Planning for Pandemic and Epidemic-Related Drug Scarcity

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The COVID-19 pandemic has highlighted problems regarding scarcity of lifesaving medicines. During pandemics and epidemics, a sudden surge in demand for medicines is often unmatched on the supply side. Moreover, the same intellectual property rights that are supposed to incentivize their creation may also limit governments’ ability to scale up production during times of crisis. Few legal safeguards exist to compel pharmaceutical companies to share the proprietary technology and know-how needed to quickly and efficiently produce needed drugs. In this chapter, we propose an ex ante approach to tackling such scarcity: Entities funding pandemic- and epidemic-related research should require recipients to produce sufficient quantities of resulting drugs. The recipient would agree in the event of a future shortage to share its technology and know-how with a qualified third-party manufacturer, in exchange for compensation. Alternatively, funding entities could more broadly utilize dormant licenses, which activate in the event of a pandemic or epidemic and which require rights holders to license out technology—and, ideally, know-how. By proactively securing such rights, funding entities could help reduce shortages, improve global access to medicines, and save lives.

**Introduction**

Pandemics and epidemics pose a substantial threat to global health care systems.[[2]](#footnote-2) When a large-scale outbreak occurs, time is of the essence to repurpose existing medicines and develop new ones to prevent or treat illness, in order 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 drugs.

IP rights play a mixed role in pandemics and epidemics. Patents provide inventors with a monopoly to make, use, sell, and import their inventions.[[3]](#footnote-3) This arguably incentivizes pharmaceutical companies to develop new medicines, and encourages them to find new uses for existing ones.[[4]](#footnote-4) Trade secrets furthermore encourage drug development by allowing companies to protect valuable know-how regarding their production. However, IP rights can also contribute to shortages. When demand surges due to a large-scale outbreak, there is a lag time before companies can scale up production.[[5]](#footnote-5) Although licensing out proprietary technology to third-party manufacturers would help speed up production, companies may nevertheless refuse. 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, both for pandemic and epidemic-specific research and development (R&D), as well more general R&D.[[6]](#footnote-6) Yet, they typically fail to secure enforceable promises from the funding recipient to ensuring that life-saving drugs are produced in sufficient quantity. Nor do such contracts generally address whether the final drug will be provided to low-income countries in adequate quantities or at an affordable cost. This can lead to global shortages of tax-payer-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.

In this chapter, we argue that when governments and non-governmental entities fund research for pandemic and epidemic-specific drug development, that they should use contractual provisions to provide safeguards to the public. Funding contracts should require the IP rights holder to commit to producing 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 further 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 drugs 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 drugs.

# I. Drug Scarcity and Inequitable Allocation of Medicines in Context

The global allocation of critically needed medicines has long been marked by profound asymmetries. High-income countries typically obtain greater supplies to the detriment of lower-income countries, even though the latter group might be disproportionately impacted by a disease. This trend is exacerbated when severe public health crises cause a spike in demand for drugs, as is 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]](#footnote-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 drugs through bilateral channels. During the COVID-19 and 2009 swine flu pandemic, these countries used advanced purchase agreements with individual pharmaceutical companies to purchase vaccine doses before any were produced.[[8]](#footnote-8) Some ordered far more doses than necessary to vaccinate their domestic populations.[[9]](#footnote-9) Others engaged in “vaccine diplomacy,” in 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]](#footnote-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 swine flu pandemic, this only occurred after the pandemic had mostly subsided.[[11]](#footnote-11)

The practice of allocating scarce medicines to the countries that can most readily pay vaccine manufacturers is known as “vaccine nationalism,” and is part of a growing trend of market power overriding need, to the detriment of public health.[[12]](#footnote-12) The allocation of COVID-19 vaccines illustrates this phenomenon. The U.S. government refused to support international procurement through COVAX, a facility co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO).[[13]](#footnote-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 buy priority access to foreign companies’ vaccines by offering them large sums of money, sparking immense backlash.[[14]](#footnote-14) The United States was not alone in aggressively stockpiling vaccines—the United Kingdom, Canada, Japan, and European Union member states all procured more vaccines than what they actually needed.[[15]](#footnote-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]](#footnote-16) Some countries placed orders, but received their vaccines late or without any advanced notice, or received doses that were about to expire.[[17]](#footnote-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 blocked it from delivering orders for several months.[[18]](#footnote-18) A major complaint against COVAX was its failure to push for technology transfers to allow countries to manufacture their own doses.[[19]](#footnote-19)

Lower-income countries are supposed to have legal tools to counter vaccine nationalism and, more broadly, problems of drug scarcity arising during public health crises. Article 31 of TRIPS allows member countries to utilize “compulsory licensing” and issue licenses for patented technology to third parties without patent-holder consent.[[20]](#footnote-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]](#footnote-21) Article 31*bis* further permits countries in need of particular drugs to import them under compulsory license from a country capable of producing it.[[22]](#footnote-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 drugs. Art. 39 requires member countries to protect trade secrets and contains no provision allowing for compulsory licensing.[[23]](#footnote-23) Without manufacturing-related know-how, a country may need years to both recreate a vaccine or other complex drug and gain regulatory approval.[[24]](#footnote-24) Lower-income countries furthermore risk higher-income countries retaliating against them for using compulsory licensing.[[25]](#footnote-25)

# II. Preparing for Pandemics and Epidemics: The Under-Explored 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]](#footnote-26) When an outbreak occurs, the process of vaccine and drug development does not start from scratch. Rather, researchers adapt and use pre-existing technology to address the specific challenges posed by a new infectious disease.

The development of vaccines against Ebola and COVID-19 provides a clear illustration. Vaccines for these diseases were both the product of years of pre-outbreak R&D and technology transfer.[[27]](#footnote-27) During the 2014–2016 Ebola vaccine race, the leading vaccine candidate had actually been developed by 2005. It did not come to market until 2019 due to a lack of private-sector interest in initiating clinical trials and seeking regulatory approval.[[28]](#footnote-28) Similarly, Moderna and Pfizer’s COVID-19 mRNA vaccines were made utilizing technology that had been in development for well over a decade.[[29]](#footnote-29)

The timing of drug development has implications for the practices surrounding technology transfer. During transnational public health crises, bargaining processes will be rushed, tinged by geopolitics and limited by resource scarcity,[[30]](#footnote-30) making it difficult to address allocative inequalities among countries. Yet, funding contracts governing R&D, transfer, and commercialization of these medicines generally pre-date 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 below 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.

# III. Safeguarding Drug Access Through Pandemic-Specific Funding Agreements

When funding the development of medicines that are likely to be needed for a pandemic or epidemic response, entities could use their funding contracts to proactively anticipate scarcity and pricing problems. First, they could insert provisions requiring pharmaceutical companies benefitting from the funding to produce any subsequently developed drug in sufficient quantity to meet public health needs. The funding contract could provide an initial grace period to allow the company time to secure raw materials and scale up drug production. Alternatively, the contract may bind the parties to decide what the appropriate grace period might be 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 company would be required to cooperate with willing third-party manufacturers by licensing out the relevant patents and by transferring the know-how needed to manufacture the drug.

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 will have a sufficient incentive to help produce the needed drugs. By doing this, the company should end up with a higher rate of profits then 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.

Second, the funder could require the pharmaceutical company to promise that any resulting drug be priced fairly for low-income countries and be made available to them in a sufficient quantity. As discussed earlier, bidding wars have put needed drugs 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 drugs.[[31]](#footnote-31) It would be far more efficient for funders to secure low-cost drug access from pharmaceutical companies when the underlying R&D is funded and require companies to work with generic drug manufacturers in low-income countries to ensure an adequate supply.

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 the drug to thirty-five manufacturers for the benefit of ninety-five lower-income countries royalty-free during the pandemic, and with a five to ten percent royalty for middle-income countries once the pandemic ends.[[32]](#footnote-32) However, not all companies are willing to participate in such programs, and some refuse to license out their most lucrative medicines. For example, both Moderna and Pfizer have refused to license out their mRNA vaccine technology, highlighting the need for more formalized licensing obligations.[[33]](#footnote-33)

Anticipating the possibility of pandemic- and epidemic-driven drug shortages in funding contracts would offer several benefits. It would allow for drug production to be rapidly scaled up by decreasing transaction costs for willing third-party manufacturers to produce the drug. When compulsory licensing is used, the third-party producer must waste time replicating the drug and gaining regulatory approval. Under our proposal, third-party manufacturers would be able to obtain access to proprietary information about the optimal way to produce the drug. Furthermore, because the third-party drugs would be made under license from the original manufacturer, they may not have to go through full regulatory approval for the drugs that they produce. They would potentially qualify as follow-on drugs (generics or biosimilars) or may, in some cases, be eligible for other shortened review pathways, as was the case with emergency use authorizations for COVID-19 vaccines.[[34]](#footnote-34) 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.

Admittedly, there are 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.[[35]](#footnote-35) Nor will licensing help if drug manufacturing capacity does not exist. 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 drugs. Finally, securing these promises in the shadow of a pandemic could lead to funding entities needing to pay more to the recipients and would likely lead to larger pharmaceutical companies declining funding.

# IV. Dormant Licensing Provisions

A “dormant license” is a set of contractual provisions agreed to by the parties before the occurrence of a specified event.[[36]](#footnote-36) Although the provisions are not active at the time that they are agreed to, they come into force if the event occurs.[[37]](#footnote-37) We propose that funding entities 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 drugs or vaccines, or components thereof, that would be subject to the dormant license. This would be modeled after the list of emerging pathogens maintained by the World Health Organization (WHO) or a similar entity. 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.[[38]](#footnote-38) 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 in providing R&D funding relating emerging infectious diseases. Such work has been grossly underfunded and has failed to attract significant R&D funding even after an outbreak occurs.[[39]](#footnote-39) For this reason, the realm of emerging pathogens of concern as identified by the WHO—or by another public health-oriented institution[[40]](#footnote-40)— constitutes a good field for our proposal: these pathogens are expected to trigger significant outbreaks in years to come, yet have generally failed to attract widespread R&D attention from big pharmaceutical companies in the pre-outbreak period.

The funding entity may tailor the dormant licensing requirements based on its priorities. For example, a funding entity supporting vaccine development might require recipients to promise that a percentage of any vaccine doses produced be allocated to an international procurement facility 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 obligate recipients to sub-license the technology on a non-exclusive basis to alleviate shortages, or require them to sub-license to preferred or pre-determined 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 international or domestic public health institution. Although we believe that the WHO is well positioned serve in this function, the parties could alternatively choose a domestic institution or some other body to fulfil this role. The licensing terms would indicate whether the qualifying event is a formal declaration or merely a declaration of concern,[[41]](#footnote-41) 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 will 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 can be extended if the parties so desire, and if so, how.

The approach outlined here offers several advantages over current licensing approaches.[[42]](#footnote-42) 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, while designed to impose some sort of limitation on licensees, a dormant license will contribute towards 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.[[43]](#footnote-43) However, small to medium-size firms engaging in R&D may be willing to agree to a dormant license, particularly for underfunded areas of research.[[44]](#footnote-44) Likewise, newer firms that are dependent on external R&D funding are more likely to agree to such provisions.

# V. Conclusion

Past and current public health crises have shown that high-income countries have failed to proactively address pandemic- and epidemic-driven drug shortages. 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, given that there was no mechanism for compelling pharmaceutical companies to share vital drug-manufacturing know-how with third-party manufacturers.

Moving forward, governmental and non-governmental entities should take a proactive approach to anticipating such scarcity by using funding as leverage for obtaining promises regarding drug supply and pricing. We propose two levels on which this can operate. More narrowly, when entities fund pandemic- or epidemic-specific drug 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 health product 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 parties, in exchange for pre-determined compensation. More broadly, they could incorporate such promises into funding agreements 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.

1. Sapna Kumar holds the John Mixon Chair in Law at the University of Houston Law Center, and is the co-director of the Institute for Intellectual Property and Information Law. Ana Santos Rutschman is a Professor of Law at Villanova Charles Widger School of Law. [↑](#footnote-ref-1)
2. *See generally* 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). [↑](#footnote-ref-2)
3. *See* TRIPS, Art. 39. [↑](#footnote-ref-3)
4. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Art. 28(1). [↑](#footnote-ref-4)
5. *See* Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases,* 65 UCLA L. Rev. 1200, 1206 (2018). [↑](#footnote-ref-5)
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), https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/. [↑](#footnote-ref-6)
7. *See generally* Sam F. Halabi & Ana Santos Rutschman, *Viral Sovereignty, Vaccine Diplomacy, and Vaccine Nationalism: The Institutions of Global Vaccine Access*, \_\_ Emory Int’l L. Rev. \_\_ (2022). [↑](#footnote-ref-7)
8. *See* David Brown*, U.S. to Donate 10 Percent of Swine Flu Vaccine to WHO,* Wash. Post (Sept. 18, 2009); Halabi & Rutschman, *supra* note 7, at \_\_ (describing these phenomena during the 2009 swine flu pandemic); 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), https://www.statnews.com/2021/12/13/we-have-enough-covid-vaccines-for-most-of-world-but-rich-countries-stockpiling-more-than-they-need/; Jon Cohen & Kai Kupferschmidt, *Fairer Shares*, Science (May 26, 2021), https://www.science.org/content/article/rich-countries-cornered-covid-19-vaccine-doses-four-strategies-right-scandalous (describing these phenomena during COVID-19). [↑](#footnote-ref-8)
9. Brown, *supra* note 7. [↑](#footnote-ref-9)
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 (Sept. 30, 2021), https://www.nytimes.com/2021/08/20/business/economy/china-vaccine-us-covid-diplomacy.html; Peter Hotez, Preventing the Next Pandemic: Vaccine Diplomacy in a Time of Anti-Science (Johns Hopkins, 2021). [↑](#footnote-ref-10)
11. Brown, *supra* note 7. [↑](#footnote-ref-11)
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/. [↑](#footnote-ref-12)
13. *See e.g*. Nat’l Pub. Radio, *U.S. Won't Join WHO-Led Coronavirus Vaccine Effort, White House Says* (Sept. 2, 2020), https://www.npr.org/sections/coronavirus-live-updates/2020/09/02/908711419/u-s-wont-join-who-led-coronavirus-vaccine-effort-white-house-says. [↑](#footnote-ref-13)
14. *See* Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 Conn. L. Rev. 57, 93–94 (2022). [↑](#footnote-ref-14)
15. Nurtih Aizenman, *Why Low-income Countries are so Short on COVID-Vaccines*, NPR (Nov. 10, 2021), https://www.npr.org/sections/goatsandsoda/2021/11/10/1052078529/why-low-income-countries-are-so-short-on-covid-vaccines-hint-its-not-boosters. [↑](#footnote-ref-15)
16. *See e.g.* Olivia Goldhill, *‘Naively Ambitious’: How COVAX Failed on its Promise to Vaccinate the World*, Stat (Oct. 8, 2021), https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/ [↑](#footnote-ref-16)
17. Francesco Guarascio, *Poorer Nations Reject over 100 mln COVID-19 Vaccine Doses as Many Near Expiry*, Reuters (Jan. 14, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/more-than-100-million-covid-19-vaccines-rejected-by-poorer-nations-dec-unicef-2022-01-13/. [↑](#footnote-ref-17)
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), https://www.ft.com/content/5349389c-8313-41e0-9a67-58274e24a019; Reuters, *India Resumes Coronavirus Vaccine Exports to COVAX* (Nov. 26, 2021), https://www.reuters.com/world/india/indias-serum-institute-resumes-covishield-vaccine-exports-under-covax-facility-2021-11-26/. [↑](#footnote-ref-18)
19. *See* Olivia Goldhill, *‘Naively Ambitious’: How COVAX Failed on its Promise to Vaccinate the World*, STAT (Oct. 8, 2021);https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world. [↑](#footnote-ref-19)
20. *See* TRIPS, Art. 31. [↑](#footnote-ref-20)
21. *See* TRIPS, Art. 31(b). [↑](#footnote-ref-21)
22. *See* TRIPS, Art. 31*bis.* [↑](#footnote-ref-22)
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 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.” [↑](#footnote-ref-23)
24. *See* Kumar, *Compulsory Licensing of Patents During Pandemics*, *supra* note 14 at 99–100. [↑](#footnote-ref-24)
25. *Id.* [↑](#footnote-ref-25)
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* [hereinafter The Story of mRNA], STAT (Nov. 10, 2020), https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/. [↑](#footnote-ref-26)
27. *See also generally* Rutschman, *IP Preparedness*, *supra* note 5. [↑](#footnote-ref-27)
28. *See e.g.* Denise Grady, *Ebola Vaccine, Ready for Test, Sat on the Shelf*, NY Times (Oct. 23, 2014), https://www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html. [↑](#footnote-ref-28)
29. *See e.g*. Garde & Saltzman, *The Story of mRNA, supra* note 26. [↑](#footnote-ref-29)
30. *See* Rutschman, *IP Preparedness*, *supra* note 5, at 1260. [↑](#footnote-ref-30)
31. 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 Int’l (Feb. 15, 2022), https://www.oxfam.org/en/press-releases/donating-unwanted-vaccine-doses-should-not-be-part-already-stretched-aid-budgets. [↑](#footnote-ref-31)
32. *See* Rebecca Robbins, *35 Companies Sign on to Produce Generic Versions of Pfizer’s Covid Pill*, NY Times (March 17, 2022),https://www.nytimes.com/2022/03/17/business/35-companies-sign-on-to-produce-generic-versions-of-pfizers-covid-pill.html. A similar license was negotiated with Merck for molnupiravir. *Id.* [↑](#footnote-ref-32)
33. *See* Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, NY Times (Nov. 9, 2021), https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html. [↑](#footnote-ref-33)
34. 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 Admin., Abbreviated New Drug Application (ANDA) (2022), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (describing the review and approval regime for follow-on small-molecule drugs in the United States); U.S. Food & Drug Admin., Biosimilar Development, Review, and Approval, https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval (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 Admin., Emergency Use Authorization for Vaccines Explained (2020), https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained. [↑](#footnote-ref-34)
35. 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 (Sept. 21, 2020),https://www.businessinsider.com/covid-19-vaccine-experts-warn-glass-vials-planes-storage-shortage-2020-9 [↑](#footnote-ref-35)
36. *See* generally Rutschman, *IP Preparedness*, *supra* note 5. [↑](#footnote-ref-36)
37. *Id.* [↑](#footnote-ref-37)
38. *Cfr.* World Health Org., *An R&D Blueprint for Action to Prevent Pandemics* (2016) (listing priority pathogens, including coronaviruses). [↑](#footnote-ref-38)
39. *See* Rutschman, *IP Preparedness*, *supra* note 5, at 1207–1218; 1244–1252. [↑](#footnote-ref-39)
40. *See e.g.* Nat’l Ins’t Allergy & Infectious Diseases, NIAID Emerging Infectious Diseases/Pathogens (2018), https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens. [↑](#footnote-ref-40)
41. *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/ [↑](#footnote-ref-41)
42. *See generally*, Rutschman, *IP Preparedness*, *supra* note 5, at 1260. [↑](#footnote-ref-42)
43. Indeed, Pfizer refused to accept any R&D funding for its mRNA vaccine from the U.S. government, likely out of concern that the government might utilize march-in rights against any resulting patents. *See* Kumar, *Compulsory Licensing of Patents During Pandemics*, *supra* note 14 at 81. [↑](#footnote-ref-43)
44. For example, Moderna accepted significant government funds for the development of its mRNA vaccine. *See* Simi V. Siddalingaiah, Cong. Rsch. Serv., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 2 (2021), https://crsreports.congress.gov/product/pdf/IN/IN11560. [↑](#footnote-ref-44)