# CHAPTER 5: ALIGNING VACCINE INNOVATION WITH PUBLIC HEALTH NEEDS

So far, the book has explored different problems in the life cycle of a vaccine. First, it surveyed the pathways to bring new vaccines to market against a backdrop of lacking incentives to R&D, in spite of the recognized public health value of vaccines and the widespread use of intellectual property rights as an incentive to vaccine R&D. Second, it examined the allocative disparities that result from the commodification of vaccines, especially in situations of product scarcity, in which lower-income populations often face considerable hurdles in obtaining access to vaccines. This section examines possible solutions to alleviate these problems. It considers proposals that would take effect at the incentives level, by increasing funding for vaccine-related R&D work; proposals that would operate at transactional level, facilitating the transfer of vaccine technology through the use of patent pools and patent pledges; and proposals to expand and fine-tune the role of vaccine-dedicated public-private partnerships as instruments for the promotion of equitable access to vaccines by populations irrespective of their socioeconomic status.

# A. Addressing Commodification Problems Through Non-IP Incentives Frameworks

There is a persistent misalignment between the legal regimes currently in place to incentivize costly and risky R&D and the public health for sustained and robust financial commitments to vaccine R&D. While the premier legal regime for promoting these goals is the patent system, there are other types of incentives worth considering.

These types of incentives are often called non-intellectual property (IP) incentives, and they have long attracted scholarly and, to a lesser extent, policy attention.[[1]](#footnote-1) Many of these incentives embody efforts to promote selected types of R&D with less reliance on market-driven considerations as those on which intellectual property is structured around.

To be sure, intellectual property and other types of R&D incentives are not mutually exclusive. For instance, in his influential analysis of the patent system, economist Fritz Machlup noted that “(p)roposals for systems of prizes and bonuses to inventors, as alternatives to patents, are almost as old as the patent system.”[[2]](#footnote-2) Yet, non-IP incentives have consistently remained marginal in the policy landscape when compared to intellectual property.

The following sections provide a cursory overview of how these incentives work, noting both their potential advantages and their inherent limitations under current economic models of production.

## Ex Ante Incentives to Vaccine R&D: The Case of Grants

One of the most common forms of attracting R&D attention to a particular field of science or technology is through grants. Grants provide funding for work on a specific project or set of projects, often in areas of basic research traditionally overlooked in private-sector R&D agendas.[[3]](#footnote-3)

Grant funding is especially important in the context of R&D in the life sciences. The US National Institutes of Health (NIH), an agency within the US Department of Health & Human Services, are the world’s largest public-sector funder in this area. As of mid-2021, the NIH spends over US $32 billion per year supporting biomedical R&D.[[4]](#footnote-4)

In the case of vaccine R&D, public-sector grants have long played an important role in catalyzing research. In the United States, the National Institute of Allergy and Infectious Diseases (NIAID), which operates under the umbrella of the NIH, is especially active in this area. As of mid-2021, 36 of the 176 funding opportunities sponsored by the NIAID were for vaccine-related work.[[5]](#footnote-5)

In an ecosystem in which market forces tend to drive much of the R&D activity, grants can be a useful tool to promote vaccine R&D, especially at the early-stage level. The awarding of a grant is based on scientific or technical promise of a project, rather than projected or potential market results. Nevertheless, studies about the role of grants in innovation policy often point out that the *ex ante* nature of grant funding is precisely the Achilles’ heel of the grant system.[[6]](#footnote-6) Unlike incentives mechanisms in which an award is made after some measurable result has been achieved, a grant may result in an R&D failure – even though research failures are valuable from a scientific perspective, contributing knowledge about R&D pathways that do not work or approaches that need refining.

By contrast, intellectual property is theoretically designed to reward some degree of innovative activity and does not reward R&D failures. As seen in chapter 3, in order to attain patent protection, all domestic intellectual property laws require that an invention meet the cumulative criteria of novelty, inventiveness and susceptibility of industrial application. In evaluating a patent application against these threshold requirements, examiners in patent offices around the world subject the invention to a “quality check,” making sure that no duplicative products or processes (and products or process only trivially different from existing ones) are protected by a patent. And while sometimes patents are improperly issued, this quality check provides some degree of screening – although it is worth noting here that, as documented by economist Bhaven Sampat and political scientist Kenneth Shadlen, the aggressive patenting culture within the pharmaceutical industry has often resulted in the issuance of poor-quality patents.[[7]](#footnote-7)

On balance, grants and patents operate in differentiated ways and cater to different segments of the R&D timeline. Under current economic models, a robust system to incentivize vaccine R&D will likely rely on both, with grants playing an especially important role in the production of foundational knowledge. However, in light of the severe dearth of funding for R&D on vaccines against emerging pathogens – and given the particular issues that arise in vaccine intellectual property, as detailed in previous chapters – policymakers should consider strengthening the vaccine grant system. Doing so comes necessarily at a cost, implicating the commitment of financial and administrative resources, and tapping into polarizing political economy debates. But virtually any interventions to correct the current shortcomings in the vaccine R&D landscape are likely to entail these types of costs. Maintaining the status quo, on the other hand, will likely magnify costs to public health, in the form of lacking preparedness frameworks to prevent and respond to outbreaks of infectious diseases.

## Ex Post Incentives to Vaccine R&D: The Case of Prizes

Concerns with *ex ante* allocation of funding resources, associated with the need to create incentives to late-stage R&D, have led several commentators to focus on sets of non-IP incentives that operate *ex post*, through the provision of a monetary or potentially monetizable reward once some measurable R&D deliverable is achieved.

One of the most discussed frameworks for incentivizing R&D using *ex post* mechanisms is through prizes. Prizes link the disbursement of funds (or the awarding of a non-monetary reward) to successful completion of a task or challenge set out by the prize administrator and evaluated according to pre-established metrics. At the same time, proponents of the increased adoption of prize-based models note that, unlike the patent system, prizes enable policymakers to de-link the price at which a drug or vaccine is sold from the profits its manufacturer makes upon entering the market.[[8]](#footnote-8) Patents artificially suppress competition, thereby allowing patent holders to charge supra-competitive prices. Under a prize model, innovators are compensated when they succeed in producing a drug or vaccine (or a component thereof), not if they succeed on the market. Monetization of R&D thus occurs through the prize, potentially associated with commercialization of the drug or vaccine at lower prices than under a patent-driven model. If only patent rights are at play, prices are bound to be higher, as they are the only tool available to innovators to recoup R&D costs and make a profit.

Economist Alberto Galasso and colleagues have theorized that, in general, prizes incentivize better innovation, whereas intellectual property, in its race-to-patent format, incentivizes speedy innovation.[[9]](#footnote-9) Some commentators have argued that monetary prizes would be especially useful in the area of pharmaceutical R&D. For example. James Love and Tim Hubbard – the director of the non-governmental organization Knowledge Ecology International and a professor of bioinformatics, respectively – have described several theoretical models for implementing “mega cash prizes” designed specifically for the development of drugs and vaccines.[[10]](#footnote-10) In the most sweeping version of their proposal, a prize system would replace patent rights in these areas – a solution that, as seen in chapter 3, would likely implicate major changes to both domestic and international intellectual property frameworks, as well as to the business model the pharmaceutical industry has long operated by.

Prizes have also been proposed at smaller scales. For instance, early in the COVID-19 pandemic, legal scholars Daniel Hemel and Lisa Larrimore Ouellette suggested that a tailored prize could assuage then-growing concerns that COVID-19 vaccines would be priced unaffordably. They suggested the implementation of a “large cash prize for any firm that develops a successful coronavirus vaccine. The prize would be payable only on the condition that the firm makes the vaccine available to patients at low or zero cost.”[[11]](#footnote-11) Similarly early in the pandemic, business scholar Chris Callahan proposed the establishment of a large prize – in the realm of “many billions of pounds” – for the expedited development of COVID-19 vaccines.[[12]](#footnote-12) The prize would be funded through contributions solicited and administered by the World Health Organization or the United Nations.

While prizes might offer some comparative advantages, they are not without drawbacks. Even though prizes are awarded *ex post*, the framework for the reward is set before commercialization, which limits the information available to price-setters about market demand for the goods in question. A government, or other prize-setter, may thus under-value or over-value a prize, or otherwise tailor it inadequately to the goal it seeks to achieve. Moreover, as with grants, greater reliance on prizes to incentivize R&D would entail increasing prize budgets in ways never before seen in the contemporary economy, as well as expanding the administrative apparatus that supports their administration.

Even if confined to the area of vaccine R&D, expanding the footprint of prize funding constitutes a monumental endeavor. Within the spectrum of non-IP incentives, the grant system has long absorbed more funding and policy preferences. While prizes remain an option for policymakers to consider, they are better understood as complementary to other incentives rather than as substitutes.

## Industry-Specific Incentives Available to Vaccine R&D: The Case of Regulatory Exclusivities and Insurance

Scholars of innovation policy have progressively identified certain types of incentives available to R&D players working specifically in the pharmaceutical arena. Albeit with some variation, patents, grants and prizes are available to both pharmaceutical and non-pharmaceutical innovation. Pharmaceutical products, including vaccines, may also qualify for additional incentives, often in non-monetary forms, that are not available to other types of technologies.

One particular set of such incentives consists in *regulatory exclusivities*, also known as “data” or “market” exclusivities.[[13]](#footnote-13) Legal scholar Yaniv Heled has defined these exclusivities as “competitive advantages resulting from statutory bars on regulatory action where such action is otherwise mandated and would have taken place but for the triggering of the bar.”[[14]](#footnote-14) If a regulatory exclusivity applies, the law precludes a drug regulator from reviewing or approving applications to bring competing products to market for a certain period of time. In practice, this means that the sponsor of a vaccine that might succeed in gaining regulatory approval on the merits of its product may nonetheless have to wait out an artificially imposed period of time in which no one competing with the reference product is allowed to come to market.

These exclusivities are not rooted in intellectual property rights, and operate independently from patents. However, in deliberately restricting competition between drug and vaccine manufacturers, they have effects that are similar to the ones triggered by the application of intellectual property rules: even without a patent, or while having one, an R&D player can get another legal entitlement to operate on the market without competition. The justification for creating yet another layer of rights that results in delays to the commercialization of health goods has long been anchored in discourses about incentives to R&D. Because pharmaceutical R&D is seen as particularly risky and costly, policymakers have responded to requests to increase incentives specific to pharmaceutical R&D, and one way in which they have done so has been through the creation of this additional layer of exclusionary rights. Hence, in some cases, drug regulators in several countries, including the United States and European jurisdictions, are barred from reviewing or approving drug and vaccine applications for certain periods of time – for reasons completely extraneous to the purposes of drug regulation, and instead formally rooted in innovation policy.

Regulatory exclusivities arise when the sponsor of a drug or vaccine obtains approval to commercialize a product that is the first to enter the market in its category. There is a broad range of qualifying products. To give but a few examples, if a sponsor obtains regulatory approval for a new chemical compound, a product that is the first to treat an orphan disease or a new biologic product, a regulatory exclusivity applies. The time during which a drug regulator is subject to the bar varies according to the type of product, and also from country to country. For example, in the case of biologics – the category vaccines belong to – the corresponding regulatory exclusivity is set for a period of twelve years in the United States, while in Canada it is set at eight years.

A vaccine sponsor thus benefits from an additional system of incentives that is specific to pharmaceutical technology – and which, at a given point in time, may be hard to reconcile with the public health need for the robust supply of health goods under competitive conditions, which tend to lower price points for consumers. Heled, who has argued that these exclusivities function as de facto “regulatory competitive shelters,” has emphasized the duplicative nature of exclusivities, in their mirroring of the artificial market scarcity already created by the patent system.[[15]](#footnote-15)

Regulatory exclusivities are not the only policy levers that afford vaccines and other pharmaceutical products forms of legal protection not available to other types of innovation. Recent work by legal scholar Rachel Sachs has highlighted the fact that *insurance* mechanisms can be viewed as form of incentive for R&D players to bring products to market:

“prescription drug insurance may be broadly understood as a “pull” mechanism of the type articulated by economists in the global health literature. It is a reward provided ex post, after the development of a successful technology. And although patients may be charged small amounts for any given prescription, drugs are paid for in large part not by the users of the technology, but by a much broader segment of the population (…) Like most other consumer goods, the size of the reward a pharmaceutical company receives will largely be determined by how their drug performs in the market, primarily measured in this case by the amount of times it is prescribed and the price of each prescription.”[[16]](#footnote-16)

Sachs’ work has explained how Medicaid reimbursement, or prospect thereof, should be regarded as yet another incentive for R&D players to invest in certain types of pharmaceutical R&D, and work by legal scholars Mark Lemley, Lisa Larrimore Ouellette and Sachs has further explored this mechanism in the context of Medicare.[[17]](#footnote-17)

In the United States, the Affordable Care Act (ACA) mandates insurance coverage for vaccines recommended by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP), which translates into most patients with private insurance not having to incur cost-sharing expenses when receiving routine vaccines.[[18]](#footnote-18) During the COVID-19 pandemic, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which added to the ACA framework by mandating similar coverage of COVID-19 vaccines.[[19]](#footnote-19) Insurers were required to cover ACIP-recommended COVID-19 vaccines fifteen days after a favorable recommendation was made.

For some types of vaccines, insertion into insurance schemes can thus function as another *ex post* incentive, as it removes some of the financial hurdles in vaccine access that a person indicated for a vaccine might otherwise have to bear. By making vaccines available to patients who do not have to incur an ad hoc payment that could otherwise dissuade them from seeking administration of the vaccine, insurance helps maintain a market for covered vaccines. Admittedly, this type of incentive may remain a relatively marginal policy lever in the case of vaccine markets, but it nonetheless adds to the roster of features that contribute to lessen the economic risk traditionally associated with engaging in vaccine R&D. Moreover, in the case of vaccines developed in response to an emerging pathogen, legislative action may be required to implement insurance coverage, as was the case in the United States during the COVID-19 pandemic.

## Limitations of Non-IP Incentives

This brief incursion into the landscape of non-IP incentives shows that intellectual property is far from being the sole instrument in the modern innovation policy toolkit. But while the book has repeatedly underscored the insufficiencies of our collective over-reliance on intellectual property – and adjacent legal frameworks anchored primarily on market-driven models of vaccine development and allocation – it is important to note that increasing the footprint of non-IP incentives alone is a hard task, and one that is unlikely to solve the overall problem of funding scarcity for vaccine R&D.

First, non-IP incentives need to be understood in their relative dimension. Incentives offered through the models surveyed above – or complementary modes such as philanthropy or R&D tax credits – pale when compared to the amount needed for vaccine R&D. To date, existing non-IP incentives, and especially those providing direct funding such as grants and prizes, have been used sparingly. Recall the R&D Blueprint released by the WHO in 2016, reporting a “lack of R&D preparedness” affecting vaccines needed to combat emerging pathogens.[[20]](#footnote-20) The Blueprint provided a holistic overview of lacking R&D pipelines – one in which IP and non-IP incentives alike were failing. As such, while policymakers should consider which non-IP incentives are worth bolstering in the vaccine R&D space, under current economic models these incentives are better understood as complementary rather than substitutive of other means of funding vaccine development.

Second, calling for greater use of non-IP incentives – and in particular those resulting in direct monetary awards – necessarily implicates finding the budgetary room for this increase. As seen in chapter 2, public sector funding for scientific and technical R&D has been shrinking over the last decades. This does not mean that these types of incentives cannot play an important role in vaccine innovation policy, but any proposals must at a minimum incorporate a pathway for sourcing these funds, a formidable task.

Third, not all non-IP incentives are created equal. Under circumstances of enriched funding streams, greater use of prizes and grants may be desirable from a policy perspective *and* consistent with public health goals of populating vaccine R&D pipelines. By contrast, continued expansion of other types of non-IP incentives may be at odds with the adoption of innovation policies designed to further public health goals. Analytical work done by Heled and several other scholars suggests that regulatory exclusivities disproportionately exacerbate exclusionary and anti-competitive market dynamics without increasing actual incentives to R&D in discernible ways.[[21]](#footnote-21)

Lastly, creating more incentives to vaccine R&D in non-patent forms does not automatically exclude the application of intellectual property rules, nor market-driven approaches to vaccine innovation. Deploying one or more of the incentives surveyed above means that an innovation lever other than intellectual property is being used, but tells us nothing about concomitant applications of intellectual property. Adopting a policy of bolstering grants or prizes for vaccine R&D, for example, presumably results in more funding being available for vaccine-related work. But if the contractual frameworks governing the awarding of grants or prizes allow for the unbridled propertization of that R&D, the same problems identified throughout the book are still likely to emerge. For instance, a grant recipient may still price the resulting R&D product unaffordably, unless prevented from doing so – either by the contract that governs the grant or by extrinsic motivations. An approach to vaccine innovation policy in alignment with public health needs would thus dictate that increasing non-IP incentives be linked to requirements that further the goal of increasing access to vaccines – in all its components, from equitable allocation to affordability – once a vaccine enters the market.

# B. Collaborative Solutions Within Intellectual Property Regimes: Patent Pools

A completely different set of tools that can help mitigate some of the drawbacks of overly market-driven modes of vaccine development and production available within intellectual property itself. This section introduces the first of two legal structures aimed at facilitating the sharing of patent-protected technologies: patent pools. It begins by describing their general characteristics, advantages and limitations; it then examines the experience of a patent pool created for the cross-licensure of technology during the COVID-19 pandemic; and it concludes by proposing the creation of a permanent vaccine-dedicated patent pool.

## Patent Pools in Context

As seen in chapter 3, the existence of multiple layers of proprietary rights covering different components of a vaccine may pose challenges at the transactional level. An R&D player willing and able to develop or manufacture a vaccine may not have all the relevant patents in its portfolio. Negotiating the transfer of the relevant vaccine technology often entails overcoming some degree of initial uncertainty about the potential licensure of patented components; a period of time- and resource-consuming negotiations between licensor and licensee; and other transaction costs, including royalties associated with the use of the patented technology. If these negotiations unfold during a pressing public health crisis, they also face the same type of compressed timelines under which pandemic and epidemic vaccine R&D occurs. At a time when funding streams are typically at their highest, the transfer of vaccine technology should ideally happen under conditions that minimize uncertainty, negotiating delays and transaction costs – and, in extreme cases, delays attributable to rent-seeking behavior as was the case with NewLink during the Ebola vaccine race.

A possible way of mitigating some of these hurdles to timely collaborations during the onset of a public health crisis is through the formation of patent pools. These pools can also be used outside the context of pandemics and epidemics, to jumpstart or maintain a relatively unencumbered licensing framework for technology needed amongst parties working on similar or complementary R&D areas.

Patent pools are contractual mechanisms that allow multiple patent holders to license their intellectual property to one another, as well as to parties outside the pool.[[22]](#footnote-22) Patent holders with interests in similar or complementary areas of technology may decide to pool a subset of their patents as a way to gain access to a wider variety of patented technologies while potentially monetizing their own intellectual property, within a system that condenses bargaining processes and reduces both uncertainty and transaction costs. The pool is formed through a contract (or series of contracts) establishing the terms of licensure of pre-determined patents belonging to the pool members. Each patent in the pool becomes available for others to use, provided that they comply with the licensing agreement, which typically requires the payment of a fee.[[23]](#footnote-23)

Patent pools can be useful to remove or lessen different types of transactional hurdles, particularly in complex areas of technology. There are several efficiency arguments in favor of pooling intellectual property.[[24]](#footnote-24) First, pools perform an important signaling function by removing uncertainty as to the status of a product or method, as well as the rightsholder’s willingness to license it. In turn, this indirectly reduces the probability of litigation arising with regard to pooled patents. Moreover, pools eliminate the need for individualized negotiations. The contractual structure in place provides access to multiple patents – as many as a licensee may deem of interest within the pool. Rightsholders rely on that same contractual structure to market their technology and create an avenue to receive compensation for uses thereof. Collectively, these features help reduce bargaining and transaction costs. A licensee must have the economic means to pay the licensing fee, but the others constraints and costs normally associated with using patented technologies disappear, or are significantly reduced.

Patent pools can be especially useful in areas in which R&D tends to occur in siloed models, as they create a pathway that facilitates the licensure of complementary or blocking patents. If different firms hold relevant patents necessary to produce a single vaccine, R&D is largely contingent on cooperation between parties who operate on a daily basis as competitors in pharmaceutical markets. Under a pool model covering the relevant patents, vaccine development is no longer contingent on the firms’ willingness to cooperate – nor the delays caused by time and cost associated with intellectual property negotiations. Legal scholar Daniel Crane once described this function of patent pools as “a form of intra-industry social contract permitting the emergence from this Hobbesian war of each against all.”[[25]](#footnote-25)

Finally, the literature on patent pools also notes that the sheer availability of technology under certain and simplified contractual framework is expected to lead to follow-on innovation that results in the public ultimately benefiting from the offering of better or more varied products, or both.[[26]](#footnote-26)

Patent pools have been in use since the mid-nineteenth century, with the first known case in the United States involving patents covering sewing machine technology.[[27]](#footnote-27) Since then they have been documented across different technological sectors, including, more recently, health-related technologies[[28]](#footnote-28) – the most well-known example being that of the Medicines Patent Pool, which was founded in 2010 and has since negotiated licenses for the commercialization of drugs needed for the the treatment of HIV/AIDS, hepatitis C and tuberculosis drugs needed in lower-income countries.[[29]](#footnote-29) In March 2020, the Medicines Patent Pool announced that it would also be temporarily active in the negotiation of COVID-19 drugs.[[30]](#footnote-30) At the time of writing, negotiations were ongoing for a license covering molnupiravir, an antiviral that was entering phase 3 clinical trials as a potential treatment for COVID-19.

## Limitations of Patent Pools: The Case of the COVID-19 Technology Access Pool

In March 2020, Costa Rica submitted a proposal to the World Health Organization in March 2020 for the formation of a COVID-19 patent pool. The proposal was designed to cover a wide array of technologies:

This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country.[[31]](#footnote-31)

One reason that Costa Rica specifically invoked for proposing a pandemic pool was the concern with the affordability of emerging drugs and vaccines, particularly with regard to populations in less affluent countries.[[32]](#footnote-32) The WHO echoed these concerns, noting that the “COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies,” and framing the patent pool as a mechanism that “sets out an alternative, in line with WHO’s efforts to promote global public health goods, based on equity, strong science, open collaboration and global solidarity.”[[33]](#footnote-33)

The proposal resulted in the swift creation of the COVID-19 Technology Access Pool (C-TAP), which was as launched in May 2020.[[34]](#footnote-34) In addition to Costa Rica, 40 countries joined the pool as sponsors. While C-TAP has been hailed as a groundbreaking achievement, it nonetheless failed to attract the commitment of any technology in the months after it was launched – a situation that stretched into 2021, with the pool remaining unpopulated at the time of writing.[[35]](#footnote-35) Public health advocate Ellen ‘t Hoen has labeled this utter lack of pooling activity “the elephant in the room” in conversations across the international community about collaborative responses to the pandemic.[[36]](#footnote-36)

The irresponsiveness of vaccine patent holders to C-TAP is hardly surprising, and it provides a window into some of the inherent limitations of collaborative models based on patent pooling. As was the case with C-TAP during COVID-19, patent pools have historically failed to attract inherently uncooperative players. In areas where innovation processes carry heightened risk and cost, firms with strong intellectual property portfolios are likely to privilege approaches that maximize the prospect of economic revenue through in-house development of technology, acquisition of smaller companies or highly selective licensure of their technology. The voluntary nature of patent pools thus often translates into limitations in the quantity and heterogeneity of participants, pooled patents and use made thereof.

In spite of these challenges, patent pools remain underexplored as a policy tool in the context of vaccine innovation policy. The chapter now turns to an illustration of how such pools can be structured, advocating for the creation of a patent pool tailored to vaccine technology.

## The Case for Vaccine Patent Pools

Policymakers should consider the formation of a pool dedicated to vaccine technology needed for R&D on emerging infectious disease pathogens. While there are several drawbacks to the use of pooling mechanisms – and the experience with C-TAP does not appear auspicious in the case of pandemic or epidemic health goods – this section makes the case that a vaccine-dedicated patent pool would constitute a strategic addition to the vaccine innovation ecosystem.

In the space of public health-oriented patent pools, there are already several cases of disease-specific pools. The Medicines Patent Pool, as noted above, focuses on three diseases, and temporarily expanded its mandate to cover COVID-19. Legal scholars Dianne Nicol and Jane Nielsen have documented the formation of a patent pool dedicated to technology targeting a specific disease (SARS) caused by an emerging pathogen (the coronavirus known as SARS-CoV).[[37]](#footnote-37) Rather than focuses on a disease or set of disease, the model proposed here would focus on a set of technology – vaccine technology.

Although tailored to technologies needed for pandemic and epidemic preparedness, the proposed pool would differ from the C-TAP model by creating a permanent pooling structure developed ahead of a specific public health crisis. In short, the pool would be designed according to a three-part formula: technology specificity*, ex ante* formation, and adoption of rules imposing equitable pricing and allocation obligations on participants in the pool.

Technology specificity allows policymakers conceiving and negotiating a pool to pay attention to the idiosyncrasies of vaccines as health technologies produced primarily through market-driven models. One aspect that the book has sought to emphasize is the fact that, even though vaccines against emerging infectious diseases are not the only type of underfunded or inequitably allocated health technology, they share characteristics and face market dynamics that set them apart from other types of pharmaceutical products. As such, it is worth considering the adoption of policies and legal solutions catering to the specificities of vaccines, as well as vaccine markets, producers and consumer – while this section focuses on patent pools, the following sections will adopt similarly vaccine-tailored approaches when making other policy and legal recommendations.

A vaccine-dedicated pool is nonetheless compatible with technological heterogeneity. As seen in chapter 1, there are multiple types of commercially available vaccines, and several other types are being researched and tested. The COVID-19 pandemic underscored the fact that it is possible to develop safe and effective vaccines targeting an emerging pathogen using radically different types of technology: some of the first vaccines to enter the market were based on mRNA technology (the Pfizer-BioNTech and Moderna vaccines), while others were based on viral vector technology (the Johnson & Johnson and AstraZeneca vaccines. A vaccine-specific pool can capture patents relating to different technological approaches to vaccine R&D.

Conversely, it is important to recognize that, given the voluntary nature of commitments to a patent pool, holders of especially valuable or otherwise strategic intellectual property will be less likely to commit those segments of their patent portfolio. Consider the case of mRNA technology. COVID-19 accelerated the testing and commercialization of vaccines based on this type of technology, which is also being tested in a variety of non-vaccine applications, ranging from cancer immunotherapy to R&D on rare genetic diseases. A cutting-edge technology that can serve as an R&D platform for multiple purposes tends to be more valuable and strategically more important than older-type or single-purpose technologies. Holders of patents on platform technology in the vaccine space are therefore less likely to make those technologies available through a pool.

A vaccine-dedicated pool can and should thus be understood strategically, and designed with the deliberate goal of attracting some vaccine intellectual property, but not all types of vaccine technology. A means to achieving this goal is by linking certain incentives to the commitment of technology to the pool: policymakers may award a prize to entities contributing a patented component or process; or a portion of grants available for vaccine R&D can be linked to the obligation of making the resulting technology available through the vaccine-specific pool. Moreover, these incentives can be customized. For example, entrance prizes can be set higher for some vaccine components, reflecting either their functional value or their relative scarcity within the pool.

Unlike the approach adopted in the formation of C-TAP, a vaccine patent pool as proposed here would be less diffuse in scope. It would enable policymakers to target a smaller number of R&D players – including, potentially, less established players in the vaccine R&D space for whom the combination of institutional networking, the possibility of an entrance prize and the prospect of royalties might be appealing.

In order to further strategic design, a vaccine pool should be negotiated outside the context of large public health crises. C-TAP was formed under quick-shifting public health, economic and business conditions. By contrast, the model proposed here would be created *ex ante*, in the sense that it would not be designed in response to an ongoing event, but rather in furtherance of public health notions of preparedness. Given the knowledge that epidemic and pandemic outbreaks of emerging infectious diseases will continue to occur, the inevitability of future vaccine races is apparent. Reactive solutions are warranted as needed, but the vaccine ecosystem – and, more generally, the public health ecosystem – lack proactive intellectual property strategies. A vaccine patent pool would be one step towards the development of such strategies.

Keeping in line with the need for tailorable solutions, a vaccine patent pool could also be structured in a two-tier format. One tier would be open for the pooling of vaccine-related technology at any time, while the other would only become active in the event of a large-scale public health crisis. The “open tier” would essentially function as a regular patent pool. The “restricted tier” would consist of committed technology that would become available for licensure according to pre-determined contractual frameworks at the beginning of a pandemic or epidemic. The trigger for the restricted tier to become active should be designated in advance and clearly identifiable: for example, a declaration of Public Health Emergency of International Concern by the WHO.

Finally, it is important to recognize that, while the creation and use of a patent pool may facilitate the use of patented vaccine technology, it might still not move the needle on issues related to access to goods developed through the use of pooled technology. A contractual framework regulating interactions within a pool typically covers issues such as permitted uses of patented technology and licensing fees, but may be silent on the downstream cost imposed on consumers of the resulting technology. As such, the distribution and pricing of a health good developed through the use of pooled technology may still occur under inequitable circumstances. These may include unaffordable prices, preferential allocation of initial units to a restricted number of wealthier consumers, or allocation according to geographical patterns that do not align with public health needs. In this sense, while pools can be instrumental in promoting collaborative R&D, they do not automatically eliminate the most concerning traits of proprietary modes of R&D. As such, a vaccine pool should be structured so that it imposes contractual obligations that go beyond the regulation of interactions between participants – for instance, by imposing an obligation that resulting health goods be commercialized at price points that consumers are able to afford in their respective geo-economic markets.

# C. Formalization of Soft Legal Approaches: The Case of Patent Pledges

This section explores the figure of the patent pledge, a mechanism that shares a key feature with patent pools, in that it signals a permissive stance of the patent holder towards the use of technology covered by intellectual property rights. There are nonetheless significant differences between pledges and pools, which this section surveys before setting forth a proposal for the creation of a vaccine-specific patent pledge for R&D on pandemic and epidemic vaccines.

## Pledges of Non-Assertion in Context

Intellectual property gives patent holders an essentially negative right, conditioning the use of patented technologies to licensure or other mechanism signaling authorization for others to use the patented product or process.

As seen above, patent pools signal the availability of proprietary technologies for licensure, likely against the payment of a royalty. While referring to technologies with a similar proprietary status, patent pledges revolve around a promise to limit the enforcement of one or more patents. The bundle of rights conferred by the patent remains in full force, but the patent holder self-limits their exclusionary powers by indicating to the public at large that the patent will not be asserted for the duration of the pledge.[[38]](#footnote-38)

For some reason – whether altruistic or strategic – a rightsholder decides to inform the public that the patent will not be enforced. As a consequence, parties who have never entered into a contractual agreement with the patent holder are able to use the patented technology without having to negotiate a license or seek any other type of permission from the rightsholder. Moreover, no direct payment or other form of consideration is required.[[39]](#footnote-39) The diffuse nature of the promise, combined with the absence of consideration, differentiates pledges from pools.

While pledges are often made through language that appears to be so diffuse as to target the general public, in practice they tend to be directed at the R&D actors in technical and scientific fields similar to, or overlapping with, the ones in which the patent holder operates. For instance, one of the most well-publicized patent pledges was made in 2014 by Tesla, a California-based manufacturer of electric vehicles, and read “Tesla will not initiate patent lawsuits against anyone who, in good faith, wants to use our technology.”[[40]](#footnote-40) Although the pledge was seemingly made to the public at large, only players in areas connected to Tesla’s have the ability to take advantage of the pledge from an R&D perspective.

Some pledges make this distinction explicit. In October, 2020 the pharmaceutical company Moderna – which produced the second mRNA COVID-19 vaccine to enter the US market –announced that “while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic.”[[41]](#footnote-41) The company’s promise is thus targeted to R&D players who are Moderna’s direct competitors and who, absent the pledge, would infringe on Moderna’s intellectual property if they used the patented technology without obtaining authorization from the company, and likely paying for it. In addition to publicizing the pledge on their website, Moderna published a representative list of patents covering its COVID-19 vaccine.[[42]](#footnote-42) Both the pledge and the listing of the patents were made available even before Moderna’s COVID-19 vaccine received was authorized for emergency use by the FDA emergency use authorization in December 2020.

Moderna’s pledge exemplifies a case of a temporally limited pledge, even though the sunset date was unknown at the time the promise was made. Tesla’s, by contrast, contained no language limiting the duration of the company’s pledge.

By notifying interested parties of a self-limitation on part of the patent holder, pledges can perform a valuable notice function,[[43]](#footnote-43) paving the way for technology held under proprietary frameworks to be used by others, even if for a limited period of time. The pledge format can therefore be particularly useful in cases in which R&D processes unfold under compressed timelines and in response to heightened social needs, as is the case with a vaccine race during a pandemic or epidemic. Yet, both within and outside the context of pharmaceutical R&D, the use of patent pledges has historically been marginal and often plagued by uncertainty.

## Limitations of Pledges

As was the case with the formation of patent pools, a pledge depends entirely on a voluntary gesture of the patent holder. However, unlike a pool, a pledge typically excludes or severely limits the possibility of monetization of the patented invention in the short-term. In the current patent-intensive R&D culture, pledges do not comport well with the pressures imposed by R&D models that default to exclusionary frameworks. As such, their adoption remains episodic.

Additionally, several ongoing or past pledges are shrouded in uncertainty, with commentators questioning whether the promises made by a given pledgor are legally enforceable. As legal scholar Jorge Contreras has explained, “(i)n order for a corporate pledge to be actionable, it should be of a type that would reasonably be assumed by the pledgor to induce action or forbearance in the pledgee.”[[44]](#footnote-44) Nonetheless, some of the most prominent pledges of non-assertion have been made in ways that may fall short of meeting this threshold. Consider, for instance, the promise made by Tesla (“Tesla will not initiate patent lawsuits against anyone who, in good faith, wants to use our technology”). The pledge was made through a website announcement, with no contractual framework developing the terms of the promise, and adopting porous language. As a rule, courts are reluctant to protect vague promises – especially those in which no consideration is offered.

Relatedly, the porosity of the language used in the Tesla pledge is problematic for reasons beyond enforceability. No definition of “good faith” or “use” was provided, even though the former limits the scope of permissible acts, and the latter refers to the material actions allowed under the pledge. As such, a party relying on Tesla’s promise faces additional uncertainty stemming from the lack of definitional clarity: until there is a judicial challenge or Tesla provides more information, no one knows what the actual scope of permissible acts under the pledge might be.

Against this backdrop of uncertainty, taking the pledge at its face value may entail a great deal of risk. If a given pledge is found unenforceable and the patents at stake have not been invalidated, an R&D actor who used the underlying technology may come to face time- and resource-consuming litigation.

Albeit narrower in its framing, Moderna’s pledge (“Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic”) is detached from any other applicable contractual or interpretive framework, and raises similar questions to the ones explored in connection with the Tesla pledge. For example, even though a determinable duration is provided, what is the meaning of “vaccines *intended* to combat the pandemic”? As worded, the promise does shed light on what kinds of vaccine R&D would qualify as meeting this threshold – for instance, does the pledge cover only late-stage R&D, or would more basic research be permissible as well, as long as it is tied to the development of a pandemic vaccine? If the resulting vaccine does not obtain FDA authorization or approval, is the requirement of intent satisfied? And, perhaps even more critical, how will royalties and other licensing terms be calculated and implemented the moment the pandemic ends?

As seen in part D of this chapter, the uncertainty surrounding Moderna’s pledge with specific regard to mRNA vaccine technology is likely to matter more from a legal interpretive perspective than from a practical viewpoint. Because the technology in question is especially complex, it is doubtful that an mRNA vaccine – and likely other types of vaccines – can be developed based exclusively on the information disclosed by patents. If the originator company, such as Moderna in this case, does not transfer additional knowledge on practical aspects of vaccine manufacturing, second-comers are likely to face unsurmountable challenges in replicating the vaccine. The following timeline helps illustrate this pro: Moderna’s pledge was made before any COVID-19 vaccines were authorized or approved by drug regulators; in December 2020, the first vaccine doses entered the market, when it was already apparent that the global supply of authorized COVID-19 vaccines was manifestly insufficient to meet pandemic needs; during the first half of 2021, pleas for increased manufacturing of COVID-19 vaccines increased; nevertheless, by mid- 2021, no single entity had availed itself of Moderna’s pledge and replicated its vaccine.

In spite of these legal and practical shortcomings, steps taken during the COVID-19 pandemic have shown that pledges can be used in productive ways. The chapter now explores how the uncertainty inherent to pledging as it is often practiced can be reduced through the “formalization” of patent pledges – their inscription into pre-existing, yet malleable, contractual frameworks.

## Formalizing Pledges: The Open COVID-19 Pledge

Early in the COVID-19 pandemic, a group led by legal scholars Jorge Contreras and Mark Lemley, and lawyers Diane Peters and Mark Radcliffe, developed a framework for a patent pledge covering technologies related to COVID-19, and implemented it in collaboration with colleagues across other disciplines.[[45]](#footnote-45) The purpose of the Open COVID-19 Pledge was to attract commitments “by holders of intellectual property to share their intellectual property for the purposes of ending and mitigating the COVID-19 Pandemic.”[[46]](#footnote-46)

Instead of merely inviting pledgors to make a statement about not enforcing their intellectual property during the pandemic, the Open COVID-19 Pledge directed interested parties to adopt a set of contractually binding frameworks. This feature set it apart from the cases described in the previous section in two ways. First, a party could only join the Pledge by agreeing to a tailorable license recognized by the Pledge as meeting its requirements: the pledgor was free to choose the contractual terms that better suited its altruistic or strategic purposes (or both), and uncertainty about the enforceability of the promise was eliminated. Second, the Open COVID-19 Pledge functioned as a centralized venue, congregating pledging activity and congregating information about pledged COVID-19 technologies. The website of the Pledge included a searchable database through which interested parties could for other COVID-19-related technologies also committed through the Pledge.

The contractual frameworks offered by the Pledge ranged from different standard licenses made available for adoption “as is” to Pledge-compatible licensing formats and “alternative” licenses.[[47]](#footnote-47) Standard licenses gave pledgors several choices on how to self-limit their rights. These licenses covered only five core contractual areas, matching the bare essentials of most technology transfer agreements: grant and scope; time limitation; regulatory exclusivity; defensive suspension; and the inexistence of a warranty.[[48]](#footnote-48) The Pledge offered three types of standard licenses, two of which cover both patent and copyright issues, and one covering patents alone.

In addition to standard licenses, the Pledge allowed for the use of custom licenses, as long as the licensing terms were deemed compatible with a set of minimum standards established by the Pledge.[[49]](#footnote-49) Compatible licenses were defined as those originally drafted by sources external to the Pledge, which were were pre-screened by the Pledge and labeled as meeting its requirements, or licenses reviewed on a case-by-case basis and found to meet the same requirements. Examples of compatible licenses included the MIT license and the Apache 2.0 license, two of the most well-known and used licenses developed in other fields of technology.[[50]](#footnote-50)

The third option was for pledgors to also adopt “alternative” licenses. These were defined as licensing frameworks that, albeit not fitting the other two categories, were nonetheless “consistent” with the Pledge.[[51]](#footnote-51) Examples included a license developed by Creative Commons license to promote the use of creative works,[[52]](#footnote-52) and GNU’s General Public License, a type of license developed to enable a wide range of uses of software.[[53]](#footnote-53)

One advantage of providing a range of licensing options is that it allows participants to tailor the permissions they wish to give to possible uses of their intellectual property during a limited period of time. For instance, even aspects like the duration of the non-assertion period can be approached in ways that reflect different approaches to the temporal uncertainties posed by a pandemic. One standard license, for example, provided a framework that was in effect “until one year after WHO declares the COVID-19 Pandemic to have ended.”[[54]](#footnote-54) Other standard licenses were set to expire in January 2023, absent an explicit extension provided by the pledgors before the term runs out.[[55]](#footnote-55) Similarly, while standard licenses did not address the issue of indemnification, custom licenses may require “the licensee to indemnify the licensor for liability directly attributable to the licensee’s actions.”[[56]](#footnote-56)

The Open COVID-19 Pledge was launched in March 2020. Founding adopters included large private-sectors companies operating across a wide spectrum of non-medical areas of technology – Facebook, Amazon, Intel, IBM, Microsoft and Hewlett Packard; Unified Patents, a California-based organization coordinating interventions to diminish the number of entities that improperly assert intellectual property rights; Fabricatorz Foundation, a Missouri-based non-profit organization working with individuals and entities developing creative technologies; Apheris AI, a German company working in the data privacy space; and the Sandia National Laboratories, one of the three R&D laboratories ran by the National Nuclear Security Administration, an agency under the US Department of Energy.[[57]](#footnote-57)

The Pledge was able to collect a large patent portfolio from pledgors across the world within weeks. Among the early pledgors there were large institutions in both the private and public sector. For instance, NASA pledged a patent covering 3D-printed respirators, Fujitsu pledged a patent covering disease diagnosis through automated software, and Facebook pledged a patent systems and methods for the detection of contextual information indicative of misinformation.[[58]](#footnote-58)

In addition to its quick implementation against the backdrop of a severe public health crisis, the formation of the Open COVID-19 Pledge was noticeable for creating a licensing framework that was both structured and flexible. From a contractual perspective, it provided exemplificative legal frameworks, which can be especially useful for first-time pledgors or patent holders with limited licensing experience. Simultaneously, it provided a set of minimum standards that could be built on by those wishing to further customize their promise of non-enforcement. These features combined to provide a mechanism to incentivize the licensure of technology while significantly reducing transaction costs and uncertainty at a time when expedited R&D was critical for pandemic response.

From a technological perspective, the Pledge was designed to cover a broad array of products and methods that may be relevant in the development of products needed to respond to a specific public health crisis. While it attracted a robust number of patent pledges, the pledged technologies did not relate to vaccine development and manufacturing. I ran searches using the Pledge’s search function in late 2020 and throughout the first half of 2021,[[59]](#footnote-59) and had informal conversations on this topic with some of the creators of the Pledge. This absence does not detract from the remarkable achievements of the Pledge – which was not designed specifically to attract vaccine technology – but rather highlights the fact that policies designed to promote collaborative R&D and technology transfer in the field of vaccines may warrant supplemental interventions, such as the one proposed in the following section.

## The Case for a Vaccine Technology Pledge

The Open COVID-19 Pledge can be regarded as a natural experiment in the formalization of patent pledges in the context of a major public health crisis. The book uses the word “formalization” to emphasize the creation of structures, both legal and organizational, that support the creation and management of a pledge. Crucially, these structures help instill definitional and operational clarity into the pledge’s framework, which has been one of the most severe limitations of many pledges, especially those made by prominent corporations to a diffuse audience. In so doing, these structures also help guarantee the enforceability of pledges, especially if they rely on recognizable licensing instruments, as was the case of the Open COVID-19 Pledge.

The highly structured and pliable contractual frameworks offered by Open COVID-19 Pledge can be used as a blueprint for the creation of future pledging frameworks tailored to different public health needs, technologies – and, potentially, even permanent pledging structures. Using the Pledge as a starting point, this section makes the case for the creation of a formalized, permanent and technology-specific patent pledge. The pool would cover vaccine-related technology, with a focus on vaccines needed for pandemic and epidemic prevention and response. In addition to formalization and permanency, the pool would offer the possibility of license customization modeled after the Open COVID-19 Pledge, and borrow several other structural features the Pledge, including its centralizing function and online presence. Furthermore, the proposed pledged could be coupled with non-IP incentives aimed at attracting participation, the sharing of non-patent information, or both.

With regard to the scope of the vaccine pledge, the proposal once again calls for a distinction between different types of vaccine technology. As noted in connection with the proposal for a vaccine patent pool, holders of patents covering platform technology – which can be used to develop different types of products, including in some cases vaccine and non-vaccine products – are generally less likely to respond to this type of technology transfer framework. Rather, such rightsholders will typically elect to perform R&D on their own, or in collaboration with a small number of close partners, often repeat players to whom the technology is licensed on an individual basis. A vaccine-dedicated patent pool would thus be designed to attract primarily pledges covering relatively simpler vaccine components and vaccine-related processes. In addition to making a centralized pledging structure available, as done by the Open COVID-19 Pledge, one way to achieve this goal would be by offering incentives to long-term participation in the vaccine pledge. For instance, holders of non-platform technology who pledge a patent for a fixed number of years would be entitled to a monetary prize. The list of technologies eligible for this or another non-IP incentive would be set in advance and revised periodically to reflect changing needs and the status quo of vaccine R&D.

There are additional ways to customize the scope of the pledge. A more atomic version of the pledge could focus solely on some types of vaccine-preventable diseases and concentrate efforts – and funding – on attracting vaccine technology in these areas. This narrower version of the proposal could be useful if the pledge-cum-incentives model is adopted and funding is limited; if policymakers wish to experiment with an initial pledge model covering disease that take a particular toll on certain geographical areas; or if they wish to focus on diseases deemed by public health experts as likely to cause a significant outbreak in the short- or medium-term – using a model reflective of, or similar to, the WHO’s R&D Blueprint.

On the opposite side of the spectrum from a funding and design perspective, another possibility would be to create enhanced prizes for the pledging of vaccine-related technology deemed especially valuable from an R&D perspective, which could include platform technology, if any were to be pledged.

Yet another way of populating a vaccine pledge would be by tying some non-IP incentives available to vaccine R&D to a requirement of participating in the pledge. For instance, policymakers in the public sector could designate a portion of the existing grant funding for vaccine-related work as reserved for applicants who agree to a contractual obligation of pledging any resulting patentable vaccine technology. A variation of this model, described below, would consist in tying the non-IP incentive to the obligation of pledging resulting vaccine-related intellectual property, but the pledge would only produce effects if and when there was a declared pandemic or epidemic.

The vaccine pledge would employ the same versatile approach to licensing that was used by the Open COVID-19 Pledge. Standard licenses would regulate a core set of contractual domains, while additional licenses reflecting tried-and-tested approaches in other fields of technology would be screened and made available to pledgors of qualifying vaccine technology where appropriate.

While the Open COVID-19 Pledge was more successful in attracting participants than the C-TAP patent pool, both mechanisms constituted a reaction to an ongoing public health crisis of extraordinary magnitude. By contrast, the proposed vaccine pledge would be created as a permanent institution. However, as was the case with the vaccine patent pool proposed above, there could be a two-tiered structure. The first tier would be active at all times and comprise pledges made with no temporal contingencies. The second would be formed by pledges of non-assertion that would only become active in the in the event of a formally declared outbreak, be it a pandemic or epidemic. The types of formal declaration qualifying as triggering the activation of this tier of the pledge would be determined in advance, and could once again be a declaration of Public Health Emergency of International Concern or a pandemic declaration by the WHO.

As all patent pledges, the one proposed here would still be constrained by voluntarism and strategic, market-driven behaviors that lead some R&D players away from non-exclusionary modes of managing their intellectual property portfolio. Moreover, if implemented in connection with prizes or other non-IP incentives awarded to encourage participation, the pledge would need to source monetary contributions in a funding climate marked by relatively few resources allocated to vaccine R&D – at least absent a considerable public health crisis.

Nevertheless, there is an argument to be made that voluntarism (coupled with funding needs, should funding be required at all) may present advantages worth considering. Operating from a perspective of searching for room within existing intellectual property frameworks to promote less exclusionary forms of R&D, voluntarism does not disrupt the status quo in the way compelled transfers of intellectual property do – as seen in the following section. Therefore, policymakers should seriously consider incentivizing the creation and adoption of voluntary mechanisms such as patent pledges and patent pools. If treated strategically and incentivized properly, these mechanisms can be especially useful in an area such as vaccine R&D on emerging pathogens, which absent an outbreak is often relegated to the backburner of pharmaceutical R&D.

Finally, if participation in the pool were incentivized indirectly – such as in the case of making a portion of existing grant funding conditional on participation in the pledge – the resources consumed by the pledge would be minimal, as no new resources would need to be committed to the incentive. If policymakers chose instead to implement a direct monetary award to attract participants (or a segment thereof) the creation of a vaccine pledge would consume a non-negligible amount of resources. That being said, the cost of a narrow intervention such as the funding of awards for a vaccine-specific pledge or pool is bound to be far less than for other types of interventions, and may help change, however slowly, the exclusionary R&D culture that currently permeates the development of vaccines against emerging pathogens.

# D. Reconsidering “Forced” Collaborations in Vaccine R&D

Having explored different voluntary mechanisms to promote the transfer of vaccine technology, the book now considers the role of non-voluntary forms of technology transfer. International and domestic legal regimes have long contemplated the possibility of forced licensure of patented goods – most notably through compulsory licensing, which has been successfully deployed in past epidemics by lower-income countries facing difficulties in accessing patented pharmaceutical products. The COVID-19 pandemic brought to the forefront proposals for a different type of legal intervention, which had never been used or received serious political or policy consideration: a waiver of intellectual property rights covering COVID-19 vaccines and other health goods needed to respond to the pandemic. The waiver was widely promoted as a tool that would help increase the production and distribution of vaccines, particularly across lower-income countries. In a departure from previous stances on intellectual property, the United States government endorsed the proposal in May 2021, even though several higher-income countries like opposed it.

This section examines the waiver in the context of the COVID-19 pandemic, and makes the case that, even though it would seemingly lessen exclusionary frameworks and promote technology transfer, it did not tend to the specific characteristics of vaccines as products of biotechnology. While powerful as a statement against the market-driven vaccine R&D status quo, the waiver would not solve the replicability problems that are a hallmark of biological products like vaccines. Unlike previous interventions compelling the sharing of patented pharmaceutical products, the proposed waiver was an example of a mismatch between a pressing public health need and the legal tool chosen to address it.

## Patent Waivers and Compulsory Licensing in Context

In October 2020, India and South Africa submitted a proposal to the World Trade Organization for a waiver of intellectual property rights covering technologies needed for the “prevention, containment or treatment of COVID-19.”[[60]](#footnote-60) As worded, the proposal would apply to a broad range of health goods: the drafters specifically highlighted the heightened public health need for diagnostics, personal protective equipment, ventilators, vaccines and drugs.[[61]](#footnote-61) For an intellectual property waiver to produce legal effects, it must be approved by the World Trade Organization’s General Council – which had not happened at the time of writing, as of mid-2021. If adopted as proposed, the waiver would remain in effect “until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”

From a legal perspective, a waiver upends the usual dynamics of the TRIPS Agreement. Ordinarily, the Agreement allows signatories to challenge countries that violate TRIPS provisions through specialized dispute settlement procedures at the World Trade Organization (WTO).[[62]](#footnote-62) The waiver requested by the governments of India and South Africa would establish that countries granting compulsory licenses on products related to COVID-19 would not be held in violation of any intellectual property rules, preventing these WTO-based challenges from occurring.

The TRIPS Agreement gives countries the ability to issue compulsory licenses on patented goods in cases of need.[[63]](#footnote-63) The World Trade Organization defines compulsory licensing as instances in which “a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.”[[64]](#footnote-64) These licenses are issued by national governments and are generally subject to a requirement that an attempt be made to obtain a voluntary license from the patent holder. In situations of “extreme urgency,” as is the case of a large public health crisis, this requirement can be waived.[[65]](#footnote-65) Early in the COVID-19 pandemic, several countries – including high-income countries such as Germany, France and Canada – amended their domestic laws to facilitate the grant of compulsory licenses.

Originally, the TRIPS Agreement restricted compulsory licensing by preventing countries from issuing licenses for patented pharmaceutical products meant primarily for export to other countries. This prohibition was highly detrimental to lower-income countries, most of which lack the manufacturing capacity necessary to produce these products in the first place. Legal scholar Jerome Reichman labeled article 31 of TRIPS “an empty gesture” towards these countries.[[66]](#footnote-66)

Article 31(f) still establishes that compulsory licensing should “be authorized predominantly for the supply of the domestic market” of the country issuing the license. However, building on the 2001 Doha Declaration on TRIPS and the Public Health, a waiver to article 31(f) was introduced to allow lower-income countries to import pharmaceutical products under a compulsory license. The waiver, which is only applicable to pharmaceuticals that lower-income countries cannot produce themselves, became effectively a permanent part of TRIPS in 2017 as article 31bis. By the time the COVID-19 pandemic began most, but not all, TRIPS signatories had ratified this amendment to the Agreement.[[67]](#footnote-67)

The different type of waiver proposed in 2020 by India and South Africa would go beyond the cases contemplated by the TRIPS compulsory licensing architecture. First, while compulsory licensing is restricted to patents and very limited cases in copyright law, the COVID-19 waiver would apply broadly to cover “patents, industrial designs, copyright and protection of undisclosed information.” Second, compulsory licensing as allowed by TRIPS occurs on a country-by-country and product-by-product basis. By contrast, the COVID-19 waiver would suspend the enforcement of intellectual property rights, and in so doing it would eliminate the need for a patchwork approach to compulsory licensing, effectively creating a temporary blanket umbrella for the exercise compulsory licensing with regard to any COVID-19- related products.

## The COVID-19 Vaccine Waiver

The proposal for such a broad waiver in the context of COVID-19 was motivated by concerns with obstacles created by intellectual property rights to the development of pandemic health goods. As the drafters explained, they were moved by “several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients.”[[68]](#footnote-68)

The reports referenced in the text of the proposal related to non-vaccine technologies, such as ventilators and personal protective equipment. For instance, one report cited in the waiver proposal referred to the case of N95 respirators, a type of face mask widely regarded as an industry standard in situations involving the spread of pathogens causing transmissible respiratory disease.[[69]](#footnote-69) N95 respirators were in high demand during the pandemic and several countries faced difficulties in their procurement. In April 2020, the Governor of Kentucky called on the main US distributor of N95 respirators – M3, a US-based multinational company – to “provide (the patents covering N95 respirators) to the nation under a license for this period of time.”

As seen throughout the book, vaccines present much more significant manufacturing and replicability challenges than personal protective equipment like N95 respirators. Yet the epicenter of the proposal submitted to the WTO quickly became the waiving of patent rights covering COVID-19 vaccines. For months after it was made, the proposal was discussed primarily in specialized circles and opposed by a substantial number of higher-income countries. As the May 2021 meeting of the WTO General Council approached, discussions about the waiver increasingly focused on the suspension of vaccine-related intellectual property rights.

On May 5, a little over six months after the proposal was originally made, the United States announced its support of the proposal. To some extent, the announcement marked a departure from previous US external intellectual property policy, which has long been known as disfavoring compulsory licensing of pharmaceutical products, or any other interventions that may lessen the exclusionary dimension of patent rights covering pharmaceuticals.[[70]](#footnote-70)

In this sense, the statement of support for the waiver made by the US Trade Representative introduced a different tone to the country’s pharmaceutical patent policy: “The administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for Covid-19 vaccines.”[[71]](#footnote-71)

The announcement received considerable praise. The Director of the WHO hailed the position taken by the United States as a “historic decision for vaccine equity.”[[72]](#footnote-72) Activists in the public health space and many commentators in the US abroad responded in a similarly enthusiastic ways to the news. At the same time, the waiver was criticized by many others. The editorial board of the *Wall Street Journal* labeled the US endorsement of the waiver a “vaccine patent theft,” framing it as an instance in which “the White House helps other governments steal.”[[73]](#footnote-73) The pharmaceutical industry condemned the shift in US policy in less inflammatory language, but underscored [[74]](#footnote-74) A point of quasi-agreement for competing views on the waiver was that the position adopted by the United States was, by and large, surprising in light of its longstanding intellectual property policy. The day after the US Trade Representative’s announcement, an article in *Nature* carried the headline *In Shock Move, US Backs Waiving Patents on COVID Vaccines*.[[75]](#footnote-75)

Even after the United States supported the waiver, most other high-income countries continued to oppose it. In mid-May, the G20 Group met in Rome for a summit on global health. G20 is an international forum convening meetings of government representatives of the twenty largest economies of the world.[[76]](#footnote-76) The following countries are permanent members: Argentina, Australia, Brazil, Canada, China, France, Germany, Japan, India, Indonesia, Italy, Mexico, Russia, South Africa, Saudi Arabia, South Korea, Turkey, the United Kingdom, the United States, and the European Union. Spain participates as a permanent guest, and additional guest countries and organizations are invited each year. Even though the original proponents of the waiver (India and South Africa) and the United States are permanent members of G20, the May 2021 Summit ended with a declaration that rejected the adoption of a waiver of patent rights for COVID-19 vaccines.[[77]](#footnote-77) While this declaration has no binding force on the WTO, it is highly indicative of the lack of broad international support for the waiver at a time when the pandemic raged throughout the Global South.

## The Case Against Vaccine Patent Waivers

The events described above provide a glimpse into the political economy surrounding the COVID-19 patent waiver. But while the waiver proposed during the COVID-19 pandemic was met with support from an unlikely source and opposition from most of the Global North, a separate question remains: absent (considerable) impediments posed by the political economy, are waivers of intellectual property rights a viable tool for promoting the transfer of vaccine technology in a future vaccine race?

The book answers that question predominantly in the negative.

Vaccines belong to a group of technologies that are especially hard to replicate. As biologics, they are virtually impossible to fully reverse-engineer. If someone who was not involved in the development process for a conventional drug or an N95 respirator wishes to replicate it, it is usually possible to do so. The process for producing copies of the drug or respirator does not have to squarely match the one employed by the originator, and departures from the originator’s manufacturing process do not affect the end product in significant ways. In fact, when the United States faced a shortage of N95 respirators and the company controlling the intellectual property on this particular good was not able to ramp up production, the US government invoked the Defense Production Act – a law – and directed a different company working in related areas of filtration technology, Hollingsworth & Vose, to produce N95 respirators, as well as N95 ventilator filters.[[78]](#footnote-78)

Vaccines, by contrast, are so highly manufacturing-dependent that attempting to replicate them by using a slightly different process is likely to compromise the efficacy of the final product. Significant amounts of relevant manufacturing information are held by vaccine manufacturers in forms other than a patent. These forms range from trade secrets to know-how shared among those who work for or partner with the company, but not with third parties. Once patents (or patent applications) are published, anyone can locate their full text through a simple online search – in addition to electronic tools made available to specialized audiences, anyone can use Google’s search engine for patent-related content, Google Patents, to read a published patent or patent application.[[79]](#footnote-79) The information contained in the patents, however, is generally far from sufficient for a third party to manufacture a vaccine without some collaboration from the original manufacturer.

Domestic patent laws mandate that the invention be described in the text of a patent. This description functions as a set of instructions to replicate the product or process covered by the patent. With complex forms of technology such as vaccines, putting together the instructions provided by all relevant patents does not teach a third party all the steps required to manufacture a vaccine. Consider the following analogy: a culinary recipe in a restaurant cookbook teaches readers – who probably did not receive any direct instruction from the person who made the original dish – how to navigate a multi-step, multi-component process to replicate a product. Yet, home cooks who have scrupulously followed recipes sometimes discover that the final product does not quite taste like or even resemble the original dish. If the recipe writer omitted a “secret ingredient” (anchovies that melt into a sauce leaving no visible trace but adding a type of flavor undiscernible to the untrained palate) or technique (whisking in a particular way to aerate the batter and give a cake a certain structure), recipe readers may approximate the original products but not be able to fully replicate it.

Pharmaceutical companies routinely use knowledge that is never shared through a patent. In some cases, a “secret ingredient” may even be listed in the composition of the product, but not highlighted in any particular way in the patent instructions, and competitors will not immediately realize the heightened importance of that component – hence failing to fully replicate the process-dependent good generated by the patent holder. In the discussions leading up to the US support for the waiver, vaccine manufacturers made it clear that they did not expect competitors would be able to replicate a vaccine without the transfer of information not taught by patents. For instance, a representative of Bharat Biotech, an Indian company manufacturing a COVID-19 vaccine, stated that “Vaccine manufacturing is not just in the patents […] If I give that to just anybody, I don’t think they’ll be able to do anything about it. They need know how and expertise… It’s needed in a package.”[[80]](#footnote-80)

Recall that the proposed waiver would cover “patents, industrial designs, copyright and protection of undisclosed information.”[[81]](#footnote-81) The two relevant areas for enabling the manufacturing of a vaccine by a third party are patents and the type of information not taught by patents referenced above, which would fall under the bracket of “undisclosed information.” By suspending patent protection, the waiver would allow these third parties to act on patent-covered information in ways they normally cannot under the duration of the patent. However, even though the waiver proposed to suspend protection of non-patent information, there are no legal or practical mechanisms that would force companies to transfer knowledge that is not codified in repositories accessible by others. Tricks of the trade and other key information would not automatically be disclosed to third parties should the waiver come into effect.

Therefore, although a waiver may be helpful in addressing some of the issues that other legal tools cannot address – such as fragmentation problems in the case of compulsory licensing – it would still be insufficient to enable third parties to replicate COVID-19 vaccines without some cooperation from the original manufacturers. This is yet another reason why it is important to understand vaccines in their technological dimension. Compelled transfers may work in other areas of technology – including pharmaceutical technologies – but likely not in the realm of biologics.

This is not to say the proposed waiver is devoid of value. Epidemiologist Gregg Gonsalves highlighted the “domino effect” of the US support for the proposal, prompting other countries and institutional actors to also express favorable views of the waiver.[[82]](#footnote-82) In embodying a non-absolutist view of intellectual property, it signaled the need for implementation of intellectual property frameworks that better align with the pursuit of public health goals. In this sense, the proposal for a waiver operated as tool in the international relations space in much more pronounced ways than it did in the technological field.

An underappreciated point during public debate about the waiver, however, was the fact that lower-income countries spent political capital mustering support for the adoption of a legal tool unlikely to solve the technological problem at the heart of vaccine scarcity. It remains to be seen what the long-term consequences of support by countries like the United States will truly mean. During the first decade of the twenty-first century, countries in the Global South successfully resorted to compulsory licensing (or the threat thereof) to lower the price at which HIV/AIDS drugs were being commercialized.[[83]](#footnote-83) Unlike vaccines, these were conventional drugs that could be reverse-engineered by competitors and replicated without cooperation of the original manufacturers. In this sense, the legal tool used by these countries – compulsory licensing – was an effective and needed means to achieve a public health goal.

Even though the use of tools such as compulsory licensing is lawful under the TRIPS Agreement, countries like the United States have long been known to attempt to discourage lower-income countries from lawfully using intellectual property mechanisms to promote goals that further their domestic public health agendas. As legal scholar Sapna Kumar has put it:

For the past several decades, the US government has treated its anti-compulsory licensing stance for pharmaceuticals as a form of moral high ground. Under both Republican and Democratic administrations, the US Trade Representative has threatened trade sanctions against countries that utilize it, maintaining that it undermines TRIPS’ minimum protections. US pharmaceutical companies have also found ways to directly retaliate when a country issues a license on one of their drugs.[[84]](#footnote-84)

The US trade representative – the same institutional representative who announced support for the COVID-19 waiver proposal – regularly spearheads the negotiation of bilateral trade agreements between the United States and lower-income countries under which the latter are granted trade benefits on the condition of agreeing to more stringent forms of intellectual protection than those imposed by the TRIPS Agreement. Legal scholar Ruth Okediji has observed that this “new intellectual property bilateralism” helps the United States and other high-income countries “secure strong global intellectual property rights” in the long-term.[[85]](#footnote-85)

It remains to be seen at what cost, if any, US support of the proposed waiver will come. Given the fact that the waiver would not have solved the technological problems of replicability that it was intended to address, further exploration in years to come of the long-term consequences of its proposal is warranted.

Finally, it is also worth keeping in mind the practical limitations of waiver models when vaccine technology is at stake. These limitations underscore the need for collaborative technology transfer frameworks to be negotiated – and preferably memorialized through contractual agreements – *ahead* of highly disruptive public crises, instead of being discussed in the volatile climate of pandemics and epidemics. In addition to being subject to a multitude of immediate constraints, this climate may all too easily disguise long-term agendas of some countries.

# E. The Expanding Role of Public-Private Partnerships

The previous sections have advocated for voluntary R&D collaborations wherever possible. These collaborations are especially needed against backdrops of product and infrastructure scarcity, as was the case during the COVID-19 vaccine race. The book now turns its attention to a particular mode of cooperation between multi-sector players in the vaccine R&D ecosystem – through the formation of public-private partnerships. Although not new, these structures have gained momentum in recent years as a way to overcome some of the recurring problems hindering the development of vaccines against emerging pathogens in the pronounced market-driven climate of modern-day pharmaceutical R&D. During the COVID-19 pandemic, the public-private partnership format was also used as an attempt to mitigate some of the allocative imbalances experienced in the distribution of limited doses of vaccines.

This section examines the emergence of public-private partnerships in the public health space, as well as their growing role at both the beginning and tail end of the vaccine R&D pipeline. The partnerships surveyed below – and especially those solely focused on vaccines – provide actual examples of the technology-specific type of approach that the book has argued for. Moreover, because many public-private partnerships in this area are formed with some degree of permanency, insights distilled from ongoing experiences are also of interest to policymakers searching for long-term models of bolstering vaccine R&D, promoting equitable distribution of vaccines, or both.

## Public-Private Partnerships in Context

While there is no universal definition of “public-private partnership,” the expression typically refers to a contractually based, long-term collaboration between parties in the public and private sectors. The PPP Knowledge Lab – an online resource made available by the World Bank Group in collaboration with several multilateral development agencies – defines a public-private partnership as “a long-term contract between a private party and a government entity, for providing a public asset or service, in which the private party bears significant risk and management responsibility, and remuneration is linked to performance.”[[86]](#footnote-86)

Focusing on public-private partnerships operating in the health-related areas, the World Health Organization offers the following definition:

Public-private partnerships are seen as an effective way to capitalize on the relative strengths of the public and private sectors to address problems that neither could tackle adequately on its own, in particular in respect of diseases that particularly affect developing countries where research by the private sector is deemed insufficient. Thus the public sector contributes both basic science and funding, and the private sector has strengths in drug discovery and bringing candidate drugs through the trials process to regulatory approval.[[87]](#footnote-87)

The bioethicist Jonathan H. Marks, who studies public-private partnerships in the context of the provision of health-related goods, has provided an exemplificative list of “public partners” as encompassing “a government agency or official, an academic research institution, a non-governmental organization, and an international non-governmental organization among others”; and “private partners” as encompassing “corporations, trade associations, and other organizations that represent industry interests.”[[88]](#footnote-88)

Within the umbrella of formalized relationships between actors in different sectors, the concept of public-private partnerships includes collaborative arrangements structured in markedly different ways. For instance, some partnerships may be designed to jumpstart the processes leading to the development or production of certain types of goods, while others may be designed with the objective of acquiring and distributing those goods. Based on this distinction, public-private partnerships are often categorized as *product development* partnerships or *access* partnerships, a taxonomy the book adopts when discussing existing partnerships involved in vaccine R&D and allocation.[[89]](#footnote-89)

Product development partnerships operate at the beginning of the R&D pipeline, seeking to attract resources to catalyze the development or production of a pre-defined good or set of related goods. This type of partnership has come to play an important role in areas entailing relatively high investment costs and risk, and often overlooked by funders and R&D players for – as is the case with historically neglected areas of pharmaceutical R&D.

Access partnerships operate predominantly at the tail end of the R&D pipeline. They seek to bring together resources to enable the purchase and distribution of products deemed necessary or beneficial for a variety of socioeconomic reasons.

From the early 2000s onwards, the number and scope of public-private partnerships operating in health-related fields grew exponentially. During the late 1990s, the number of new partnerships becoming active in this area ranged from one (1995, 1996) to four (1997) per year.[[90]](#footnote-90) In 2001, seven new partnerships were launched, and the number of new entrances per year started climbing steadily from 2005 onwards: in 2006, eighteen new partnerships were launched; three years later the number had doubled to thirty-six; by 2012, a total of sixty-three partnerships became active. Until 2003, most new entrants were partnerships based in North America. After that, and especially from 2008 onwards, the majority of new partnerships was based in Europe, with Asia occupying a distant third place after North America.

Existing health-oriented public-private partnerships vary significantly in size and scope. For example, the Innovative Medicines Initiative (IMI), the largest public-private partnership in the life sciences in the world, was broadly designed as a product development partnership between the European Union and EFPIA (the European Federation of Pharmaceutical Industries and Associations), which represents thirty-three countries and forty pharmaceutical companies.[[91]](#footnote-91) In the first ten years (2008–18), IMI garnered €5.3 billion in funding (approximately USD 6.46 billion per mid-2021 conversion rates).[[92]](#footnote-92) Launched in 2008 with the objective of improving “health by speeding up the development of innovative medicines, particularly in areas where there is an unmet medical or social, public health need,” IMI funds the development of pharmaceutical products across a wide spectrum.[[93]](#footnote-93) As of 2021, IMI is involved in 171 discrete projects, covering disparate areas ranging from digital pathology to R&D on respiratory syncytial virus, a common pathogen that can cause trigger serious symptoms among very young and older populations.[[94]](#footnote-94) An overview of the “health priorities” set by IMI is telling of the breadth of the partnership. Its strategic agenda for the 2014–2020 period lists the following priority areas: osteoarthritis, cardiovascular diseases, diabetes, neurodegenerative diseases, psychiatric diseases, respiratory diseases, immune-mediated diseases, ageing-associated diseases, cancer, rare and orphan diseases, and vaccines.[[95]](#footnote-95)

By contrast, other public-private partnerships focus on much narrower sets of diseases or medical problems, or on specific types of health-related technologies.[[96]](#footnote-96) An example of the former is the Drugs for Neglected Diseases Initiative (DNDi), created in 2003 as a product development partnership to spur the development of “urgently needed treatments for neglected patients” at affordable prices.[[97]](#footnote-97) DNDi concentrates its work on a selected number of diseases, all of which prevalent in lower-income countries: Chagas disease, cutaneous and visceral leishmaniasis, river blindness hepatitis C, mycetoma, pediatric HIV and sleeping sickness.[[98]](#footnote-98) Between 2003 and 2021, DNDi helped fund and develop eight new treatments for diseases in its area of action. Starting in 2020, in response to the extraordinary public health challenges posed by the COVID-19 pandemic, DNDi temporarily broadened its scope to include work related to coronaviruses.[[99]](#footnote-99)

Another example of a narrowly focused public-private partnership is the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), launched in 2016 with the goal of “investing in the development of new antibiotics and other life-saving products to combat the most dangerous drug-resistant bacteria.”[[100]](#footnote-100) Instead of tailoring its activity to one or more diseases, CARB-X focuses on a growing medical problem, antimicrobial resistance, which happens when pathogens mutate and pharmaceuticals previously effective in the prevention or treatment of disease cease to work. CARB-X finances the development of different types of products relevant in this, including antibiotics and vaccines. Between 2016 and 2021, the partnership provided USD 333.6 million in funding to 89 R&D projects.[[101]](#footnote-101)

These examples point to the growing footprint of public-private partnerships operating in different corners of global health. Before turning to the narrower universe of vaccine-dedicated partnerships – and arguing, that in spite of their flaws, they should be expanded further – the book pauses to examine some of the drawbacks of public-private partnerships models in general.

## Shortcomings of (Over)Reliance on Public-Private Partnerships

Multi-stakeholder, large-scale partnerships bring resources and expertise to the concentrated, underfunded market of vaccine R&D. Yet, they do not cure all of the underlying shortcomings of vaccine R&D, and they leave unanswered the question of how to support vaccine R&D more generally. For instance, rare diseases and unknown pathogens[[102]](#footnote-102) are unlikely to be the primary focus of attention of transnational collaborations equipped with massive funding, legal and bureaucratic structures.

A first line of arguments cautioning against excessive reliance on public-private partnerships stems from their intrinsic nature. In a world of limited resources, R&D approaches based on partnerships are sectoral by definition, even within sub-fields of pharmaceutical research. As with other types of ad hoc initiatives, they do not overcome the problem of fragmentation: internally, they create a consolidated R&D space, but they do not solve external fragmentation, and potentially add to it.[[103]](#footnote-103)

The sheer scale of well-funded, multi-player collaborations entails the development of a decision-making and management apparatus that renders the creation of partnerships a protracted process. They thus constitute a slow form of responding to emerging health problems.

If one advantage of public-private partnerships is to bring together actors from different sectors that would otherwise operate independently, the corresponding disadvantage is that the interests of diverse actors may not align. Within a partnership, asymmetries between partners may also result in imperfect coordination,[[104]](#footnote-104) or dominance of one party’s agenda over the public interest.[[105]](#footnote-105) Legal scholar Margaret Chon has noted that:

the heterogeneity of PPPs is also their all-too-obvious Achilles heel. As hybrid actors, PPPs attempt to accommodate both commercial and non-commercial interests, directly raising the question of whether public interest norms in IP can be expressed when hybrid actors are motivated instrumentally for profit in addition to social mission within networks consisting of simultaneous instrumental and epistemic exchange. Similar questions have been asked of purely commercial actors in the corporate social responsibility (CSR) context.[[106]](#footnote-106)

Even in cases of convergence of interests, a partnership alone may not be able to bridge the gap between the early development stages of a product and the later ones, including commercialization. The common split between product development and access partnerships means that the divide between preclinical development and later stage R&D might not always be bridged.[[107]](#footnote-107)

A related aspect of multi-party coordination relates to the assumption that partnerships reduce transaction costs in R&D, therefore increasing the opportunities for collaborative innovation. This might not necessarily be true.[[108]](#footnote-108) Prior to the beginning of the collaboration, parties who have never worked together may estimate costs differently or, given the uncertainties associated with biopharmaceutical research and regulatory review, transaction cost may change as R&D moves forward.[[109]](#footnote-109)

Although partnerships like CEPI have relatively flexible approaches to the allocation and management of proprietary rights, this is also not a guarantee that all parties in a project will be rewarded equally. As legal scholar Liza Vertinsky has put it:

patents are likely to systematically over-reward the private sector participants, who tend to engage in later stage developments that are more readily patented. Conversely, they are likely to under-reward the public-sector participants, who are concentrated in upstream areas of early stage research that is often either freely shared or licensed to the private sector on terms favorable to the private sector.[[110]](#footnote-110)

Additional criticism of public-private partnerships has included observations directed at the substitution effect of partnerships for the role of states and transnational institutions like the United Nations[[111]](#footnote-111) and the World Health Organization.[[112]](#footnote-112)

Perhaps the most striking downside of public-private partnerships in health-related areas arena regards the sustainability of funding models.[[113]](#footnote-113) CEPI benefits from a broad network of funders that enables the partnership to support long-term R&D projects. However, that is not the case with most partnerships. In a survey conducted by the WHO in 2014, “nearly all” respondents indicated concerns with the “sustainability of their efforts” and their ability to “ensuring continuity of funding.”[[114]](#footnote-114)

Finally, many types of pharmaceutical R&D – including vaccine R&D – depend heavily on philanthropy. Currently, reliance on funding from the Gates Foundation is so overwhelming that an undisclosed respondent to the WHO survey stated that “but for Gates, we’d be dead.”[[115]](#footnote-115)

These overarching constraints inform the dynamics of the universe inhabited by public-private partnerships in the specific areas of vaccine R&D and vaccine procurement, to which the book now turns.

## The Role Vaccine-Focused Public-Private Partnerships

The following section surveys examples of partnerships dedicated to a specific type of technology – vaccines. As seen earlier, there are public-private partnerships that, although not presenting themselves as vaccine-dedicated, fund R&D on vaccines. The cases that the chapter now turns to are relevant to the themes explored in the book not only because of their vaccine-centric nature, but also because these partnerships are technology-specific. Each one of them was created in direct response to the particular challenges long experienced in the development and distribution of new vaccines: the underfunding of socially valuable R&D; and the equitable allocation of vaccine doses, especially to populations in need in lower-income countries.

There are now vaccine-dedicated partnerships at both ends of the R&D pipeline. The book provides an overview of two partnerships created in direct response to shortcomings in the response to recent public health crisis: CEPI, formed in the wake of the 2014–16 Ebola outbreak; and Covax, which came quickly together in the early stages of the COVID-19 pandemic.

### The Coalition for Epidemic Preparedness Innovations (CEPI)

The Coalition for Epidemic Preparedness Innovations (CEPI) was launched at Davos in 2017 “to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks.”[[116]](#footnote-116) The partnership was formed in response to faltering funding and support for R&D on vaccines needed to prevent or respond to outbreaks caused by emerging pathogens. In this sense, it operates as a product development partnership, seeking to attract monetary commitments from different sectors, and coordinating the development – and to some extend the distribution – of vaccines. The partnership describes its role as both a funder and facilitator of vaccine R&D and distribution: “We focus on vaccine development, licensure, and manufacturing while supporting the efforts of our partners in vaccine discovery and delivery.”[[117]](#footnote-117)

In addition to responding to a long-felt need in vaccine R&D, CEPI was created in the wake of the 2014–16 Ebola outbreak. One reason a vaccine-dedicated product development partnership was able to attract the necessary support at that point in time was precisely the failures and delays in the commercialization of Ebola vaccines that were made apparent during the outbreak, as recounted in chapter 3. To this day, CEPI’s website and documentation reference the case of the Ebola vaccine candidate that could have come to market years before its launch date as indicative of the need for solutions to bolster vaccine R&D that are not predominantly market-based:

Events like the devastating 2014/15 outbreak of Ebola in West Africa—which killed more than 11,000 people and had an economic and social burden of over $53 billion—showed us that very few vaccines are ready to be used against these threats.

The world’s response to this crisis fell tragically short. A vaccine that had been under development for more than a decade was not deployed until over a year into the epidemic. That vaccine was shown to be 100% effective, suggesting that much of the epidemic could have been prevented.[[118]](#footnote-118)

While conceived as vaccine-specific, CEPI does not operate on all fields of vaccine R&D. Given its focus on emerging infectious diseases, the partnership has narrowed its list of “priority diseases” to selected areas, matching the pathogens identified in the 2016 WHO Blueprint as likely to cause outbreaks in the near future, and for which R&D has long remained underfunded: Ebola viruses, Lassa virus, Middle East Respiratory Syndrome coronavirus (MERS), Nipah virus, Rift Valley Fever virus and Chikungunya virus.[[119]](#footnote-119) Like several other public-private partnerships, in early 2020 CEPI added COVID-19 to the roster of diseases it provides funding and other support for.

Conversely, even though CEPI’s approach is technology-specific in the sense that its sole focus is on vaccine-related technology, the partnership funds and helps develop vaccines produced through multiple technological approaches. To give but a few examples, at the time of writing CEPI is funding recombinant and live attenuated vaccines against COVID-19, inactivated vaccines against Chikungunya, and recombinant viral vector vaccines against the Lassa, MERS and Nipah viruses.

Moreover, the partnership is also funneling resources toward the development of vaccine platform technology, which it describes as “platform technologies that can be used for rapid vaccine development against unknown pathogens (Disease X).”[[120]](#footnote-120) As explored in chapter 3, the unpredictably of which pathogens will cause significant outbreaks in the near- and medium-term, allied to the possibility of the emergence of a new pathogen, has long been one of the contributing factors to lukewarm investment in the field of vaccines against emerging pathogens.

The initial five-year budget for CEPI was calculated at between USD $600 million and $1 billion.[[121]](#footnote-121) A year into its existence CEPI has received USD $625 million from donors.[[122]](#footnote-122) The largest donors are the governments of Norway, Japan, and Germany, as well as the Bill & Melinda Gates Foundation and the Wellcome Trust, the fourth largest foundation in the world.

CEPI-funded vaccines are subject to a requirement described by the partnership as “equitable access.” CEPI’s 2017 Preliminary Business Plan provided an initial definition of the requirement, as an obligation that “[g]lobal access arrangements will be negotiated in contracts between CEPI and vaccine developers to ensure affordability and availability in Low and Middle Income Countries (LMICs).”[[123]](#footnote-123) CEPI’s Policy Documentation shed additional light on the meaning of “access” in this context by explaining that agreements should impose two conditions.[[124]](#footnote-124) First, should an outbreak occur, recipients of CEPI funding must provide “access to investigational vaccine stockpiles for phase III trials and emergency deployment.” And second, in the case of vaccines funded by CEPI that succeed in gaining approval from a domestic drug regulator, “access to the licensed vaccine” means that it must be made available to indicated population at affordable prices.

The CEPI enterprise is relatively young, and as such it is not possible to perform a meaningful assessment of the efficacy of the partnership’s equitable access policy at the time of writing. However, it suggests that it is feasible from a practical perspective to include pricing considerations into the contractual frameworks that govern the development of new vaccines. Recall the statement by the US Secretary of Health and Human Services in the early stages of the COVID-19 pandemic, implying that at any attempts to impose affordability obligations on recipients of public-sector funding for vaccine R&D is bound to irreversibly lower incentives for companies to invest in future vaccine R&D.[[125]](#footnote-125) CEPI was designed to provide funding that, under standard R&D funding models is lacking for vaccine work – as such, it creates the forward-looking incentives that opponents of affordability provisions appear to worry about, while *simultaneously* conditioning the funding incentive to the recipient’s agreement to commercialize the resulting vaccine at affordable prices. This brings into alignment both the economic and public health dimensions of vaccine development. The public-private partnership provides a monetary incentive for work in a chronically underfunded area, but imposes conditions aimed at furthering the public health goal of making vaccines available to indicated populations – rather than only to those who can afford them.

Operating under this model, CEPI has entered into agreements with heterogenous players, including private-sector vaccine manufacturers. For example, it is currently funding Moderna for work on vaccine candidate targeting the coronavirus that causes Middle East Respiratory Syndrome (MERS), as well as work targeting other pathogens performed by other well-known vaccine manufactures, such as Inovio (US), Novavax (US), CureVac (Germany) and Valneva (France). This suggests that there is not a profound incompatibility between attracting vaccine manufacturers and imposing affordability requirements. It is possible that some actors in the vaccine R&D ecosystem might shy away from vaccine-related work if the possibility of setting supra-competitive prices is not available to them; yet others are likely to accept a contractual imposition of affordable pricing.

In any event, it is useful to keep in mind that, unlike the earliest COVID-19 vaccines to enter the market, most vaccines against emerging pathogens are not moneymakers. Actors who are strongly driven by economic returns have much more profitable areas of pharmaceutical R&D available to them. CEPI’s Preliminary Business Plan explicitly recognized this: “It is anticipated that vaccines developed with CEPI support will not be profitable.”[[126]](#footnote-126) Against this backdrop, ensuring that key public health tools like vaccines are made available to those who need them through affordability requirements is a much more modest ask for policymakers and funders to make than in other areas of pharmaceutical R&D.

Lastly, a related takeaway from the limited number of years in which CEPI has been operating concerns the cases in which vaccines do become profitable, and reinforces the point that affordable commercialization of vaccines is not incompatible with intellectual property-driven models and with profits. Immediately after stating the assumption that profitability would constitute the exception and not the norm, CEPI’s Preliminary Business Plan added the following:

In the event that a vaccine developed with CEPI support does develop economic value, agreements between CEPI and the vaccine developer will ensure either that CEPI’s investment is reimbursed or that the economic value is shared through royalties or other risk sharing agreements. Any rewards that accrue to vaccine developers should be proportionate to the level of risk undertaken and to the nature of the R&D, infrastructure, IP or other contributions a developer has made.[[127]](#footnote-127)

This policy underscores the idea that models of vaccine R&D that make use of intellectual property – which remain the overwhelmingly predominant status quo – are not automatically incompatible with the adoption of contractual frameworks that promote public health goals. Should a CEPI-funded vaccine turn a profit, both the R&D players and the public-private partnership are entitled to recover their investment in proportional ways. Moreover, CEPI is under the obligation of returning any profits to its funding pool.[[128]](#footnote-128)

This articulation with intellectual property frameworks also gives parties contracting with CEPI the possibility of negotiating intellectual property provisions on an *ad hoc* basis.[[129]](#footnote-129) This gives both the partnership and the funding recipient flexibility to adjust contracts to specific situations. As a default, CEPI does not acquire ownership of any patents or other intellectual property brought by the funding recipient or generated during work on a CEPI-funded vaccine.[[130]](#footnote-130) This dissociates CEPI’s funding and coordinating functions from the acquisition and management of intellectual property rights.

Importantly, CEPI policies, under the umbrella of prompting funding recipients to “foster broader research efforts and innovation of vaccines for emerging infectious diseases that lack market potential,” requires that patent-protected vaccine technology be made available to third parties on a “non-exclusive, royalty-free, sub-licensable, worldwide license.”[[131]](#footnote-131) This approach contrasts sharply with one taken by the US public sector, as seen in connection with the development of US Army’s Zika vaccine candidate, for which the funding entity proposed issuing an exclusive license.

Finally, CEPI layers obligations of clinical trial data sharing on top of the requirements set forth in domestic laws, which as seen in chapter 2 often go unmet. These requirements bind funding recipients to publish results – including negative results – in a timely fashion, free of charge, and through a publicly available platform.[[132]](#footnote-132)

As a whole, this contractual framework balances the current preference for proprietary modes of R&D with public health imperatives of development and distribution of health goods, as well as with scientific precepts of knowledge dissemination and enablement of follow-on research. The book makes no pronouncement as to how well CEPI’s policies have been implemented in practice, given the relative newness of this particular public-private partnership. Nonetheless, it notes that from a legal and policy perspective, CEPI’s principles and contractual approach provide a blueprint that can serve as a starting point for ongoing and future efforts to inscribe vaccine R&D into frameworks that do not lose sight of public health needs.

### The COVID-19 Vaccine Global Access Facility (Covax)

CEPI was the first – and remains the only – vaccine-dedicated product development public-private partnership. The first access partnership to focus exclusively on vaccines appeared much earlier. The Global Alliance for Vaccines and Immunizations (Gavi), was launched in 2000 “to “improv(e) access to new and underused vaccines” in lower-income countries.[[133]](#footnote-133) Funded by donors and contributions from countries to whom it provides vaccines, Gavi has become the epicenter of procurement of childhood vaccines for the Global South. Currently, it has seventeen vaccines in its portfolio, covering areas that range from polio and cholera to measles and rubella.[[134]](#footnote-134)

The strategy that Gavi pioneered in the field of vaccines is one that has long been deployed in local, regional and international trade. After securing funding for a particular purpose – often one not attainable by most players in the field – a buyer places a high-volume order, which brings down the marginal cost of each item.[[135]](#footnote-135) As an economic agent, Gavi secures funding for goods that, absent this drop in marginal cost, would be unaffordable to governments of lower-income countries negotiation on their own. By repeatedly spiking demand for childhood vaccines bound for lower-income markets, Gavi gives vaccine manufacturers in wealthier countries the incentive to manufacture doses of vaccine for markets that are normally neglected, and in so doing lowers the cost of vaccines for governments in these markets. Between 2000 and 2019, vaccines procured by Gavi were administered to over 822 million children in seventy-seven countries.[[136]](#footnote-136)

The basic strategy used by Gavi to help bring vaccines to countries that, on their own, have long been unappealing to most market-driven R&D players was also used during the COVID-19 vaccine race in response to escalating concerns with vaccine nationalism – the skewed allocation of emerging vaccines to higher-income countries, as described in chapter 4. Also structured as a vaccine-specific access public-private partnership, the COVID-19 Vaccine Global Access Facility (Covax) was swiftly conceived and rolled out as a financing and procurement mechanism aimed at promoting the equitable distribution of vaccines across the globe.[[137]](#footnote-137)

Covax is led jointly by CEPI, Gavi and the World Health Organization, and works in partnership with UNICEF on vaccine delivery. Unlike most other access partnerships, COVAX not designed as a standalone entity, being integrated into a larger institutional network – the Access to COVID Tools (ACT) Accelerator.[[138]](#footnote-138) C-TAP was launched in April 2020 by the WHO, the European Commission, the government of France and the Bill & Melinda Gates Foundation. It was created as a “support structure” for work in closely related areas, known as “pillars.” C-TAP has three pillars – diagnostics, therapeutics and vaccines – with a fourth, the health systems connector, intersecting with the previous three.

Covax is the vaccines pillar of C-TAP. It plays a role throughout the arc of vaccine development and distribution through three distinct organizations which focus on different stages of this arc. CEPI is involved in the funding, development and manufacturing of vaccine candidates.[[139]](#footnote-139) The WHO oversees policy issues related to emerging vaccines and the process of allocating doses as they become available. Finally, Gavi brings in its expertise at the procurement and vaccine delivery levels.

While Gavi’s procurement work in the field of childhood vaccines is aimed only at lower-income countries, Covax is open to any country wishing to join, irrespective of income level. When Covax was launched in April 2020, all interested countries were invited to join. Countries that chose to participate in Covax’s procurement system for COVID-19 vaccines were required to commit to purchase a certain amount of vaccine doses. At this point in time, there were several leading vaccine candidates being development by pharmaceutical companies but none had been authorized or approved. Placing vaccines orders was thus both necessary as countries needed to secure doses for administration as soon as the vaccines were greenlighted by drug regulators, but also risky since it was impossible to know with certainty which vaccines would make it to market first, and which might encounter late-stage hurdles, or possibly even fail unexpectedly.

The dynamics of Covax procurement diffused this risk to some extent. Because Covax negotiated with multiple private-sector vaccine manufacturers at the same time, a country that chose to join the procurement scheme would stand in line to receive vaccine doses from a pool of multiple vaccine candidates. Moreover, participating countries obtained these vaccine doses at a price previously negotiated between Covax and individual pharmaceutical companies. From the perspective of these companies, the commitments entered into by countries joining Covax functioned as “carrots” – incentives to start or continue producing vaccine doses at risk, with the assurance that, should their candidates receive market approval or authorization, those commitments represented monetizable orders. In the context of a raging global public health crisis and a volatile economy, Covax functioned as a risk-sharing and portfolio diversification mechanism while attempting to promote access to vaccines outside the nationalistic framework used by high-income countries.

In June 2020, Covax entered into its first procurement agreement, pre-ordering 300 million doses of the vaccine candidate developed by British-Swedish pharmaceutical company AstraZeneca.[[140]](#footnote-140) The vaccine was first authorized for emergency use in late December in the United Kingdom. Agreements with other vaccine manufacturers followed, and by mid-March 2021, Covax had shipped over 29 million doses of COVID-19 vaccines to forty-six participants. It sourced three different vaccines: the vaccine manufactured by the Serum Institute in India, which became the first COVAX-supported vaccine to be administered, forty-three days after the beginning of COVID-19 vaccination in the United Kingdom; the AstraZeneca vaccine, manufactured by the South Korean pharmaceutical company SK-Bio; and the Pfizer-BioNTech vaccine, the first COVID-19 vaccine commercialized in the United States under an emergency use authorization. By late May 2021, the number of distributed Covax-procured vaccines had climbed to 72 million, distributed among 126 participants.[[141]](#footnote-141)

A large and heterogenous group of players thus managed to come together with remarkable rapidity as highly disruptive events unfolded, and procure some of the most sought-after and scarce commodities in the world at the time. In addition to the sheer speed with which the partnership was formed and began entering into binding agreements, another striking aspect of Covax was the fact that it relied squarely on the same contractual mechanism that is used to further vaccine nationalism – advance purchase orders.

As a purchaser, Covax did what individual high-income countries were already doing in the COVID-19 pandemic, and had done in previous public health crises: it entered a race to acquire as many vaccine doses as possible given the resources and bargaining power at is disposal. But because Covax was bargaining and buying on behalf of countries straddling income levels, the partnership functioned as a non-nationalistic actor on the demand side, capturing a portion of the limited supply globally available. In so doing, it adapted existing trade mechanisms and contractual frameworks to introduce a blueprint for the first truly global vaccine procurement scheme.

There were, however, aspects of the implementation of this scheme that were far from ideal, and that once again worked to the disadvantage of lower-income countries. Some of these shortcomings were perhaps unavoidable, given the remedial nature of the intervention that led to the formation of Covax: however swiftly a global procurement structure may have come together, it was nonetheless negotiated and implemented during a highly disruptive crisis, when vaccine nationalism was already in full swing and considerable amounts of vaccine doses had already been reserved by high-income countries. The playing field was no longer level by the time Covax entered the vaccine acquisition race. It is therefore not surprising that the volume of vaccine doses that countries could obtain through Covax was relatively low – the partnership offered each participating country the possibility of signing up for enough doses to cover up to 20% of their population in the long-term.[[142]](#footnote-142) This presents a quantitative problem. Given the much higher threshold projected for herd immunity against COVID-19 to occur, Covax procurement by itself was not enough to provide countries with as much vaccine required to meet public health needs. While higher-income countries might be able to cover this gap by contracting bilaterally with vaccine manufacturers, many lower-income countries could not afford that option, or could only afford it in much more limited terms than their counterparts in the Global North. Covax was thus able to lessen some of the effects of vaccine nationalism, but did not eliminate the problem.

There were also qualitative problems in Covax’s approach to vaccine allocation. The partnership was designed with the ultimate goal of providing equitable access to vaccines to all participants – a goal that is reflected in the proportional approach to vaccine allocation. Yet, there were differences in the policies applicable to lower- and higher-income countries. These differences derived from the use of two types of financing mechanisms to secure advance purchase orders: some countries self-financed their own orders, while others received financial assistance in order to enter into the Covax procurement scheme. The self-financing group was formed by countries that are formally categorized as high-income and upper middle-income. The group that received financial assistance was formed by countries that are formally categorized lower middle-income and low-income countries.

The policy developed by Covax, made available in June 2020 and labeled as promoting “equitable access,” placed different conditions on vaccine allocation depending on whether a participant was self-funded or had received financial support.[[143]](#footnote-143) As they received their proportional share of vaccine doses, self-funded countries were free to decide how and according to which principles to distribute them to their populations. On the other hand, countries who had received financial support were asked to distribute their proportional shares according to allocative criteria established through “guidance from the global allocation frame work under development by WHO.”[[144]](#footnote-144) While tied to a distinction in the financing of vaccine procurement, this disparate treatment bears no connection to matters *of* procurement. It constitutes an intrusion on the setting of public health policies at the national level – one that was not explained by Covax for any reasons other than differences in the economic means through which orders were paid for.

In addition to this conditioning of the establishment of domestic allocative priorities in lower-income countries, Covax policy made yet another surprising distinction between self-funded countries and those that had received financial support. If countries in the latter group were able to negotiate the purchase of additional doses of vaccines from sources other than Covax and received enough doses to cover 20% of their domestic population, the partnership asked them to wait for their share of Covax-funded vaccines until all other countries participating in Covax – self-funded or not – had received their Covax allocation:

if a country in this group successfully concludes a bilateral deal and receives enough doses to cover e.g. 20% of their population, the Facility [COVAX] requests that these countries delay receipt of any additional doses from the Facility until all other Facility country participants have received enough supply to also cover their highest priority populations.[[145]](#footnote-145)

The policy, however, did not apply to self-funded countries. From a public health perspective, this made little sense. Self-funded countries tended to be higher-income countries, and hence more likely to be able to bolster their vaccine supply through bilateral channels. This group of countries also included the major actors in vaccine nationalism, who had already captured most of the global vaccine supply before joining Covax. Restricting the ability of lower-income countries of acquiring much-needed doses in a playing field that is already skewing vaccine allocation towards higher-income countries is at odds with the geographical of the pandemic, as well as its socioeconomic impact.

A final limitation of the Covax model is that it did not require countries that came to possess excedentary vaccine doses to share them with countries still struggling to obtain enough vaccine. In a reference to doses obtained through bilateral agreements, the policy did state that self-funded countries were “encouraged (but not required) to donate vaccines if they have more than they need.”[[146]](#footnote-146) The final section of this chapter will argue that this limitation, and the ones described above, can and should be corrected ahead of future vaccine races.

Even though these limitations are significant, the formation of Covax marks an important moment in the development of strategies against inequitable distribution of vaccines during large transnational public health crisis. The discussion on vaccine nationalism in chapter 4 had made the case that collaborative modes of allocation of scarce vaccine supply are preferable to nationalistic ones – Covax provided an example of how such collaborative modes can be implemented in practice. In so doing, it created a blueprint that can be adapted for future pandemics and epidemics.

Admittedly, that blueprint incorporates several flawed policies, some of which are hardly justifiable even when taking into account the extreme urgency and pressures created by the pandemic, and against which Covax was developed. That these flaws need remedying does not mean that a fairer and more robust global procurement of vaccines cannot be built by expanding the features of Covax’s architecture that were successful, and correcting those that were not.

## The Case for Expanding International Vaccine Procurement

The book here proposes the creation of a permanent structure dedicated to the procurement of vaccines needed for pandemic and epidemic preparedness. This structure could evolve organically out of Covax, or be developed to substitute it, should Covax be extinguished after the COVID-19 pandemic. Irrespective of its formation, institutional permanency is critical to move vaccine procurement past remedial, short-lived responses to large-scale public health crises.

A permanent structure is also in a better position to navigate the time-consuming and politically fraught bargaining processes necessary to enable greater centralization and internationalization of vaccine procurement *ahead* of future outbreaks. The hasty negotiations that led to the formation of Covax also exposed the challenges faced by emerging international organizations as multilateral venues: early in the COVID-19 pandemic, the United States, Russia, India, Brazil and Argentina decided not to join the negotiations for the formation of Covax.[[147]](#footnote-147) Long-term diplomacy and other persuasive efforts will likely be required to create a truly global vaccine procurement structure, tasks that temporary institutional actors in the international arena are ill-equipped to perform.

In a similar vein, permanency is instrumental for the development of funding strategies that will allow a centralizing entity to have a bigger footprint in international vaccine procurement when outbreak-induced vaccine races occur. As market-driven models of vaccine production and distribution are poised to remain the norm, contractual bilateralism and vaccine nationalism are unlikely to disappear. However, by expanding the relative purchasing power of a large player, the international community can begin to lessen the inequalities in the allocation of vaccine doses obtained under conditions of scarcity. This can be achieved by incrementally raising quantitative procurement targets, which necessarily entails increasing financial commitments in support of greater acquisition of vaccine doses – for instance, by going beyond the mark established by Covax of procuring doses that would cover up to 20% of the population of each participating country. While consistent with global public health needs, this is by no means a small ask: even at smaller scale and against the background of a devastating public health crisis, Covax remained underfunded throughout most of the COVID-19 pandemic.[[148]](#footnote-148)

In addition to permanency and enhanced funding, it is imperative that a global vaccine procurement structure improve upon Covax’s allocative model. To act as a true driver of equitable vaccine allocation, such a structure should not make allocative distinctions based on financing mechanisms. The restrictions that Covax policy imposed on lower-income countries curtailed their already-limited ability to maneuver in markets disproportionately dominated by high-income purchasers of health goods.

Complementarily, this structure should impose a binding contractual obligation *on all countries* to share excedentary doses of vaccines. Current paradigms for sharing vaccine surplus rely on donation models that are not subject to any triggering mechanisms that can be counted upon. Instead, they rely on the goodwill of individual countries, which are often the same that have resorted to bilateralism to capture vaccine doses through a nationalistic approach. Activist Akin Olla has described the current dynamics of vaccine donation – and the fact that many countries delay donations or outright choose not to donate excedentary doses – as a “new colonialism.”[[149]](#footnote-149)

Moving forward, international procurement should incorporate mechanisms containing some type of trigger for mandatory vaccine-sharing obligations for countries with a vaccine surplus. This trigger should be based on measurable criteria – for instance, when a country acquires sufficient doses to vaccinate its population, or a set percentage thereof, depending on the characteristics of the underlying disease and on projections related to herd immunity. Several studies conducted during the COVID-19 pandemic showed that several high-income countries bought vaccine doses that greatly exceeded their domestic needs (even when a buffer was factored in to account for unforeseen needs) and did not share surplus doses with countries struggling to acquire doses for their own populations.[[150]](#footnote-150) This phenomenon, often described as “vaccine hoarding,” illustrates the need for a mandatory model of vaccine-sharing. Alone, such a trigger will not end vaccine colonialism, but it would constitute a first step towards lessening some of the most acute effects of the inequitable geopolitics of vaccine allocation.

1. Amy Kapczynski, “The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism” (2012) 59 *UCLA Law Review* 970; Daniel J. Hemel & Lisa Larrimore Ouellette, “Beyond the Patents-Prizes Debate” (2013) 92 *Texas Law Review* 303. [↑](#footnote-ref-1)
2. Machlup, “An Economic Review,” note 254, at 15. [↑](#footnote-ref-2)
3. W. Nicholson Price II, “Grants” (2019) 34 *Berkeley Technology Law Journal* 1, at 5–6. [↑](#footnote-ref-3)
4. US National Institutes of Health, “Grants & Funding” (2021), https://www.nih.gov/grants-funding. [↑](#footnote-ref-4)
5. US National Institute of Allergy and Infectious Diseases, “Opportunities & Announcements” (2021), https://www.niaid.nih.gov/grants-contracts/opportunities?search=vaccine. [↑](#footnote-ref-5)
6. See generally Price, “Grants,” note 384, 9–16. [↑](#footnote-ref-6)
7. Bhaven N. Sampat & Kenneth C. Shadlen, “Secondary Pharmaceutical Patenting: A Global Perspective” (2017) 46 *Research Policy* 693. [↑](#footnote-ref-7)
8. James Love, “De-Linking R&D Costs from Product Prices” (April 6, 2011), https://www.who.int/phi/news/phi\_cewg\_1stmeet\_10\_KEI\_submission\_en.pdf. [↑](#footnote-ref-8)
9. Alberto Galasso et al., “A Theory of Grand Innovation Prizes” (2018) 47(2) *Research Policy* 343–62. [↑](#footnote-ref-9)
10. James Love & Tim Hubbard, “Prizes for Innovation of New Medicines and Vaccines” (2009) 18 *Annals of Health Law* 155, 156. [↑](#footnote-ref-10)
11. Daniel Hemel & Lisa Larrimore Ouellette, “Want a Coronavirus Vaccine, Fast? Here’s a Solution” (March 4, 2020) *Time Magazine*. [↑](#footnote-ref-11)
12. Chris Callaghan, “Would a Longitude Prize Speed Production of a Covid-19 Vaccine?” (March 28, 2020) *World University Rankings*. [↑](#footnote-ref-12)
13. Yaniv Heled, “Regulatory Competitive Shelters” (2015) 76 Ohio State Law Journal 299. [↑](#footnote-ref-13)
14. Heled, “Regulatory Competitive Shelters,” note 394, at 305. [↑](#footnote-ref-14)
15. Heled, “Regulatory Competitive Shelters,” note 394. See also Heled, “Patents v. Statutory Exclusivities in Biological Pharmaceuticals - Do We Really Need Both” (2012) 18 *Michigan Telecommunications & Technology Law Review* 419. [↑](#footnote-ref-15)
16. Rachel Sachs, “Prizing Insurance: Prescription Drug Insurance as Innovation Incentive” (2016) 30 *Harvard Journal of Law & Technology* 153. [↑](#footnote-ref-16)
17. Mark A. Lemley et al., “The Medicare Innovation Subsidy” (2020) 95 *New York University Law Review* 75. [↑](#footnote-ref-17)
18. US Department of Health and Human Services, “Where and How to Get Vaccines,” https://www.hhs.gov/ash/oah/adolescent-development/physical-health-and- nutrition/vaccines/where-and-how-to-get-vaccines/index.html. [↑](#footnote-ref-18)
19. Public Law No: 116–136 (03/27/2020). Coronavirus Aid, Relief, and Economic Security Act or the CARES Act. [↑](#footnote-ref-19)
20. World Health Organization, “R&D Blueprint,” note 8. [↑](#footnote-ref-20)
21. Heled, “Regulatory Competitive Shelters,” note 394, and “Patents v. Statutory Exclusivities,” note 396. [↑](#footnote-ref-21)
22. World Intellectual Property Organization, “Patent Pools and Antitrust – A Comparative Analysis” (2014), at 3, https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\_pools\_report.pdf. [↑](#footnote-ref-22)
23. See generally Jorge L. Contreras, “Intellectual Property Pools and Aggregation,” in *Intellectual Property Licensing and Transactions: Theory and Practice* (forthcoming); Robert P. Merges, “Institutions for Intellectual Property Transactions: The Case of Patent Pools,” in *Expanding the Boundaries of Intellectual Property, Innovation Policy for the Knowledge Society*, Rochelle Cooper Dreyfuss et al. eds. (Oxford University Press, 2001). [↑](#footnote-ref-23)
24. WIPO, “Patent Pools and Antitrust,” note 403, at 9 (describing the pro-competitive effects of patent pools). [↑](#footnote-ref-24)
25. Daniel A. Crane, “Patent Pools, RAND Commitments, and the Problematics of Price Discrimination,” in *Working Within the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, Rochelle C. Dreyfuss et al., eds. (Oxford University Press, 2010) [↑](#footnote-ref-25)
26. See e.g. Erik Hovenkamp & Herbert Hovenkamp, “Patent Pools and Related Technology Sharing,” in *Cambridge Handbook of Antitrust, Intellectual Property, and High Tech*, Roger D. Blair & D. Daniel Sokol, eds. (Cambridge University Press, 2017). [↑](#footnote-ref-26)
27. Adam Mossoff, “The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s” (2011) 53 *Arizona Law Review* 165. [↑](#footnote-ref-27)
28. See generally Esteban Burrone, “Patent Pooling in Public Health,” in *The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development*, Margaret Chon et al., eds. (Cambridge University Press, 2018). [↑](#footnote-ref-28)
29. Medicines Patent Pool, “About Us,” https://medicinespatentpool.org. [↑](#footnote-ref-29)
30. Medicines Patent Pool, “Disease Areas,” https://medicinespatentpool.org/what-we-do/disease-areas#pills-COVID-19. [↑](#footnote-ref-30)
31. Letter from Costa Rica to the World Health Organization, Knowledge Ecology International (March 23, 2020), https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf. [↑](#footnote-ref-31)
32. Ed Silverman, “WHO is Asked to Create a Voluntary Intellectual Property Pool to Develop Covid-19 Products” (March 24, 2020) *Stat*, https://www.statnews.com/pharmalot/2020/03/24/covid19-coronavirus-costa-rica-intellectual-property/. [↑](#footnote-ref-32)
33. World Health Organization, “Solidarity Call to Action: Making the Response to COVID-19 a Public Common Good,” https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019- ncov/covid-19-technology-access-pool/solidarity-call-to-action/. [↑](#footnote-ref-33)
34. World Health Organization, “COVID-19 Technology Access Pool,” https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019- ncov/covid-19-technology-access-pool. [↑](#footnote-ref-34)
35. Michael Safi, “WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began” (January 22, 2021) *The Guardian*. [↑](#footnote-ref-35)
36. Ellen ‘t Hoen, “The Elephant in the Room at the WHO Executive Board” (January 22, 2021) *Medicines Law & Policy*, https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/ [↑](#footnote-ref-36)
37. Dianne Nicol & Jane Nielsen, “Opening the Dam: Patent Pools, Innovation and Access to Essential Medicines” (2010), 232–62, in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, Thomas Pogge, Matthew Rimmer, Kim Rubenstein, eds. (Cambridge University Press, 2010). [↑](#footnote-ref-37)
38. Jorge L. Contreras, “Patent Pledges” (2015) 47 *Arizona State Law Journal* 543, 546. [↑](#footnote-ref-38)
39. Contreras, “Patent Pledges,” note 419, at 546. [↑](#footnote-ref-39)
40. Elon Musk, “All Our Patent Are Belong to You” (2014), https://www.tesla.com/blog/all-our-patent-are-belong-you (the title of the article pledging Tesla’s patents is a play on an internet meme). [↑](#footnote-ref-40)
41. Moderna, “Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic” (October 8, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19. [↑](#footnote-ref-41)
42. Moderna, “Program Patents,” https://www.modernatx.com/patents. [↑](#footnote-ref-42)
43. Contreras, “Patent Pledges,” note 419, at 595–6. [↑](#footnote-ref-43)
44. Contreras, “Patent Pledges,” note 419, at 594. [↑](#footnote-ref-44)
45. Jorge L. Contreras et al., “Pledging Intellectual Property for COVID-19” (2020) 38 *Nature Biotechnology* 1146–9. [↑](#footnote-ref-45)
46. Open COVID-19 Pledge, “Frequently Asked Questions,” https://opencovidpledge.org/faqs/. [↑](#footnote-ref-46)
47. Open COVID-19 Pledge, “About the Licenses,” https://opencovidpledge.org/licenses/. [↑](#footnote-ref-47)
48. See e.g. “OCL-PC v1.0 License,” https://opencovidpledge.org/v1-0/. [↑](#footnote-ref-48)
49. Open COVID-19 Pledge, “About the Licenses,” note 428. [↑](#footnote-ref-49)
50. See Open Source Initiative, “The MIT License,” https://opensource.org/licenses/MIT; Apache, “Apache License, Version 2.0,” https://www.apache.org/licenses/LICENSE-2.0. [↑](#footnote-ref-50)
51. Open COVID-19 Pledge, “About the Licenses,” note 428. [↑](#footnote-ref-51)
52. Creative Commons, “Attribution-ShareAlike 4.0 International (CC BY-SA 4.0),” https://creativecommons.org/licenses/by-sa/4.0/. [↑](#footnote-ref-52)
53. GNU Operating System, “GNU General Public License,” https://www.gnu.org/licenses/gpl-3.0.en.html. [↑](#footnote-ref-53)
54. See e.g. Open COVID-19 Pledge, “Open COVID License 1.0 March 31, 2020,” https://opencovidpledge.org/v1-0/. [↑](#footnote-ref-54)
55. See e.g. Open COVID-19 Pledge, “OCL-PC v1.1,” https://opencovidpledge.org/v1-1-ocl-pc/. [↑](#footnote-ref-55)
56. Open COVID-19 Pledge, “About the Licenses,” note 428. [↑](#footnote-ref-56)
57. Open COVID-19 Pledge, Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19, https://opencovidpledge.org (last visited August 30, 2020). [↑](#footnote-ref-57)
58. Open COVID-19 Pledge, “NASA-JPL-3D Printed Respirators” (May 20, 2020), https://opencovidpledge.org/2020/05/20/nasa-jet-propulsion-laboratory/; Id., “Fujitsu – Faster Disease Diagnosis Using Computer Software” (June 3, 2020), https://opencovidpledge.org/2020/06/03/fujitsu-faster-disease-diagnosis-using-computer-software/; US Pat. 20200118682, Medical Diagnostic Aid and Method; Id., “Facebook – Combating the Spread of COVID-19 Related Misinformation” (August 11, 2020), https://opencovidpledge.org/2020/08/11/facebook-combating-the-spread-of-covid-19-related-misinformation/; US Pat. 20190163794, Contextual Information for Determining Credibility of Social-Networking. [↑](#footnote-ref-58)
59. Open COVID-19 Pledge, “Featured IP,” https://opencovidpledge.org/partner-ip/. [↑](#footnote-ref-59)
60. Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment Of Covid-19 (October 2, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf. [↑](#footnote-ref-60)
61. Communication, note 441. [↑](#footnote-ref-61)
62. TRIPS Agreement, article 64. [↑](#footnote-ref-62)
63. TRIPS Agreement, article 31. [↑](#footnote-ref-63)
64. World Trade Organization, “Compulsory Licensing of Pharmaceuticals and TRIPS,” https://www.wto.org/english/tratop\_e/trips\_e/public\_health\_faq\_e.htm. [↑](#footnote-ref-64)
65. TRIPS Agreement, article 31. [↑](#footnote-ref-65)
66. Jerome H. Reichman, “Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options” (2009) 37 *Journal of Law, Medicine and Ethics* 247–63, at 248. [↑](#footnote-ref-66)
67. World Trade Organization, “Amendment of the TRIPS Agreement,” https://www.wto.org/english/tratop\_e/trips\_e/amendment\_e.htm. [↑](#footnote-ref-67)
68. Communication, note 441. [↑](#footnote-ref-68)
69. Morgan Watkins, “Kentucky Gov. Andy Beshear Calls on 3M to Release Patent for N95 Respirator Amid Pandemic” (April 3, 2020) *Louisville Courier Journal*. [↑](#footnote-ref-69)
70. Sapna Kumar, “Compulsory Licensing of Patents During Pandemics,” at 14 (manuscript on file with author). [↑](#footnote-ref-70)
71. Office of the US Trade Representative, “Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver” (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver. [↑](#footnote-ref-71)
72. World Health Organization, “WHO Director-General Commends United States Decision to Support Temporary Waiver on Intellectual Property Rights for COVID-19 Vaccines” (May 5, 2021), https://www.who.int/news/item/05-05-2021-who-director-general-commends-united-states-decision-to-support-temporary-waiver-on-intellectual-property-rights-for-covid-19-vaccines. [↑](#footnote-ref-72)
73. Editorial Board, “Biden’s Vaccine Patent Theft,” *Wall Street Journal* (May 5, 2021). [↑](#footnote-ref-73)
74. Jonathan Gardner & Ned Pagliarulo, “Pharma Erupts as Biden Administration Backs Waiver of Vaccine Patent Rights” (May, 6, 2021) *BioPharma Dive*. [↑](#footnote-ref-74)
75. Amy Maxmen, “In Shock Move, US Backs Waiving Patents on COVID Vaccines” (May, 6, 2021) *Nature*. [↑](#footnote-ref-75)
76. G20, “About the G20,” https://www.g20.org/about-the-g20.html. [↑](#footnote-ref-76)
77. Francesco Guarascio, “G20 Snubs COVID Patent Waiver, Waters Down Pledge on WHO’s Funding,” (May 18, 2021) *Reuters*. [↑](#footnote-ref-77)
78. US Department of Defense, “DOD Announces Defense Production Act Title 3 COVID-19 PPE Project: $2.2 Million Investment Will Increase U.S. Domestic Production of N95 Mask Respirator and Mask Ventilator Filter Production by Over 30 Million Combined Over the Next 120 Days,” https://www.defense.gov/Newsroom/Releases/Release/Article/2200654/dod-announces-defense-production-act-title-3-covid-19-ppe-project-22-million-in/. [↑](#footnote-ref-78)
79. Google Patents, https://patents.google.com. [↑](#footnote-ref-79)
80. Ed Silverman, “Millions Sign Petitions Urging the US to Back a WTO Proposal for Greater Covid-19 Vaccine Access,” (April 23, 2021), *Stat*, https://www.statnews.com/pharmalot/2021/04/23/covid19-coronavirus-vaccine-wto-biden-intellectual-property/. [↑](#footnote-ref-80)
81. Communication, note 441. [↑](#footnote-ref-81)
82. Gregg Gonsalves, “The Covid-19 Vaccine Patent Waiver: A Crucial Step Towards a ‘People’s Vaccine,’” 373 *British Medical Journal* n1249 (2021). [↑](#footnote-ref-82)
83. World Health Organization, “Access to Affordable Medicines for HIV/AIDS and Hepatitis,” https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf. [↑](#footnote-ref-83)
84. Kumar, “Compulsory Licensing,” note 451, at 14. [↑](#footnote-ref-84)
85. Ruth Okediji, “Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection” (2004) 1 *University of Ottawa Law & Technology Journal*, 125, at 142. [↑](#footnote-ref-85)
86. PPP Knowledge Lab, “PPP Reference Guide: Introduction,” https://pppknowledgelab.org/guide/sections/1-introduction. [↑](#footnote-ref-86)
87. World Health Organization, “Public-Private Partnerships (PPPs),” https://www.who.int/intellectualproperty/topics/ppp/en/. [↑](#footnote-ref-87)
88. Jonathan H. Marks, “What’s the Big Deal?: The Ethics of Public-Private Partnerships Related to Food and Health,” at 5. [↑](#footnote-ref-88)
89. Jon F. Merz, “World Health Organization, Intellectual Property and Product Development Public/Private Partnerships” (May 16, 2005), Final Report to the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health, 17. [↑](#footnote-ref-89)
90. See Mark D. Lim et al., “Consortium Sandbox: Building and Sharing Resources” (June 25, 2014) *Science Translational Medicine* at 1–2. [↑](#footnote-ref-90)
91. IMI, “IMI Mission and Objectives,” https://www.imi.europa.eu/about-imi/mission-objectives. [↑](#footnote-ref-91)
92. IMI, “10 Years of Transforming Medical Research,” https://www.imi.europa.eu/news-events/10-years-transforming-medical-research. [↑](#footnote-ref-92)
93. IMI, “How IMI Works,” https://www.imi.europa.eu/about-imi/how-imi-works. [↑](#footnote-ref-93)
94. IMI, “Project Factsheets,” https://www.imi.europa.eu/projects-results/project-factsheets. [↑](#footnote-ref-94)
95. IMI, “Strategic Research Agenda” https://www.imi.europa.eu/about-imi/strategic-research-agenda. [↑](#footnote-ref-95)
96. See e.g. Frederick M. Abbott, “Public-Private Partnerships as Models for New Drug Development: The Future As Now,” in *Public-Private Partnerships, Public-Private Partnerships, Global Intellectual Property Governance and Sustainable Development*, Ahmed Abdel-Latif, Margaret Chon and Pedro Roffe eds., (Cambridge University Press, 2018), at 33-34. [↑](#footnote-ref-96)
97. Drugs for Neglected Diseases Initiative, https://dndi.org. [↑](#footnote-ref-97)
98. Drugs for Neglected Diseases Initiative, “Diseases,” https://dndi.org/diseases/. [↑](#footnote-ref-98)
99. Drugs for Neglected Diseases Initiative, “COVID-19,” https://dndi.org/diseases/covid-19/. [↑](#footnote-ref-99)
100. Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), https://carb-x.org. [↑](#footnote-ref-100)
101. CARB-X, https://carb-x.org. [↑](#footnote-ref-101)
102. See World Health Organization, “R&D Blueprint,” note 8 (adding an “unknown pathogen” to the list of diseases likely to trigger outbreaks in the foreseeable future). [↑](#footnote-ref-102)
103. CEPI, Preliminary Business Plan 2017–2021 (2016), at 15, https://perma.cc/FU2R-HJNG (“Ad-hoc initiatives for vaccine development are fragmented and unpredictable”). [↑](#footnote-ref-103)
104. National Academies Press, “The Role of Public-Private Partnerships in Health Systems Strengthening: Workshop Summary” (hereinafter “NAP Workshop Summary”) (2016), at 42 (examining the relationship between corporate and non-corporate partners). [↑](#footnote-ref-104)
105. But see Peter K. Yu, “Intellectual Property, Human Rights and Public-Private Partnerships,” in *Public-Private Partnerships*, note 477, at 398 (calling for public-private partnerships to abide by a human rights-enhancing framework). [↑](#footnote-ref-105)
106. Margaret Chon, “PPPs in Global IP” [Public-Private Partnerships in Global Intellectual Property], in *Methods and Perspectives in Intellectual Property*, Graeme B. Dinwoodie, ed., (Edward Elgar, 2014) at 269. [↑](#footnote-ref-106)
107. Merz, *supra*, note 470, at 15 (noting that some product development partnerships reported being forced to engage in late-stage clinical R&D before being able to secure a commercial partner). [↑](#footnote-ref-107)
108. See Jens K. Roehrich et al., “Are Public-Private Partnerships a Healthy Option? A Systematic Literature Review” (2014) 113 *Social Science & Medicine* 110, 113. [↑](#footnote-ref-108)
109. Roehrich, note 489. [↑](#footnote-ref-109)
110. Liza Vertinsky, “Boundary-Spanning Collaboration and the Limits of Joint Inventorship Doctrine” (2017) 55 *Houston Law Review* 401, 426–7. [↑](#footnote-ref-110)
111. See Kenny Bruno & Joshua Karliner, “Tangled Up In Blue: Corporate Partnerships at the United Nations” (September 1, 2000) *CorpWatch*, https://corpwatch.org/article/tangled-blue. [↑](#footnote-ref-111)
112. Kent Buse & Amalia Waxman, “Public-Private Health Partnerships : A Strategy for WHO” (2001) 79(8) *Bulletin of the World Health Organization: The International Journal of Public Health* 748-754. [↑](#footnote-ref-112)
113. See Merz, “World Health Organization,” note 470, at 14 (describing the phenomenon of “donor fatigue”). But see NAP Workshop Summary, note 485, at 57 (discussing the role of public-private partnerships as a sustainable financing mechanism for health systems). [↑](#footnote-ref-113)
114. *Id., ib.* [↑](#footnote-ref-114)
115. *Id., ib.* [↑](#footnote-ref-115)
116. Coalition for Epidemic Preparedness Innovations (CEPI), “Why We Exist,” https://cepi.net/about/whyweexist/. [↑](#footnote-ref-116)
117. CEPI, “A Sustainable Partnership,” https://cepi.net/about/whyweexist/. [↑](#footnote-ref-117)
118. CEPI, “Why We Exist,” note 498. [↑](#footnote-ref-118)
119. CEPI, “Our Portfolio,” https://cepi.net/research\_dev/our-portfolio/. [↑](#footnote-ref-119)
120. CEPI, “Our Portfolio,” note 500. [↑](#footnote-ref-120)
121. CEPI, Preliminary Business Plan 2017–2021 (2016), note 484, at 47. [↑](#footnote-ref-121)
122. Catherine Cheney, CEPI, “A Year In: How Can We Get Ready for the Next Pandemic?” (February 5, 2018) DEVEX. [↑](#footnote-ref-122)
123. CEPI Preliminary Business Plan, note 502, at 12. [↑](#footnote-ref-123)
124. CEPI, “CEPI Policy Documentation,” at 4, https://perma.cc/YJS8-YBQL. [↑](#footnote-ref-124)
125. Wetsman, “Health Secretary,” note 351. [↑](#footnote-ref-125)
126. CEPI Preliminary Business Plan, note 502, at 12. [↑](#footnote-ref-126)
127. CEPI Preliminary Business Plan, note 502, at 12. [↑](#footnote-ref-127)
128. CEPI Policy Documentation, note 505, at 8. [↑](#footnote-ref-128)
129. CEPI Policy Documentation, note 505, at 10. [↑](#footnote-ref-129)
130. CEPI Policy Documentation, note 505, at 3. [↑](#footnote-ref-130)
131. CEPI Policy Documentation, note 505, at 10. [↑](#footnote-ref-131)
132. CEPI Preliminary Business Plan, note 502, at 3. [↑](#footnote-ref-132)
133. Gavi, “About Our Alliance,” https://www.gavi.org/our-alliance/about [↑](#footnote-ref-133)
134. Gavi, “Vaccine Support,” https://www.gavi.org/support/nvs/ [↑](#footnote-ref-134)
135. Patricia M. Danzon et al., “Vaccine Supply: A Cross-National Perspective” (2005) 24 *Health Affairs* 706, 707. [↑](#footnote-ref-135)
136. Gavi, “Facts and Figures,” https://www.gavi.org/programmes-impact/our-impact/facts-and-figures. [↑](#footnote-ref-136)
137. Gavi, “Covax, The ACT-Accelerator Vaccines Pillar,” https://www.gavi.org/sites/default/files/document/2020/COVAX-Pillar- backgrounder\_3.pdf. [↑](#footnote-ref-137)
138. World Health Organization, “The Access to COVID-19 Tools (ACT) Accelerator,” https://www.who.int/initiatives/act-accelerator. [↑](#footnote-ref-138)
139. Gavi, “Covax,” note 518. [↑](#footnote-ref-139)
140. Gavi, “Gavi Launches Innovative Financing Mechanism for Access to COVID-19 Vaccines” (June 4, 2020), https://www.gavi.org/news/media-room/gavi-launches-innovative-financing-mechanism-access-covid-19-vaccines. [↑](#footnote-ref-140)
141. Gavi, “Covax Vaccine Roll-Out” (May 27, 2021), https://www.gavi.org/covax-vaccine-roll-out. [↑](#footnote-ref-141)
142. Gavi, “Covax Explained,” https://www.gavi.org/vaccineswork/covax-explained. [↑](#footnote-ref-142)
143. Gavi, “COVID-19 Vaccine Global Access (Covax) Facility, Preliminary Technical Design: Discussion Document” (June 11, 2020), at 2, https://perma.cc/HD4D-V2WK. [↑](#footnote-ref-143)
144. Preliminary Technical Design: Discussion Document, note 524, at 11. [↑](#footnote-ref-144)
145. Preliminary Technical Design: Discussion Document, note 524, at 11. [↑](#footnote-ref-145)
146. Preliminary Technical Design, note 524, at 4. [↑](#footnote-ref-146)
147. Richard Milne and David Crow, “Why Vaccine ‘Nationalism’ Could Slow Coronavirus Fight” (May 13, 2020) *Financial Times*. [↑](#footnote-ref-147)
148. See e.g. Sigal Samuel, “Why COVAX, the Fund to Vaccinate the World, is Struggling” (May 20, 2021) *Vox*, https://www.vox.com/future-perfect/22440986/covax-challenges-covid-19-vaccines-global-inequity. [↑](#footnote-ref-148)
149. Akin Olla, “Welcome to the New Colonialism: Rich Countries Sitting on surplus Vaccines” (Apr. 14, 2021) *Guardian*, https://www.theguardian.com/commentisfree/2021/apr/14/rich-countries-surplus-covid-vaccines [↑](#footnote-ref-149)
150. Duke Global Health Institute, “Will Low-Income Countries,” note 377. [↑](#footnote-ref-150)