturing of mRNA-based therapeutics. Such therapeutics will likely play a substantial role in the management of non-communicable diseases (NCDs), including cancer, and infectious diseases in the future. Because of this, ensuring local access to mRNA technologies for COVID-19 has the potential to come with significant future benefits in efforts against other diseases.

But despite these long-term benefits, expanding capacity for local production of mRNA vaccines needs to be an urgent and immediate priority. This is because, mRNA vaccines have among the highest efficacy rates against the SARS-CoV-2 virus that causes COVID-19 and have proven more easily adaptable, as compared to the adenoviral vaccines, to respond to COVID-19 variants, thus far.³⁶ Furthermore, according to experts, existing manufacturing facilities, including those producing injectable medicines, could be repurposed to make mRNA vaccines. In some cases, such facilities have, in fact, been adapted in as little as six months.^{37, 38}

Of the two mRNA COVID-19 vaccines commercially available and approved by the US FDA, the Moderna vaccine (Emergency Use Authorization) has an advantage over Pfizer-BioNTech vaccine (full licensure) in duration of generating antibodies³⁹, which could have an impact on protection, and on operational conditions, given that it does not require ultra-cold conditions in the supply chain. Analysis from the Graduate Institute’s Global Health Centre shows that the companies which developed these mRNA vaccines have been based in high-income countries and generally tended to partner with other companies based in high-income countries in manufacturing and technology transfer.⁴⁰

The fundamental and enduring barrier to expanded access to COVID-19 vaccines is the control given by governments to those who successfully fulfill their criteria for being named the first inventor of a technology, or, similarly, having fulfilled the criteria to have a trade secret protected by law. These protections were internationalized through TRIPS. From its inception, TRIPS has raised significant concerns with respect to access to medicines, since pharmaceutical patents apply whether or not the medicine is needed by a small number of patients with the ability to pay for it, or one that affects millions or tens of millions who live in poverty. Such was the case during the early 2000s, when HIV/AIDS exploded in Africa and early retroviral medications were priced well out of the reach of those who needed it. The activism of the HIV/AIDS community and their supporters were critical to this change in international law.

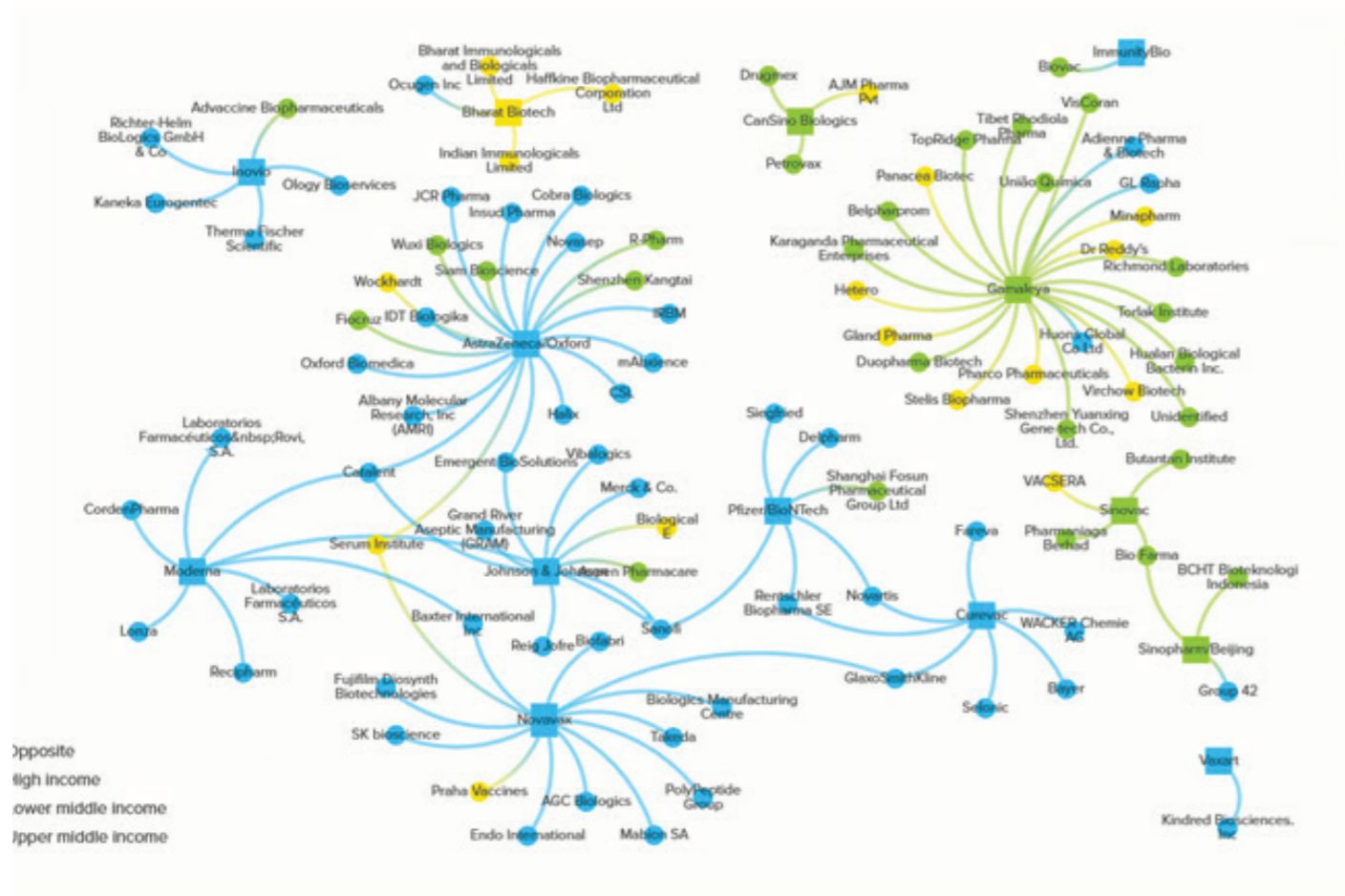


Figure 1 Relationships between COVID-19 Vaccine Developers & Manufacturers, by country income groups. The Graduate Institute. Used with permission.⁴¹

In light of that experience, the World Trade Organization, driven by a dispute and then resolution between the governments of Brazil and the United States, adopted the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health. Developed to protect access to medicines for HIV/AIDS, tuberculosis, malaria and “other epidemics,” the Doha Declaration established that treatments for diseases affecting low- and middle-income countries required that normal rules of trade defer to global health interests.

But the same type of problems addressed by the Doha Declaration have resurfaced for COVID-19. TRIPS Article 27 protects patents, including those necessary to produce vaccines and Article 31 protects trade secrets and undisclosed information.

There are provisions for relief, but they are narrow and largely inapplicable to vaccines. Under TRIPS, Article 31 provides for the possibility of compulsory licensing to a producer other than the right-holder, but without a manufacturing site overseen and staffed by scientific experts, to say nothing of other supporting regulatory officials, requiring licensure does little, just as it had done little since the early, sensational episodes with HIV/AIDS and some cancer drugs.

Government, parastatals (e.g. state-owned enterprises), and/or private sector manufacturers have to seek licenses for the manufacturing and marketing of COVID-19 vaccines or, alternatively, issue public use or compulsory licenses or other safeguards as part of the TRIPS flexibilities. Conditions of licenses can include limited geographical scope for marketing and distribution, royalty terms, conditions for further sharing of technology or out-licenses for COVID-19, and use of related technology for non-COVID-19 use, etc.

“We are calling for the original manufacturers of mRNA #COVID19 vaccines to contribute their technology and know-how to a central hub, and for manufacturers in low- and middle-income countries to express interest in receiving that technology” Dr Tedros, Director General, World Health Organization, April 19, 2021⁴²

WHO’s COVID-19 mRNA Vaccine Technology Transfer Hub initiative aims to facilitate the exchange of know-how, quality control and licenses from technology holders to governments and manufacturers.⁴³ The prospective WHO Hubs will also provide other means of support, including training of key personnel. The growth of this initiative, along with the first and currently only established hub, the South African mRNA tech transfer hub, needs to be supported. As do the two regional vaccine production and manufacturing hubs established in Argentina and Brazil by PAHO for the supply of inputs needed for mRNA vaccine production.⁴⁴ The most crucial form of support needed is the transfer of know-how since in some cases, such as with South Africa, there is no current IP barrier.

Originator vaccine companies are, however, currently refusing to support the proposed WHO hubs, the existing South African hub, and comparable national initiatives. For example, South Korea is poised to become a manufacturing hub and could rapidly make up to a billion doses, but the originator mRNA vaccine companies thus far have not agreed to enter into an agreement for technology transfer.⁴⁵ Similarly, the consortium operating the South African hub has only reached deadlocks so far in its talks with vaccine companies.⁴⁶

Although they often cite concerns about quality control and capacity, the real reason suspected behind the originator companies’ refusal to engage in technology transfer is two-fold: their unwillingness to split the market share for COVID-19 vaccines with competitors and, more importantly, their fear of losing market share and profits for future medical innovations based on the same mRNA technology. Thus far, all the power on this issue has been left in the hands of the private sector which will continue to use that power to protect their present and prospective profits unless there is an intervention from the public sector.

“We would love to get a discussion with Moderna, about a license to their intellectual property — this would make life so much simpler, but for the moment all attempts have resulted in no reply ...” – Dr Martine Friede, Coordinator, Initiative for Vaccine Research, World Health Organization⁴⁷

The crux of the issue, then, is whether intergovernmental organizations or agreements can shift the calculus of originator vaccine companies such that they favor a more supportive role or whether unilateral national actions can force or threaten them into one. At the national level in countries like the U.S. and Germany, or the supranational level such as the European

Commission, decision-makers have legal powers with which to compel companies to engage in technology transfer with these and other hubs. In the absence of a multilateral solution, national mechanisms to compel technology transfer have to be relied on since it is unlikely the originator vaccine companies will shift to cooperative methods without at least a credible threat of regulatory intervention.⁴⁸ If decision-makers with the most authority over vaccine manufacturers decline to act, then countries in the global south still have legal and economic tools available.

Given the likely chronic nature of COVID-19, intergovernmental organizations and national governments should pursue strategies for procurement, and in some cases, production of vaccines to address the acute need to vaccinate their populations as part of a public health emergency as well as actions now to sustain affordable access in the long-term. The following sketches out a series of mutually supportive yet independent actions that various actors for global health governance at both the national and international level can and should take to expand access to vaccines for this and future pandemics.

Available Intergovernmental Actions to Address Intellectual Property Barriers to COVID-19 Vaccines

Both the Organization for Economic Co-operation and Development (OECD) coordination of technology transfer and the Pandemic Influenza Preparedness' Framework's expansion to an all-pathogens arrangement are means toward the end of local production and capacity. Given that 1% of all vaccines administered in Africa are manufactured on the continent, such an aim is of obvious importance.

The Pandemic Influenza Preparedness Framework was an innovation developed at the World Health Organization in 2011. In 2007, Indonesia refused to share H5N1 with the Global Influenza Surveillance Network, a decades-old laboratory system managed by the World Health Organization, on the basis that it freely shared pathogens that were later patented and developed into vaccines unaffordable for most Indonesians. Understanding the potential threat to a critical part of global health preparedness, the World Health Assembly developed a compromise agreement whereby countries would continue to share samples with the system, renamed the Global Influenza Surveillance and Response System, but, should an influenza pandemic develop, they would be assured access to antiviral medications, real-time production of vaccines, or the transfer of production technologies. Companies using the system would not only enter into agreements with WHO to assure such access, but contributed annually to the cost of running the system. If possible for influenza, why not other pathogens like SARS-CoV-2, the virus that causes COVID-19?

1. At the WTO: Negotiating the TRIPS Waiver

One of the obvious ways to address intellectual property barriers to COVID-19 vaccine access is to, temporarily or permanently, dispense with intellectual property protections for the technologies used to produce them. TRIPS, the international agreement establishing high floors for intellectual property protection, is one of the most important of these barriers. While TRIPS is the focus of this analysis, it is important to note that many bilateral and regional agreements offer protections that exceed TRIPS, although those protections may be addressed through the recommendations outlined below.



Tedros Adhanom Ghebreyesus
@DrTedros

We live in a global village. As long as #COVID19 circulates somewhere, it's still a threat everywhere. We can't put out half a fire.

That's why we need #VaccinEquity:

- Share doses
- Share know-how
- Share technology
- Waive intellectual property

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On October 2, 2020, the governments of India and South Africa submitted a TRIPS waiver proposal akin to that adopted for HIV/AIDS, tuberculosis, and malaria, covering "patents, industrial designs, copyright and protection of undisclosed information" applicable to "medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need."⁵⁰

Although historically a defender of strong intellectual property protections worldwide, the U.S. declared its support in principle in May 2021 for a TRIPS waiver applicable to vaccines. Yet the proposal has remained mired in WTO bureaucracy with the next significant discussion to occur in December 2021, and a significant decision on waiver unlikely before 2022.





Even then, it is not clear how much a TRIPS waiver alone will accomplish toward improving equitable vaccine access. As we've mentioned above, in June 2021, the WHO commenced a project to develop an African vaccine hub in partnership with African Biologics and Vaccines and Biovac in South Africa, but at least at the time of writing, the WHO had not convinced Moderna to share the necessary knowledge in order for that vaccine hub to materialize.

Although the waiver is far more likely to benefit a country like India, with advanced vaccine manufacturing infrastructure, the TRIPS waiver on its own is unlikely to result in significant increases in global COVID-19 vaccine capacity. It is, however, an important first step. The following recommendations are aimed at articulating what more is needed. In addition to a TRIPS waiver there are a number of other policies that need to be implemented to foster and sustain production of mRNA and non-mRNA vaccines including in LMICs.

2. At the OECD: Facilitating Licensing and Tech Transfer

While there are a number of international organizations that could play a role in facilitating the licensing and know-how for COVID vaccines, the OECD is an appealing candidate. Its member governments oversee the production and protection of the most important COVID-19 vaccine technologies and host most associated personnel. It has in the past used its authority to attempt to establish guidelines for the conduct of international businesses and it maintains a centralized bureaucracy for the receipt and adjudication of certain issues raised as to businesses' conduct. That bureaucracy could be adapted to facilitate the transfer of knowledge to manufacturing sites in low- and middle-income countries. Indeed, an effort to accomplish similar technology transfer has been successful in the context of influenza vaccine production.

3. At the WHO: Making the Pandemic Influenza Preparedness Framework an All-Pathogens Technology Transfer Entity

Indeed, the impressive, even if imperfect, results of the global commitment to increasing vaccine manufacturing capacity for influenza shows one path forward for other pathogens, including SARS-CoV-2. This commitment was born out of a struggle, which became prominent from 2005 onwards, by nations in the Global South against two related injustices: (1) the inequitable distribution of influenza vaccine manufacturing capacity meant they would have to beg for access to vaccines in a pandemic; and (2) that countries which shared crucial samples of emergent influenza strains did not receive any direct benefits in return for their contribution to influenza surveillance and vaccine development.⁵¹

Pursuant to a 2005 resolution of its Member States and following a year of consultation, the WHO launched the Global Action Plan for Influenza Vaccines (GAP) in September 2006.⁵² The GAP encompassed a ten-year strategy to increase equitable access to pandemic influenza vaccines, including through increasing global production capacity to be able to produce enough vaccine to immunize 70% of the world's population in a compressed timeframe.⁵³ At the launch of the GAP, the global production capacity for influenza vaccines was approximately 500 million doses of seasonal vaccine and 1.5 billion doses of pandemic vaccine with the vast majority of production concentrated in high-income countries.⁵⁴ Ten years later, at the close of the GAP, this annual production capacity was estimated to have almost tripled, including expansion of production capacity in low- and middle-income countries (LMICs). These achievements were due in significant measure to a technology transfer project under GAP where WHO, supported by partners including US BARDA and PATH, provided seed funding and technical support to vaccine manufacturers located in LMICs.

Although the GAP contained a promise of eventual progress on overall supply it did not include any guarantees of near-time access to vaccines during an influenza pandemic. In December 2016, against the backdrop of a company's use of samples contrary to WHO protocols and broader concerns about access to vaccines, Indonesia announced its unilateral refusal to share influenza virus samples without reciprocal guarantees of access to vaccines developed using them.⁵⁵ Following this, in 2007, Indonesia was joined by other Global South countries in a 2007 Jakarta Declaration that demanded that sharing of pandemic influenza virus samples and viral information be accompanied with greater access to resultant vaccines.⁵⁶ This sparked off negotiations for what eventually became the Pandemic Influenza Preparedness (PIP) Framework. The PIP Framework was founded upon an 'equal footing' principle: all countries would be placed on an equal footing in the sense that, just as all countries would share samples and information to the world, benefits derived from the network would accrue to nations based on need, rather than on a preferential basis. Although it was adopted by WHO's Member States, the

Framework is not a treaty and is not binding on any nations, instead all legal relationships are between WHO and those influenza labs and manufacturers that receive influenza virus samples from WHO.

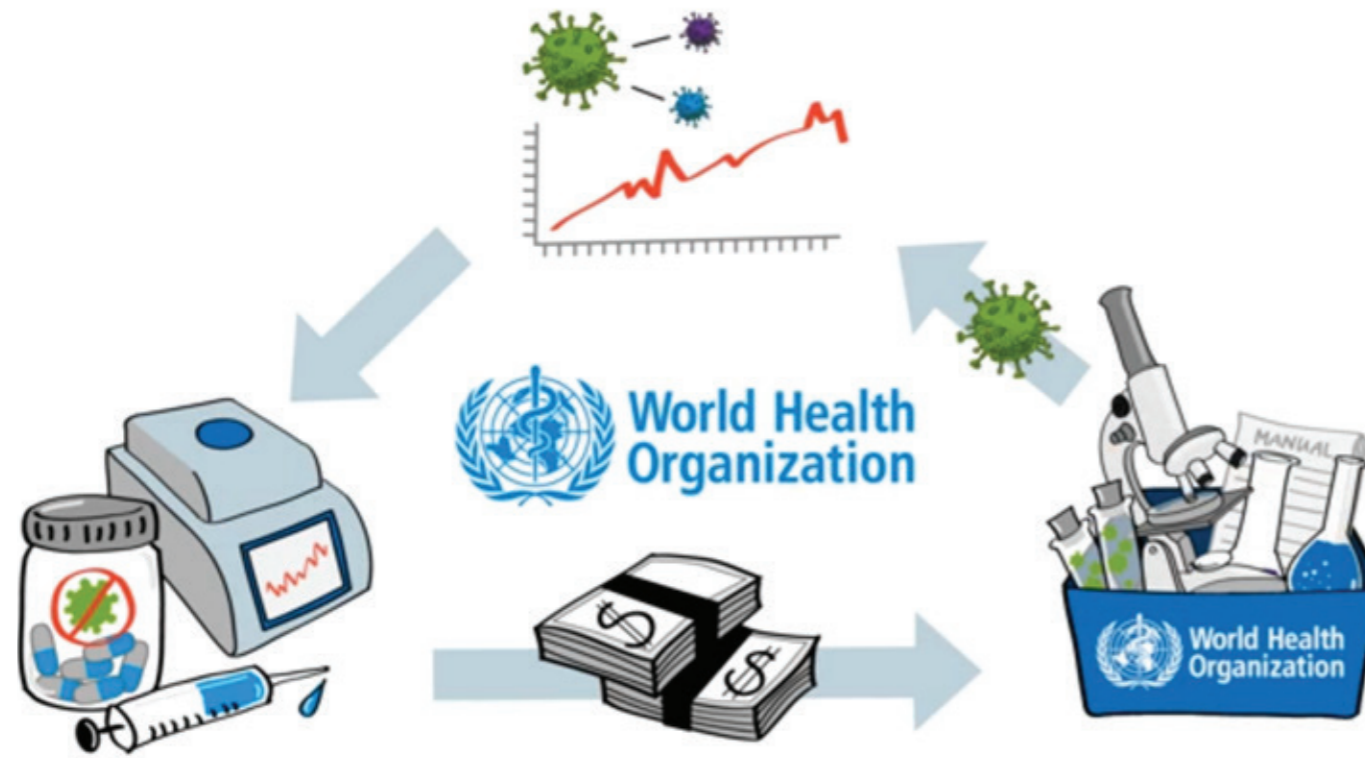


Image 1: An image extract from “WHO: PIP Framework – Partnership Contribution dated Mar 26, 2015”. Used with permission.⁵⁷

There are two components to the PIP Framework: (1) the sharing of influenza viral samples to members of the WHO Global Influenza Surveillance and Response System (GISRS); and (2) and GISRS’s sharing of viral samples with vaccine manufacturers in return for their agreement to share benefits with WHO and its members.⁵⁸ All vaccine manufacturers and some other related industrial players who access GISRS pay ‘partnership contributions’ to support the system. This model ameliorated the previous reliance on ad hoc influenza vaccine donations and created a system in which influenza vaccines would be contractually guaranteed to low-income countries in exchange for biological material through a negotiated Standard Material Transfer Agreement (SMTA) aligned with the model annexed to the PIP-Framework.⁵⁹ The PIP Framework stipulates that, in exchange for biological material, vaccine manufacturers will agree to guarantee a percent of their real-time

vaccine production to the WHO or agree to share technologies, including know-how and intellectual property, either indirectly with developing country manufacturer or indirectly through WHO.⁶⁰

The PIP Framework is by no means perfect. As of August 2020, none of the companies with which WHO has concluded SMTAs have agreed to technology transfers.⁶¹ The Framework has, moreover, not yet been tested by a public health emergency involving pandemic-potential influenza. It is possible that the governments which host influenza manufacturing capacity would simply expropriate all available vaccines regardless of any SMTA commitments doing so would override. Since the Framework is not a treaty, governments would not be breaching any legal obligation in so doing. The manufacturers would, in turn, likely be protected from any liability for failing to deliver by clauses on exceptional intervening events provided for in their SMTAs. Despite these imperfections and its limited scope, the PIP Framework was the first international agreement to address inequalities of vaccine access and has been described as a “milestone for global health”.⁶²

Since 2015, several expert groups and governments have argued the PIP Framework should include all pathogens that may threaten global health security.^{63 64 65} The GISRS has already been adapted to provide surveillance of COVID-19 variants and this expansion could be formalized in tandem with the PIP-Framework’s expansion.⁶⁶ Such an arrangement would create an all-pathogen surveillance and response system designed to facilitate the sharing of pathogen samples, as well as related genetic sequencing data (GSD), and make recommendations, as with influenza, on the composition of new COVID-19 vaccines.⁶⁷ Manufacturers of vaccines, therapeutics and diagnostics would be granted access to novel samples and GSD in exchange for providing partnership contributions and entering into SMTAs. To further strengthen the model SMTA should be reconfigured to require commitments to technology transfer unless manufacturers commit to provide 100% of relevant pandemic pathogen vaccine production to WHO, COVAX or equivalent future coalitions for equitable distributions. These SMTAs would include provisions to ensure that the transfer of technology from companies in Europe, North America, and East Asia to producers in low- and middle-income countries include know-how fundamental to next-generation platforms such as mRNA.

4. At WHO and UNESCO: Building a Global Scientific Technical Corps

As this report has emphasized, the ability to manufacture vaccines starts with the researchers and technical expertise which must then have access to advanced facilities. Any of these steps may be hindered by intellectual property protections, but eliminating those protections alone may do little to foster technology transfer and the expansion of the technical base, especially people.

Under WHO and UNESCO leadership, a global scientific corps should be developed to respond and assist countries to build vaccine manufacturing capacity. Because low and middle-income countries not only lack access to know-how but also to scientists themselves, governments should agree to adequately support an international capacity building service. There are many examples of such dedicated scientific personnel including those scientists who undertake investigations for the International Atomic Energy Agency and the United Nations Secretary-General's Mechanism to investigate allegedly unlawful uses of biological and chemical agents.

In the United States, a similar model was used to expand research capacity in the agricultural context over the course of the 19th Century. In the 1862 Morrill Act, the U.S. government funded the establishment of universities that would specialize in agricultural and mechanical research and development. These so-called 'land-grant' universities became the backbone of national research efforts in sciences of highest importance. The Smith Lever Act formalized these arrangements by in 1914, establishing federal agencies' partnership with land-grant universities to apply research and provide education in agriculture.

Similarly, CGIAR, the backbone agricultural research hubs that undergirded the Green Revolution, maintain research and outreach personnel, as well as working in partnership with the U.N. Food and Agricultural Organization. A similar corps, funded through voluntary contributions by medical schools and biomedical companies, could fuel a similar technical corps for international assistance. Indeed, this kind of scientific support already features in the development assistance provided by wealthier governments.



5. With the G7 and Financial Institutions: Funding Local Production

In addition to technical know-how and licenses, funding is needed to support the development of local vaccine manufacturing and development capacity. According to an Imperial College of London analysis that was commissioned by Médecins Sans Frontières (MSF) the estimated cost of starting up mRNA vaccine manufacturing with a production target of 100 million doses at an existing manufacturing site "could be as little as US\$127 million for Pfizer-BioNTech's vaccine and \$270 million for Moderna's vaccine".⁶⁸

For example, while it "has yet to develop a comprehensive plan to ensure global vaccination",⁶⁹ existing U.S. law allows the government to fund the development of vaccine manufacturing abroad. According to PrEP4All, as of the end of August 2021 at least \$10 billion of the \$16.05 billion in funding in the American Rescue Plan Act (ARPA) for the procurement or manufacturing of COVID-19 vaccines, drugs, diagnostics, and personal protective equipment, remains unspent. Crucially, these unspent funds could be used to support building new vaccine manufacturing capacity including, "building new publicly owned or privately-owned manufacturing capacity",⁷⁰ instead of the current plan to purchase hundreds of millions of doses to donate to LMICs.⁷¹ Similarly, under the Team Europe initiative, the EU has been channeling one billion Euros into supporting technical transfer to and the development of manufacturing capacity in African countries but the scaling up of this funding is desperately needed.⁷²

Meanwhile, the World Bank's sister organization that focuses on the private sector, the International Finance Corporation (IFC), has led a consortium of development banks and agencies such as Agence française de développement (AFD), the U.S. International Development Finance Corporation (DFC), the European Commission, the European Investment Bank (EIB) to provide financing for vaccine production hubs in Africa, including in South Africa (Aspen Pharmicare), Senegal (Institut Pasteur de Dakar) and Rwanda.⁷³ The goal is to support vaccine production for COVID-19 and then other vaccines.⁷⁴



Available National Actions to Address Intellectual Property Barriers to COVID-19 Vaccines

The aforementioned solutions are based entirely on voluntary arrangements and support mapped over existing bureaucratic infrastructure at the OECD and the WHO. Coercive measures are, however, justified in the circumstances and provided for in existing legal instruments. For example, the TRIPS agreement permits coercive government measures under Article 31 on compulsory licenses. Yet it is important to identify and catalogue other public international law measures that may be used to address intellectual property barriers to COVID-19 vaccine access. These public law measures are distinguished from private law mechanisms, which can entail the use of provisions within contracts between governments and companies, or restrictions arising from the government itself being the patent holder. It is important to recognize the ability of governments to enforce their use of such powers varies, and the most significant leverage rests with the handful of high-income countries in which the vaccine originator companies are headquartered or already have sizable manufacturing operations.

Most powers that governments use to expropriate or nationalize a service such as vaccine manufacturing require fair compensation be provided those affected. Such requirements also tend to be mirrored in obligations under international instruments such as trade and investment agreements, including TRIPS. The cost of compensation is, however, small compared to the cost of the ongoing pandemic. For example, the total ~US\$200 billion market value of Moderna is still only a small fraction of the estimated US\$9.2 trillion cost of vaccine inaccessibility, with at least half of that loss incurred in wealthy countries.⁷⁵ Of course, outright expropriation could apply to specific technologies and would unlikely target entire companies.

Contractual approaches can also help address intellectual property barriers to greater and more widespread production of COVID-19 vaccines. Nearly all biomedical products brought to market rely on publicly funded research and, in the specific context of COVID-19, many of the producers were beneficiaries of public-sector funding. The originator vaccine companies built their mRNA vaccines for COVID-19 using generous public grants provided in 2020 to support their investments, mitigate the risks of costly product failures, and expand on technological ground broken over the course of decades by publicly funded researchers. This not only creates an argument in favor of treating the resultant technology as a global public good and supports the use of extraordinary powers of expropriation, but also means funder governments should and often do have private law rights. For example, governments can assert their rights via the contractual arrangements they entered into with vaccine manufacturers and utilize their intellectual property rights they gained by developing research fundamental to today's most successful vaccines.

Because the legal protections for mRNA vaccines are strongest in the United States, it is also worth noting the availability of the U.S. Defense Production Act (DPA), which could be used to compel U.S.-based pharmaceutical corporations to transfer mRNA technology to mRNA technology hubs and manufacturers, including those outside of the United States. As authors Rizvi and Kapczynski point out, the scope of the DPA has expanded since its World War II origins to include, “military or critical infrastructure assistance to any foreign nation... infrastructure assistance and protection... [and] emergency preparedness activities”.^{76,77} The use of the DPA would likely trigger claims for compensation from vaccine originating companies but the amount of compensation would be lessened by the narrow scope of the power's use.⁷⁸ In particular, if the US government only directed vaccines to populations outside of the most lucrative high-income markets it would lessen the profit lost by these companies.⁷⁹ Similarly the reliance the affected companies, in particular Moderna, had on US government investment and inventions in developing their vaccine can be used to offset some of any claimed losses.⁸⁰ The specter of DPA use helped to bring about the collaboration between J&J and Merck, in which J&J did share tech know how and provide a manufacturing license to Merck.⁸¹

The contract which structured the US government's investment in Moderna's mRNA vaccine reserved options for facilitating technology transfer was one of only two companies with which the strongest form of funding agreement was agreed.^{82 83} In particular, the US government has the following rights: (1) the right to produce the Moderna vaccine itself, (2) to force Moderna to license the vaccine's productions to others, and (3) rights to access Moderna's data relating to the vaccine.⁸⁴ Similar private law rights arise from the US government's ownership, via the NIH, of a patent on prefusion coronavirus spike proteins essential for the vaccine mechanism of action of the Pfizer-BioNTech vaccines and required for Moderna's manufacture of its own vaccines.^{85 86} The use of these rights to expand vaccine production and access outside of the United States will be controversial and likely to attract legal challenges but in all cases do create leverage with which to impel voluntary compliance.⁸⁷

Similarly, Germany's federal constitution, the Basic Law, provides for the permissibility of expropriation subject to it being in the public interest. Any such expropriation though must be legislatively authorized and accompanied with fair compensation.⁸⁸ In this case, such legislative authorization exists with the Patentgesetz (Patent Act) and the Infektionsschutzgesetz (Infection Prevention Act). The Patent Act permits the state to use an invention if doing so is in the public interest and such use can include licensing another's use of the invention.⁸⁹ Under the Infection Prevention Act, the Ministry of Health can, by decree, take “Maßnahmen zur Sicherstellung der Versorgung” (measures to ensure the supply) of needed products, such as vaccines, when doing so is in the “öffentlichen Wohlfahrt” (public interest).^{90 91}

Under these laws, it is possible for the German government to order the licensing of vaccines is granted to other manufacturers without going through the usual compulsory licensing procedure. Moreover, the government can also require their transfer of know-how. The permissibility of such a move would be subject to the Germany courts accepting that ensuring the supply of vaccines needed by those outside of the country is within the statute's scope. Even if this was accepted,

the courts would need to be satisfied that there is (1) a public interest in the world's vaccination that outweighs the private interest in retaining control of their property, and (2) that transfer of licenses and know-how is necessary for advancing the world's vaccination.⁹² ¹ There is precedent for such drastic moves as seen in how, in response to perceived shortage of domestic vaccines in early 2021, the head of Bavaria's government and the CSU called for the establishment of a "Not-Impfstoffwirtschaft" (emergency vaccine economy), stipulating that if voluntary agreement was not reached, they would also require the conversion of all capacity to vaccine production.⁹³

Germany has potential rights and real public opinion leverage over the technology developed by the company CureVac. As part of its 300 million Euro investment in its vaccine development, Germany took a 23% ownership stake in the company.⁹⁴ CureVac also received loans from the European Investment Bank and an additional, string free, grant of 252 million Euros from the German government.⁹⁵ ⁹⁶ Unfortunately, the CureVac vaccine failed to measure up in its Stage III trials and its development and production has since been downsized.⁹⁷ It's unclear the extent to which Germany's ownership share provides it leverage over the disposition of the real and intangible assets assembled by CureVac.⁹⁸ It is,

¹ France has a similar provision but it more narrowly provides that the measures taken must be confined to particular territorial districts in which a state of health emergency is declared—see Art. L3131-15 of the French Public Health Code, <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000042103698/2020-07-11/>

however, clear that CureVac should not be permitted to sit on the intellectual property and production capacity it has established while waiting for a more lucrative future opportunity to return to COVID-19 vaccine production. Instead, all legal powers under the shareholding and under German public law should be used to compel and encourage wholesale intellectual property and technology transfer to WHO mRNA hubs and manufacturers of the global south willing to pick up from where CureVac left off.⁹⁹

Similar considerations apply to Sanofi's mRNA vaccine which received positive results in trials but was abandoned by the company in September 2021 due to concerns for the commercial viability of production given the dominance of the Pfizer-BioNTech and Moderna vaccines.¹⁰⁰ This decision came after this vaccine's development was subsidized by the French and other governments with US\$31 million in direct public funding and \$US4.9 billion in advance purchase agreements to help mitigate risks associated with the research.¹⁰¹ MSF has requested Sanofi to voluntarily transfer its technology, as well as provide access to its logistics and supply chain already developed, to the South African WHO mRNA hub.¹⁰² Instead of allowing the time and resources expended on developing the Sanofi vaccine to go to waste, governments should use all legal leverage at their power to force technology transfer.

"Considering the public funding that Sanofi received for its COVID-19 vaccine portfolio, the corporation has a responsibility to ensure that its mRNA vaccine eventually reaches the people. MSF also calls on the French government, as well as other governments that funded Sanofi's research, to put pressure on the corporation to take a rational decision of sharing this technology instead of abandoning it." – Alain Alsalhani, Vaccines and Special Projects Pharmacist at MSF's Access Campaign¹⁰³

While the European Union does not have an equivalent authorization to that of the US DPA or that provided for in Germany's Infection Prevention Act, the European Council does have broad powers to use "appropriate" measures when "severe difficulties arise in the supply of certain products" (Article 122 of the Treaty of the Functioning for the European Union). The Legal Service of the Council have interpreted this provision as a viable legal mechanism to compel vaccine manufacturers to share intellectual property.¹⁰⁴ ¹⁰⁵ Having said this, this interpretation was provided in relation to vaccine shortages within the EU and it is unclear whether it could be successfully used to address to external supply issues.

There are several other countries that may become hosts for the manufacturing of mRNA vaccines which could expand the number of national governments with the ability to impose conditions. For example, Moderna is prospectively establishing manufacturing sites in Australia and the government of Australia has broad existing powers under its Biosecurity Act to issue appropriate and minimally restrictive directions needed to control the spread of COVID-19 to other countries, prevent its spread to Australia, and give effect to WHO recommendations on COVID-19.¹⁰⁶

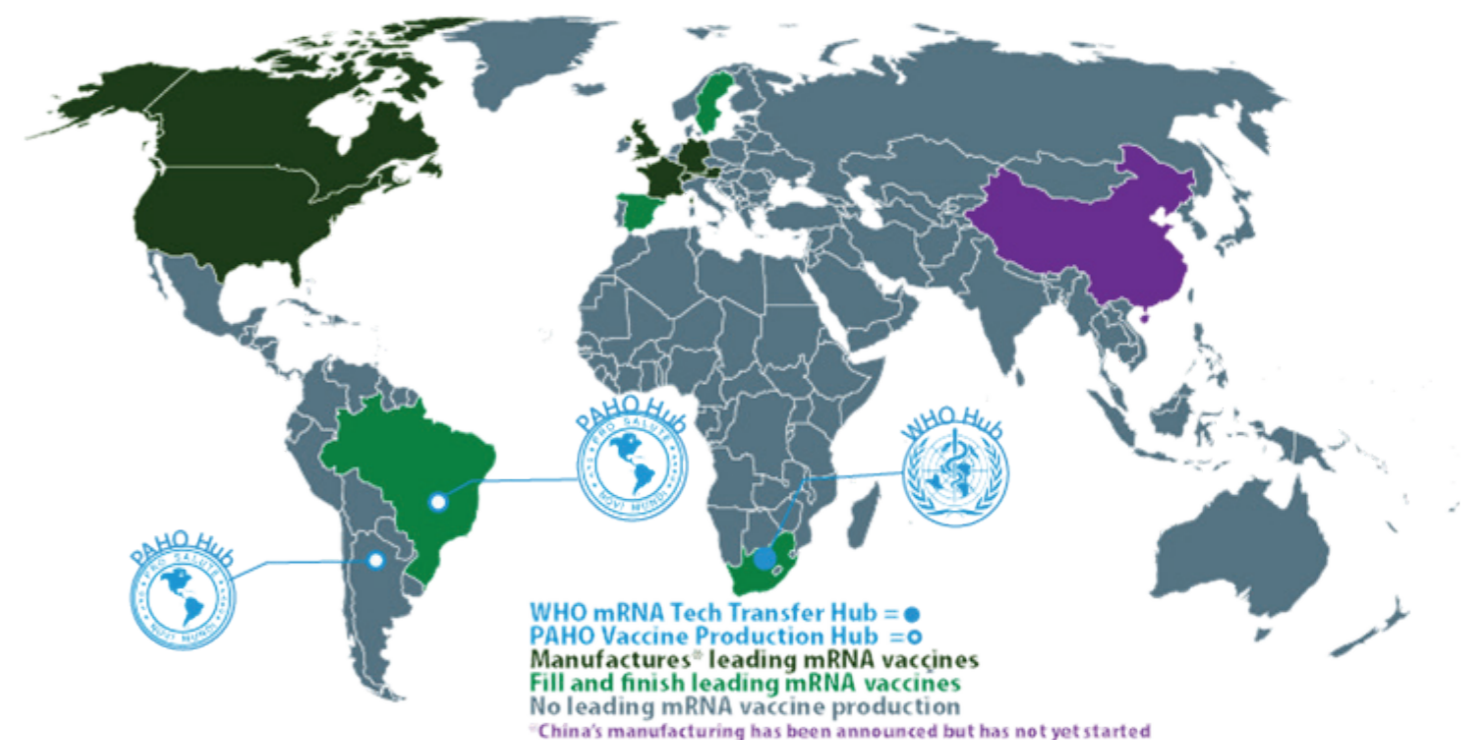


Figure 2 Countries with current and prospective manufacturing or fill and finish capacity for the vaccines developed by Pfizer-BioNTech and Moderna as well as the countries selected as mRNA Vaccine Hub by WHO and PAHO.

“What we are actually saying is: ‘We’re going to do this. So you can come in and try and maintain some control by actually producing vaccines locally, or we’re going to do it without you. And then you’ve lost control.’— Dr Martine Friede, Coordinator, Initiative for Vaccine Research, World Health Organization¹⁰⁷

Many countries with vaccine manufacturing capacity but without existing mRNA manufacturing operations that go beyond the fill-and-finish stage—such as Argentina, South Africa, and Indonesia—have powers equivalent to the US DPA. Based on responses to a WHO call for expressions of interest in mRNA vaccine hubs, there are also at least 22 other LMICs that have indicated their willingness in receiving technology to produce mRNA vaccines. It is unlikely these countries could enforce requirements that vaccine originating companies share intellectual property, enter into licensing agreements or facilitate technology transfers. They could, however, use public powers of emergency direction and expropriation provided for under constitutions and statutes to marshal resources and predict national capacity domestically and in coordination with another to salvage global health. When these powers are not available in a usable form, countries should consider legislating for them as seen in a bill submitted to Congress in Argentina to classify vaccine production facilities as public utilities.^{108 109} These actions could be taken even the absence of support from the vaccine originator companies and action from the countries which should be regulating them to ensure they do not put profit before health—i.e. the U.S. and Germany.

“This landmark initiative is a major advance in the international effort to build vaccine development and manufacturing capacity that will put Africa on a path to self determination.” – South African President Cyril Ramaphosa, June 21, 2021¹¹⁰

Such powers could be used to support the initiative at the WHO mRNA hub in South Africa to reverse engineer the Moderna COVID-19 vaccine as well as to help establish similar initiatives elsewhere. By using these broad legal powers to bring existing capacity and resources behind trailblazing initiatives to work around the intransigence and moral failure of global north companies and countries, a real opportunity to accelerate the established local production capacity could be created. At the same time, fully resourcing and coordinating these initiatives will confront the vaccine originating companies with a credible threat that, by refusing to transfer technology in a structured way now, they will lose wholesale control over their technology. This would likely serve to further incentivize those originator companies to enter into voluntary licensing and supportive technology transfers, which in turn will benefit global health.

Recommendations

The following recommendations offer a starting point for governments, professional bodies and civil society groups to consider ways they can adapt current tools to meeting the growing challenge of addressing intellectual property barriers to COVID-19 vaccines.

Recommendation 1: The World Trade Organization should immediately commit to a broad vaccine waiver for diseases with pandemic potential, those listed on the WHO Blueprint, and those listed in Annex 2 of the International Health Regulations (2005).

Governments, researchers and civil society have previously worked together to address TRIPS barriers to medicines critical to address epidemics and pandemics, notably the Doha Declaration. The techniques and approaches developed to broaden access to medicines and vaccines in the early 2000s can be applied in the current context. While governments will need to take the lead and sometimes encourage industry, it is possible to add flexibilities to the TRIPS regime for COVID-19 medical countermeasures, especially vaccines.

Recommendation 2: OECD Governments, in concert with private sector researchers, should work with vaccine manufacturers and research universities in low- and middle-income countries to transfer know-how and manufacturing inputs to regional manufacturing hubs that build on facilities already committed to influenza vaccine production. Such leveraging would rationalize access to sufficiently pure water, human resources, and other vaccine inputs to manufacture vaccines that combat current and future pandemic viruses.

The availability of vaccine development and manufacturing capacity does now, and will in the future, depend on the assistance of wealthier governments with access to capital, human resources, and raw materials. As the world has witnessed with influenza vaccine manufacturing capacity, it is possible to orchestrate technology transfer that meaningfully builds global capacity to respond to pandemic emergencies. The OECD already has bureaucratic infrastructure and coordinating mechanisms to undertake such an effort for mRNA technologies.

Recommendation 3: The Pandemic Influenza Preparedness Framework should be converted to an all-pathogens agreement that combines private sector support and contracting with WHO-administered access to end-product antivirals and vaccines and transfer of relevant technology.

The Pandemic Influenza Preparedness Framework provides an existing platform whereby industry enters into agreements with WHO and sustains the cost of an essential global health preparedness system. The PIP Framework could be adapted to include SARS-CoV-2 and perhaps other pathogens and its list of promised benefits could include diagnostics and equipment. Such an expansion could operate independently of a pandemic treaty now under consideration during a Special Session of the World Health Assembly in November, or could be initiated outside of that more burdensome process.



Recommendation 4: Under WHO and UNESCO leadership, a global scientific corps should be developed that could respond and assist countries aiming to build vaccine manufacturing capacity. Because middle-income countries not only lack access to know-how but also to scientists themselves, governments should agree to adequately support an international capacity building service built along the lines of extension and outreach agents in the U.S. landgrant university context.

The availability of capital and equipment is not enough. Trained scientists, industrial engineers, and supporting technicians are necessary for vaccine development and manufacturing capacity to expand. There are good models for building an international corps of experts and current development assistance appropriations may be directed for such a purpose.

Recommendation 5: Governments, in their procurement and joint development agreements with manufacturers, should include fair provisions for the transfer of technology.

While orchestrated technology transfer offers a long-term promise for expanding capacity, the most likely and direct route for that transfer to take place is for the major procuring governments like the United States, the United Kingdom, the member states of the European Union, Japan, and others to include the ability to facilitate that technology transfer with the companies themselves. One of the most important developments over the COVID-19 pandemic has been the provisions included in agreements with CEPI and between AstraZeneca and Oxford that prioritized access to vaccines and technology. Those lessons should be applied for future pandemic preparation.

Recommendation 6: Civil society organizations and professional associations should mobilize their membership networks to target both governments and vaccine manufacturers to fulfill ethical and moral obligations to share technology and know-how.

Civil society plays an essential role. In the early 2000s, they effectively forced the market to change how it viewed devastating diseases like HIV/AIDS and similar mobilizing is possible for COVID-19 vaccines. Already there is significant public pressure for Moderna to back up its pledge not to enforce patents with agreements to assist WHO establish mRNA centers of excellence in South America and Africa. The importance of civil society organization should not be underestimated.



Conclusion

On November 29, 2021, the World Health Assembly will convene to consider a new international agreement that will focus on global pandemic prevention and preparedness. That agreement, and all related national efforts, must address management of intellectual property barriers erected over the course of this and the past several pandemics including conditions for open science, access, affordability, and transparency.¹¹¹ The initiatives include the U.S. governments proposed \$65 billion 'Apollo' -style pandemic preparedness program,^{112, 113} Germany's pandemic preparedness,¹¹⁴ and the EU Health Emergency Preparedness and Response Authority (HERA), among others.

Intellectual property, of course, is not the only issue relevant to the current response nor the international agreement to be formed. An essential step is addressing the most glaring examples and drivers of inequitable access to COVID-19 vaccines. This includes honoring the moratorium on boosters, called for by Dr. Tedros and other global health leaders.¹¹⁵ Also essential is removing bans on exports of COVID-19 related supplies and transferring excess doses. With such a yawning gap in access to vaccines, a situation in which excess supplies sit unused or worse, are allowed to expire should not be permitted.¹¹⁶ But even in these cases, intellectual property is the foundation of the higher prices companies receive for boosters in the U.S. versus initial doses in poorer countries and the associated export limitations.

As this report has shown, intellectual property protections have directly imposed material barriers to a coordinated, equitable, and rational global response. For public health emergencies, the fundamental bargains at the heart of patent and trade secret protections must give way to approaches that prioritize global public health. Adopting a TRIPS waiver, creating international infrastructure for global vaccine manufacturing capacity, replete with financial support, and leveraging the tremendous value transmitted through public funding of research are basic and straightforward tools that must be incorporated into any framework going forward.

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