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Planning for Pandemic and Epidemic-Related Scarcity of Medicines

Sapna Kumar and Ana Santos Rutschman

Pandemics and epidemics pose a substantial and growing threat to global health care systems.[1] When a large-scale outbreak occurs, time is of the essence to repurpose existing health technologies and develop new medicines to prevent or treat illness, to avoid straining hospitals, and to reduce deaths. Delays in implementing licensing agreements for relevant intellectual property (IP) rights and manufacturing know-how can hinder ramping up production of needed medicines.

Intellectual property rights play a mixed role in pandemics and epidemics. Patents provide inventors with the right to exclude others from making, using, selling, and importing their inventions, among other actions.[2] Coupled with regulatory exclusivities, patents are often credited with incentivizing pharmaceutical companies to develop new medicines and to find new uses for existing ones.[3] Trade secrets furthermore encourage the development of medicines by allowing companies to protect valuable know-how, such as complex pharmaceutical manufacturing processes.[4]

[1] *See generally* Marco Marani et al., *Intensity and Frequency of Extreme Novel Epidemics*, 118 PNAS (2021); David Blumenthal et al., *Covid-19 – Implications for the Health Care System*, 383 New Engl. J. Med. 1483 (2020); Alan D. Kaye et al., *Economic Impact of COVID-19 Pandemic on Healthcare Facilities and Systems: International Perspectives*, 35 Best Pract. Res. Clin. Anaesthesiol. 293 (2020).

[2] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 28(1).

[3] *See generally* Fritz Machlup, *An Economic Review of the Patent System*, Subcommittee on Patents, Trademarks, and Copyrights of the Senate Committee on the Judiciary, 85th Cong., 2d Session 1, 33 (1958) ("The thesis that the patent system may produce effective profit incentives for inventive activity and thereby promote progress in the technical arts is widely accepted"). *But see, e.g.*, Mitja Kovac & Lana Rakovec, *The COVID-19 Pandemic and Long-Term Incentives for Developing Vaccines: Patent Law under Stress*, 25 J. World Int'l Prop. L. 292 (2022) (surveying the shortcomings of patent incentives theory in the specific context of pharmaceuticals needed for pandemic preparedness). *See also* Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Innovation System?*, 2 Innovation Pol'y & Econ. 51 (2002) (surveying other incentives mechanisms).

[4] *See* Olga Gurgula & John Hall, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. IP Law & Practice 1242, 1244 (2021).

Intellectual property rights, however, can also contribute to medicine shortages. When demand for life-saving medicines surges due to a large-scale outbreak, there is a lag time before companies can scale up production.[5] Although licensing proprietary technology to third-party manufacturers would help speed up production, companies may nevertheless refuse to collaborate. They might also choose to sell these medicines at exorbitant prices, or delay making them available to low- and middle-income countries in order to prioritize orders for higher-paying customers.

Governments in high-income countries provide pharmaceutical companies with substantial funding, for pandemic- and epidemic-specific research and development (R&D), as well as for more general R&D.[6] Yet they typically fail to secure enforceable promises from the funding recipient to ensuring that life-saving medicines are produced in sufficient quantity. Nor do such contracts generally address whether the final medicine will be provided to low-income countries in adequate quantities or at an affordable cost. This can lead to global shortages of taxpayer-funded drugs at a time when they are most needed. Existing measures under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have proven to be inadequate for addressing these problems.

This chapter argues that when governments and nongovernmental entities fund research for pandemic- and epidemic-specific drug development, they should use contractual provisions to provide safeguards to the public. Funding contracts should require the IP rights holder(s) to commit to taking all reasonable measures to produce sufficient quantities of any resulting life-saving drug in the event of a public health emergency. Were a shortage to arise, the relevant pharmaceutical company would be required to cooperate with willing third-party drug manufacturers to increase supply, in exchange for compensation. Complementarily, we argue that medical research funders should contractually secure promises to ensure fair pricing and access to life-saving medicines in low- and middle-income countries during public health emergencies.

We additionally propose that funders of medical research utilize a contractual mechanism called a "dormant license," which could impose some, or all, of the obligations outlined above. These licenses would be negotiated ahead of crisis situations and activate automatically when a pandemic or epidemic is declared to ensure an adequate supply of needed medicines.

1 SCARCITY OF MEDICINES AND INEQUITABLE ALLOCATION IN CONTEXT

The global allocation of critically needed medicines has long been marked by profound asymmetries. Although low-income countries are often disproportionately

[5] *See* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. Rev. 1200, 1206 (2018).

[6] *See, e.g.*, Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, Health Aff. Forefront (May 14, 2021), www.healthaffairs.org/do/10.1377/forefront.20210512.191448/ (last visited Dec. 5, 2023).

impacted by infectious disease outbreaks, high-income countries typically obtain greater supplies of medicines to treat them. This trend is exacerbated when severe public health crises cause a spike in demand for medicines, as is typically the case with pandemics and epidemics. COVID-19 is the most recent of a series of outbreaks in which the Global North purchased most of the treatment and vaccine supply.[7]

Market-based dynamics drive this inequality. High-income countries have both the resources and the bargaining power to capture much of the initial supply of pandemic and epidemic medicines through bilateral channels. During the COVID-19 and 2009 swine flu pandemics, these countries used advanced purchase agreements to buy vaccine doses from pharmaceutical companies before any were actually produced.[8] Some countries ordered far more doses than necessary to vaccinate their domestic populations.[9] Others engaged in "vaccine diplomacy," through which they allocated vaccines to allies, as opposed to those with the greatest need, in order to secure some form of regional or international advantage or influence.[10] This left lower-income countries with scant access to critically needed medicines during worsening public health crises, and it forced them to wait for global manufacturing capacity to increase or for donated doses. During the 2009 swine flu pandemic, donations only occurred after the pandemic had mostly subsided.[11]

The practice of allocating scarce medicines to the countries that can most readily negotiate with and pay vaccine manufacturers is known as "vaccine nationalism"; it is part of a growing trend of market power overriding need, to the detriment of public health.[12] The allocation of COVID-19 vaccines illustrates this phenomenon. The US government initially refused to support international procurement through

[7] *See generally* Sam F. Halabi & Ana Santos Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, 36 Emory Int'l L. Rev. 1 (2022).

[8] *See id.* (describing these phenomena during the 2009 swine flu pandemic); David Brown, *U.S. to Donate 10 Percent of Swine Flu Vaccine to WHO*, Wash. Post (Sep. 18, 2009); Olivia Goldhill, *We Have Enough Covid Vaccines for Most of the World. But Rich Countries Are Stockpiling More than They Need for Boosters*, STAT (Dec. 13, 2021), www.statnews.com/2021/12/13/we-have-enough-covid-vaccines-for-most-of-world-but-rich-countries-stockpiling-more-than-they-need/ (last visited Dec. 5, 2023); Jon Cohen & Kai Kupferschmidt, *Fairer Shares*, Science (May 26, 2021), www.science.org/content/article/rich-countries-cornered-covid-19-vaccine-doses-four-strategies-right-scandalous (last visited Dec. 5, 2023) (describing these phenomena during COVID-19).

[9] Brown, *supra* note 8.

[10] *See* Halabi & Rutschman, *supra* note 7. *See also* Sui-Lee Wee & Steven Lee Myers, *As Chinese Vaccines Stumble, U.S. Finds New Opening in Asia*, NY Times (Sep. 30, 2021), www.nytimes.com/2021/08/20/business/economy/china-vaccine-us-covid-diplomacy.html (last visited Dec. 5, 2023); Peter J. Hotez, Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-Science (2021).

[11] Brown, *supra* note 8.

[12] *See* Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, Geo. J. Int'l Aff. Online (Jul. 3, 2020), https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/ (last visited Dec. 5, 2023).

the COVID-19 Vaccines Global Access (COVAX), a facility co-led by the Coalition for Epidemic Preparedness Innovations, Gavi and the World Health Organization (WHO).[13] Instead, the Trump Administration launched Operation Warp Speed, providing billions of dollars to pharmaceutical companies that were working to develop COVID-19 vaccines and placing advanced purchase agreements with six companies. It attempted to secure priority access to foreign companies' vaccines by offering them large sums of money, sparking immense backlash.[14] The United States was not alone in aggressively stockpiling vaccines – the United Kingdom, Canada, Japan, and some European Union member states procured more vaccines than they actually needed.[15]

Various countries chose to support COVAX with the goal of facilitating the manufacturing and distribution of COVID-19 vaccines to all countries. However, COVAX fell short of its promises.[16] Some countries placed orders, but received their vaccines late or without any advanced notice, or received doses that were about to expire.[17] Middle-income countries that did not receive promised vaccines were forced to later negotiate separate deals with vaccine manufacturers, pushing them to the back of the line. The Serum Institute of India was supposed to be a major supplier, but India's vaccine export ban in 2021 blocked it from delivering orders for several months.[18] A major complaint against COVAX was its failure to push for technology transfers to allow countries to manufacture their own doses.[19]

Lower-income countries are supposed to have legal tools to counter vaccine nationalism and, more broadly, problems of medicine scarcity arising during public health crises. Article 31 of TRIPS allows member countries to utilize "compulsory

[13] *See, e.g.*, Scott Neuman, *U.S. Won't Join WHO-Led Coronavirus Vaccine Effort, White House Says*, NPR (Sep. 2, 2020), www.npr.org/sections/coronavirus-live-updates/2020/09/02/908711419/u-s-wont-join-who-led-coronavirus-vaccine-effort-white-house-says (last visited Dec. 5, 2023).

[14] *See* Sapna Kumar, *Compulsory Licensing of Patents during Pandemics*, 54 Conn. L. Rev. 57, 93–94 (2022).

[15] Nurtih Aizenman, *Why Low-Income Countries Are so Short on COVID-Vaccines*, NPR (Nov. 10, 2021), www.npr.org/sections/goatsandsoda/2021/11/10/1052078529/why-low-income-countries-are-so-short-on-covid-vaccines-hint-its-not-boosters (last visited Dec. 5, 2023).

[16] *See, e.g.*, Olivia Goldhill, *"Naively Ambitious": How COVAX Failed on Its Promise to Vaccinate the World*, STAT (Oct. 8, 2021), www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/ (last visited Dec. 5, 2023).

[17] Francesco Guarascio, *Poorer Nations Reject over 100 mln COVID-19 Vaccine Doses as Many Near Expiry*, Reuters (Jan. 14, 2022), www.reuters.com/business/healthcare-pharmaceuticals/more-than-100-million-covid-19-vaccines-rejected-by-poorer-nations-dec-unicef-2022-01-13/ (last visited Dec. 5, 2023).

[18] *See, e.g.*, Stephanie Findlay, Michael Peel & Donato Paolo Mancini, *India Blocks Vaccine Exports in Blow to Dozens of Nations*, Financial Times (Mar. 25, 2021), www.ft.com/content/53493890-8313-41e0-9a67-58274e24a019 (last visited Dec. 5, 2023); *India Resumes Coronavirus Vaccine Exports to COVAX*, Reuters (Nov. 26, 2021), www.reuters.com/world/india/indias-serum-institute-resumes-covishield-vaccine-exports-under-covax-facility-2021-11-26/ (last visited Dec. 5, 2023).

[19] *See* Goldhill, *supra* note 16.

licensing" and issue licenses for patented technology to third parties.[20] During emergencies, including pandemics and epidemics, a government need not engage in time-consuming negotiations with the patent holder prior to issuing a compulsory license.[21] Article 31*bis* further permits countries in need of particular drugs to import them under compulsory license from a country capable of producing them.[22] Theoretically, these provisions should allow lower-income countries to produce or import the medicines that they need during a pandemic or epidemic.

TRIPS, however, lacks a mechanism for compelling pharmaceutical companies to share the know-how that is needed for third-party manufacturers to quickly replicate medicines. Article 39 requires member countries to protect trade secrets and contains no provision expressly allowing for compulsory licensing.[23] Without manufacturing-related know-how, a country may need years to both recreate a vaccine or other complex medicine and to gain regulatory approval.[24] Lower-income countries furthermore risk higher-income countries retaliating against them for using compulsory licensing.[25]

2 PREPARING FOR PANDEMICS AND EPIDEMICS: THE UNDEREXPLORED ROLE OF CONTRACTS

An underappreciated point in the literature is the fact that many components needed to produce medicines for pandemic and epidemic response are developed well in advance.[26] When an outbreak occurs, the process of developing drugs and vaccines does not start from scratch. Rather, researchers adapt and use preexisting technology to address the specific challenges posed by a new infectious disease.

The development of vaccines against Ebola and COVID-19 provides an illustration of this point. Vaccines for these diseases were the product of years of pre-outbreak R&D and technology transfer.[27] During the 2014–2016 Ebola vaccine race, the leading vaccine candidate had actually been developed by 2005. It did not come

[20] *See* TRIPS, art. 31.
[21] *See* TRIPS, art. 31(b).
[22] *See* TRIPS, art. 31*bis*.
[23] *See* TRIPS, art. 39. Note that it might be possible for countries to rely on the security exception under article 73(b), which states that TRIPS shall not be construed "to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests."
[24] *See* Kumar, *supra* note 14, at 99–100.
[25] *Id.*
[26] For instance, even though it only became commercially applicable during COVID-19, vaccine mRNA technology had long been in development; *see, e.g.*, Damien Garde & Jonathan Saltzman, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race*, STAT (Nov. 10, 2020), www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/ (last visited Dec. 5, 2023).
[27] *See generally* Rutschman, *supra* note 5.

to market until 2019 due to a lack of private sector interest in initiating clinical trials and seeking regulatory approval.[28] Similarly, Moderna and Pfizer's COVID-19 mRNA vaccines utilized technology that had been in development for well over a decade.[29]

The timing of drug development has implications for the practices surrounding technology transfer. During large transnational public health crises, bargaining processes will be rushed, tinged by geopolitics and limited by resource scarcity,[30] making it difficult to address allocative inequalities among countries. Yet funding contracts governing R&D, transfer, and commercialization of these medicines generally predate the outbreak causing a spike in demand. Consequently, at least some of the contractual requirements governing the sharing and transferring of technology during a pandemic or epidemic can be established when demand is lower – well before bidding wars to pre-purchase most of the vaccines or treatments occur.

We therefore suggest that bargaining regarding the transfer of technology take place as far in advance as possible. Furthermore, attempts to promote the fair allocation of pandemic and epidemic health goods should occur ideally in the pre-pandemic or epidemic period. We discuss two different approaches that R&D funders could use to address affordability and/or equitable allocation obligations in funding contracts governing R&D on these goods. Many existing proposals to expand access to medicines during pandemics and epidemics occur ex post by constraint – as product scarcity and nationalist behaviors combine to exclude populations in lower-income countries. By contrast, our proposed framework would operate largely ex ante, creating binding contractual obligations that arise if and when pandemic or epidemic-driven scarcity occurs.

3 SAFEGUARDING ACCESS TO MEDICINES THROUGH PANDEMIC-SPECIFIC FUNDING AGREEMENTS

When funding the development of medicines that are likely to be needed for a pandemic or epidemic response, funding entities could use their contracts to proactively anticipate scarcity and pricing problems. One possibility would be to insert provisions into funding contracts requiring pharmaceutical companies benefitting from the funding to produce any subsequently developed medicine in sufficient quantity to meet public health needs.[31] In order to determine whether a

[28] *See, e.g.*, Denise Grady, *Ebola Vaccine, Ready for Test, Sat on the Shelf*, NY Times (Oct. 23, 2014), www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html (last visited Dec. 5, 2023).

[29] *See, e.g.*, Garde & Saltzman, *supra* note 26.

[30] *See* Rutschman, *supra* note 5, at 1260.

[31] *See* Ken Shadlen, *To Speed New COVID Vaccines, Look to Patenting*, Issues in Sci. & Tech (Aug. 11, 2020).

particular medicine is tied to funding received under our proposed model, a contract could specify an identification formula or mechanism. For instance, funding could be tied to applied for or granted patents. Under this approach, if funding under the contract results in a patent that covers part of the resulting medicine, then the product as a whole would be covered by the licensing terms.[32]

The funding contract could provide an initial grace period to allow the company time to secure raw materials and scale up production of the medicine in question. Alternatively, the contract may bind the parties to decide what the appropriate grace period is once a pandemic or epidemic is declared; this approach would cater to the specificities of a given public health crisis. If the shortage persists, the funder could require the company to license out the relevant patents and know-how to willing third-party manufacturers to scale up production more quickly.

The contract would specify a compensatory royalty rate to be paid to the company under such circumstances. The goal would be to set the rate as close to fair market value as possible, while ensuring that third-party manufacturers have sufficient incentive to help produce the needed medicine. By doing this, the company should end up with a higher rate of profits than if the shortage had continued. The funding contract would further specify significant financial penalties for companies that fail to cooperate and could bar future funding to an uncooperative recipient.

The funder could furthermore require the pharmaceutical company to promise that any resulting medicine be priced fairly for low-income countries and be made available to them in sufficient quantity. As discussed earlier, bidding wars have put needed medicines out of reach for much of the Global South during pandemics and epidemics. What assistance high-income governments provide typically comes in the form of donating excess medicines.[33] It would be far more efficient for funders to secure low-cost access from pharmaceutical companies when the underlying R&D is funded and to require companies to work with generic drug manufacturers in low-income countries to help ensure an adequate supply.

We acknowledge that funding for R&D in this area is often provided by entities in higher-income countries – the same countries that have repeatedly tried to secure early vaccine access for recent pandemics, notwithstanding the pressing need of those living in lower-income countries.[34] Although it is unlikely that vaccine nationalism will be fully eliminated ahead of future global public health crises,

[32] A contract may specify that the licensing terms will apply to the medicine in question even if it is covered by other patents that are not the result of tied funding.

[33] This practice of countries buying up excessive vaccine doses, then counting donations of the excess against their total aid budgets, has been criticized by some charity groups. *See Donating Unwanted Vaccine Doses Should Not Be Part of Already Stretched Aid Budgets*, Oxfam International (Feb. 15, 2022), www.oxfam.org/en/press-releases/donating-unwanted-vaccine-doses-should-not-be-part-already-stretched-aid-budgets (last visited Dec. 5, 2023).

[34] *See* Halabi & Rutschman, *supra* note 7. *See also* Rutschman, *supra* note 12.

the COVID-19 pandemic has highlighted the frailty of these approaches.[35] Countries lacking the vaccines likely prolonged the pandemic by giving rise to mutations that could evade the vaccines' protection.[36] In light of the need for global cooperative efforts to prevent and respond to pandemics and large-scale epidemics, the time is ripe for funders in higher-income countries to consider the imposition of requirements that align with this goal.[37]

Moreover, we note that some pharmaceutical companies already utilize licensing agreements to benefit low-income countries. For example, the United Nations-backed Medicines Patent Pool (MPP) negotiated a voluntary license with Pfizer for its oral COVID-19 drug Paxlovid. This allowed MPP to sublicense it royalty-free to thirty-five manufacturers for the duration of the pandemic, benefitting ninety-five lower-income countries; a 5–10 percent royalty will apply for middle-income countries thereafter.[38] However, not all companies are willing to participate in such programs, and some withhold their most lucrative medicines from such agreements. For example, both Moderna and Pfizer have refused to license out their mRNA vaccine technology, highlighting the need for more formalized licensing obligations.[39]

Anticipating the possibility of pandemic- and epidemic-driven shortages of medicines in funding contracts would offer several benefits. It would allow for production to be rapidly scaled up by decreasing transaction costs for third-party manufacturers that are willing to produce the medicine. When compulsory licensing is used, the third-party producer must waste time replicating the medicine and gaining regulatory approval. Indeed, for biologics such vaccines, the timeline for bringing a biosimilar vaccine to market could exceed the duration of the public health emergency. Under our proposal, third-party manufacturers would be able to obtain access to proprietary information about the optimal way to produce the medicine, eliminating such unnecessary delays.

Another benefit to our proposal is that the third-party-produced medicine may not have to go through full regulatory approval, because it would be made under license from the original manufacturer. Depending on the applicable national regulatory

[35] *See, e.g.*, United Nations Department of Economic and Social Affairs, Recover better: Economic and Social Challenges and Opportunities (2020).

[36] *See* James Darwin N. Lagman, *Vaccine Nationalism: A Predicament in Ending the COVID-19 Pandemic*, 43 J. Pub. Health e375–e376 (2021).

[37] Although our proposal could be implemented by national governments acting alone, it could also be part of a pandemic treaty. *See* Katrina Perehudoff et al., *A Pandemic Treaty for Equitable Global Access to Medical Countermeasures: Seven Recommendations for Sharing Intellectual Property, Know-how and Technology*, 7 BMJ Global Health e009709 (2022).

[38] *See* Rebecca Robbins, *35 Companies Sign on to Produce Generic Versions of Pfizer's Covid Pill*, N.Y. Times (Mar. 17, 2022), www.nytimes.com/2022/03/17/business/35-companies-sign-on-to-produce-generic-versions-of-pfizers-covid-pill.html (last visited Dec. 5, 2023). A similar license was negotiated with Merck for molnupiravir. *Id.*

[39] *See* Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. Times (Nov. 9, 2021), www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html (last visited Dec. 5, 2023).

frameworks, such medicines would potentially qualify as follow-on drugs (generics or biosimilars) or may be eligible for other shortened review pathways, as was the case with emergency use authorizations for COVID-19 vaccines.[40] The third-party manufacturer could also potentially benefit from the rights holder's connections with raw material providers. Furthermore, the funding contract would pre-set the compensation rate, so that time-consuming negotiations do not have to take place once a shortage has arisen.

There are, admittedly, some limitations to our proposal. During the COVID-19 pandemic, there were shortages of supplies that licensing would not have been able to mitigate, such as glass vials to hold vaccine doses.[41] Nor will licensing help if medicine manufacturing capacity is insufficient or if logistical limitations arise. For cutting-edge technology such as mRNA vaccines, a shortage of skilled personnel might also exist, and it could take time to train employees at third-party manufacturing facilities to produce highly novel medicines. Finally, securing these promises in the shadow of a pandemic could lead to funding entities paying more to the recipients and would likely lead to larger pharmaceutical companies declining funding.

4 DORMANT LICENSING PROVISIONS

A "dormant license" is a set of contractual provisions agreed to by the parties before the occurrence of a specified event.[42] Although the provisions are not active at the time that they are agreed to – even if other portions of the agreement have taken effect – they come into force if the event occurs.[43] We propose that funding entities

[40] Governmental drug regulators generally provide some form of abbreviated approval pathways for follow-on drugs and biologics (the latter category referring to large-molecule drugs, such as vaccines and monoclonal antibodies). *See, e.g.*, U.S. Food & Drug Administration, Abbreviated New Drug Application (ANDA) (2022), www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (last visited Dec. 5, 2023) (describing the review and approval regime for follow-on small-molecule drugs in the United States); U.S. Food & Drug Administration, Review and Approval, www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval (last visited Dec. 5, 2023) (describing the review and approval regime for follow-on large-molecule drugs in the United States). *See also* 21 U.S.C. § 355(j) (requiring that sponsors demonstrate bioequivalence between a follow-on small-molecule drug and the reference drug, rather than requiring the submission of preclinical (animal) and clinical (human) data to establish safety and effectiveness); 42 U.S.C. § 262(k) (requiring sponsors to demonstrate biosimilarity or interchangeability of a follow-on biologic and the reference biologic and similarly doing away with the submission of preclinical and clinical trial data). *See also* U.S. Food & Drug Administration, Emergency Use Authorization for Vaccines Explained (2020), www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (last visited Dec. 5, 2023).

[41] Norman Miller, *The Rollout of a COVID-19 Vaccine Is under Threat: Leading Experts Tell Us They're Worried about a Shortage of Glass Vials, Cargo Planes, and Cold-storage Units*, BUS. INSIDER (Sep. 21, 2020), www.businessinsider.com/covid-19-vaccine-experts-warn-glass-vials-planes-storage-shortage-2020-9 (last visited Dec. 5, 2023).

[42] *See* generally Rutschman, *supra* note 5.

[43] *Id.*

attach a dormant license when funding R&D for medicines that are typically needed to prevent and respond to pandemics and epidemics. They should condition funding on the acceptance of contractual terms designed to promote the affordability and equitable allocation of the medicines covered by the license.

We recommend a flexible framework to identify relevant medicines, or components thereof, that would be subject to the dormant license. This would be modeled after the list of emerging pathogens maintained by the WHO or a similar group. Funding entities would designate certain emerging pathogens or diseases as "priority" targets and would reserve some funding for recipients who agree to the dormant license terms.[44] Ideally, the funding recipient would also guarantee the affordability and equitable distribution of any subsequently developed products. However, the funding entity may make strategic choices about which areas of R&D are best suited for the dormant licensing model based on political economy constraints.

Dormant licenses are particularly well suited to providing funding for R&D on emerging infectious diseases. Such work has been grossly underfunded and has failed to attract significant funding even after an outbreak occurs.[45] For this reason, the realm of emerging pathogens of concern, as identified by the WHO – or by another public health-oriented institution[46] – constitutes a good field for our proposal. These pathogens are expected to trigger significant outbreaks in years to come, yet are underrepresented in large pharmaceutical companies' development pipelines.

The funding entity may tailor the dormant licensing requirements based on its priorities. For example, a funding entity that supports vaccine development might require recipients to promise that a percentage of any vaccine doses produced be allocated to an international procurement facility – such as COVAX – in the event of a relevant outbreak. It could choose to impose pricing requirements by adopting a formula to calculate pricing at the time of commercialization or impose requirements specific to commercialization in lower-income countries. It could furthermore obligate recipients to sublicense the technology on a nonexclusive basis to alleviate shortages, or require them to sublicense to preferred or predetermined partners. Overall, the terms can be adapted depending on the specifics of the technology, the field of R&D, and the profile of the target funding recipients to maximize both goals of health equity and practical implementation.

To increase certainty for the funding recipient, we suggest that the trigger for the dormant license be a formal declaration of an epidemic or pandemic by an agreed-upon public health institution. Although we believe that the WHO is well positioned to serve in this function, the parties could alternatively choose a domestic

[44] *See* WHO, *An R&D Blueprint for Action to Prevent Pandemics* (2016) (listing priority pathogens, including coronaviruses).

[45] *See* Rutschman, *supra* note 5, at 1207–1218, 1244–1252.

[46] *See, e.g.*, National Institute of Allergy & Infectious Diseases, NIAID Emerging Infectious Diseases/Pathogens (2018), www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens (last visited Dec. 5, 2023).

institution or some other body to fulfill this role. The licensing terms would indicate whether the qualifying event is a formal declaration or merely a declaration of concern,[47] and would identify the institution or institutions producing the qualifying trigger. The contract should also specify how to calculate the period for which the dormant license would remain active, such as the number of months counted from a formal declaration that a pandemic or epidemic is over. It should furthermore address whether the term could be extended if the parties were to desire, and if so, how. Finally, as was the case with our previous proposal, the funding contract could also establish financial penalties for funding recipients that fail to abide by the terms of the license, as well as potentially bar the awarding of future funding to the recipient in breach of the agreement.[48]

The approach outlined here offers several advantages over current licensing approaches.[49] First, the licensing terms are negotiated before a large-scale public health crisis unfolds, when there are fewer bargaining pressures. Second, a dormant license furthers the goal of increasing legal certainty by setting clear obligations and corresponding rewards before the need for expedited R&D arises. And third, although the dormant license is designed to impose some sort of limitation on licensees, it would contribute toward monetization of the licensed product or products, as it integrates compensation for the rights holder.

The presence of dormant licensing provisions in funding contracts will admittedly not be attractive to all firms. Large and established pharmaceutical companies, such as Pfizer, are likely to refuse any funding with such conditions.[50] However, several types of firms engaging in pharmaceutical R&D may be willing to agree to a dormant license, particularly for underfunded areas of research. For instance, prior to the COVID-19 pandemic, Moderna was a relatively small company which had never brought a product to market, yet received substantial government funding.[51] Smaller companies, companies that are generally dependent on external R&D

[47] *See* Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. Travel Med. 1–2 (2020), https://pubmed.ncbi.nlm.nih.gov/33284964/ (last visited Dec. 5, 2023).

[48] *See supra*: "The funding contract would further specify significant financial penalties for companies that fail to cooperate and could bar future funding to an uncooperative recipient."

[49] *See generally* Rutschman, *supra* note 5, at 1260.

[50] Pfizer refused to accept any R&D funding for its mRNA vaccine from the US government, likely out of concern that the government might utilize march-in rights against any resulting patents. *See* Kumar, *supra* note 14, at 81.

[51] *See, e.g.*, Damian Garde & Jonathan Saltzman, *The Story of mRNA: How a Once-Dismissed Idea Became a Leading Technology in the Covid Vaccine Race*, STAT (Nov. 10, 2020), www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/ (last visited Dec. 5, 2023). Moderna also accepted significant government funds for the development of its mRNA vaccine during the COVID-19 vaccine race. *See* Simi V. Siddalingaiah, Congressional Research Service, IN11560, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials* 2 (2021), https://crsreports.congress.gov/product/pdf/IN/IN11560 (last visited Dec. 5, 2023).

funding, and especially companies seeking to establish a relationship with government funders are all more likely to agree to the provisions that we propose.

5 CONCLUSION

Past and current public health crises have shown that high-income countries have failed to proactively address pandemic- and epidemic-driven shortages of critically needed medicines. Worse still, high-income countries frequently hoard scarce medicines with little thought for whether those located in the Global South have access. Governments and institutions providing funding for pharmaceutical development have generally taken few steps to proactively ensure the adequate production, as well as the fair pricing and allocation of medicines. During the COVID-19 pandemic, existing flexibilities under TRIPS provided little relief, because pharmaceutical companies could not be compelled to share vital medicine-manufacturing know-how with third-party manufacturers.

Moving forward, governmental and nongovernmental entities should take a proactive approach to anticipating such scarcity by using funding as leverage for obtaining promises regarding medicine supply and pricing. We propose two levels on which this can operate. More narrowly, when entities fund pandemic- or epidemic-specific R&D, they could extract contractual promises to make any resulting medicine in sufficient quantity to meet demand and to require that the recipient provide the medicine to lower-income countries at reasonable prices. In the event of scarcity, the funding recipient would be obligated to license out its technology to willing third-party manufacturers in exchange for predetermined compensation. More broadly, they could incorporate such promises into other R&D funding agreements – such as for emerging pathogen research – by using a dormant license that triggers in the event of a pandemic or epidemic. These strategies provide funding entities with a flexible mechanism for mitigating pandemic- and epidemic-driven shortages and preventing distributional inequalities, which could ultimately save lives.