A Global Pandemic Remedy to Vaccine Nationalism

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The COVID-19 pandemic has had devastating effects on our social, economic, and political lives. While the race to develop vaccines has yielded results in record time, ensuring widespread, affordable access to these vaccines remains a major challenge. Vaccines are now in a race against new, more virulent variants of COVID-19, and unless everyone can be vaccinated soon, these new variants may lead to many more deaths. Current vaccine supplies fall far short of what is needed, however, and in what has become known as "vaccine nationalism," wealthier countries have poured billions of dollars into advance purchasing agreements that guarantee themselves preferential access. The distribution inequities resulting from this nationalistic response undermines the interest all countries have in speedy and universal inoculation.

At the heart of the problem is the fact that the pharmaceutical industry has taken a market-driven rather than a public-health driven approach to vaccine development and distribution. A market-driven approach makes sense to some extent, as the pharmaceutical companies must have some means of recovering their investments in the risky research and development required to create new vaccines. Patent protections and other exclusive rights are widely regarded as necessary incentives for investment in pharmaceutical innovation, as they allow supracompetitive pricing. In times of global public health crises, however, the ordinary principles of exclusivity must give way to the pressing need for immediate, affordable, and widely available access. We desperately need other manufacturers to be able to help boost vaccine supplies and lower vaccine prices.

Recognizing the need for flexibility in times of emergency and building upon knowledge gained from existing international and domestic compulsory licensing laws, we propose a global, centralized scheme to provide access to vaccines during pandemics. In many ways our proposal mirrors some of the World Health Organization's (WHO) COVID-19 vaccine initia-

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tives but consolidates and expands them into a much more efficacious form. Under the proposed model, the WHO's declaration of a pandemic would trigger a global procurement and distribution scheme for vaccines. The proposed scheme would be mandatory and would require that all countries operate as one buyer vis-à-vis vaccine developers. A single buyer scheme provides buyers with significant economic leverage, allowing them not only to negotiate vaccine pricing and distribution from a better bargaining position but also to discourage defection. This procurement scheme would be supported by the power to issue global compulsory licenses of patent, trade secret, regulatory data, and other assets necessary for vaccine production to become effective if and when consensual negotiations with vaccine developers fail. The success of such a global procurement initiative, especially at times of emergency where each country is tempted to defect and take a nationalistic approach, depends on mandatory global participation and a firm commitment to the scheme.

Introduction

The deadly COVID-19 pandemic has had devastating medical, social, and economic effects worldwide. The public's interest in life-saving treatments and vaccines for this infectious disease is clearly both pressing and universal.[1] The impulse toward what journalists term "vaccine nationalism,"[2] however, stands in the way of combatting the common COVID-19 enemy. Before the US Food and Drug Administration (FDA) approved the first vaccines for use in late 2020, developed countries had already bought up billions of doses for their own use.[3] In an effort to secure a sufficient supply of vaccines for their own populations, wealthier countries have poured billions of dollars into bids for preferential access to emerging vaccines. Bidding wars have erupted, triggering a procurement race.[4] The EU has even begun monitoring exports of vaccines on suspicions that AstraZeneca and other pharmaceutical companies are defaulting on their supply contracts with the EU in order to sell their vaccines at higher prices elsewhere.[5] Inevitably, the nationalist scramble to buy up vaccine supplies

1. *Treatments and a Vaccine for COVID-19: The Need for Coordinating Policies on R&D, Manufacturing and Access*, Organisation for Economic Co-Operation & Development [OECD] 1, 20–21 (May 29, 2020), https://read.oecd-ilibrary.org/view/?ref=133_133372-v717pcul4c&title=treatments-and-a-vaccine-for-COVID-19-the-need-for-coordinating-policies-on-RD-manufacturing-and-access&_ga=2.220290075.2035222667.1631662433-1816998729.1631048711 [https://perma.cc/LJ7B-UQCV].

2. Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 Wash. U.J.L. & Pol'y 167, 183 (2021) [hereinafter Rutschman, *The COVID-19 Vaccine Race*].

3. Jenny Lei Ravelo, *Is COVAX Part of the Problem or the Solution?*, Devex (Mar. 21, 2021), https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334 [https://perma.cc/FZT6-X6KU].

4. Lucy Hooker & Daniele Palumbo, *COVID Vaccines: Will Drug Companies Make Bumper Profits?*, BBC (Dec. 18, 2020), https://www.bbc.com/news/business-55170756 [https://perma.cc/TLQ3-TWAH]; William Wan & Carolyn Y. Johnson, *The Biggest Challenge for a Coronavirus Vaccine Could Be Getting Countries to Share*, Wash. Post (June 4, 2020), https://www.washingtonpost.com/health/2020/06/04/biggest-challenge-coronavirus-vaccine-could-be-getting-countries-share/ [https://perma.cc/F9QF-4N4P]; Ezequiel Carman, *An Alternative to Shortages and Bidding Wars for a COVID-19 Vaccine*, Global Americans (Dec. 10, 2020), https://theglobalamericans.org/2020/12/an-alternative-to-shortages-and-bidding-wars-for-a-COVID-19-vaccine [https://perma.cc/9EUD-YZ9V].

5. Erin Cunningham & Loveday Morris, *E.U. Threatens Drug Companies with Legal Action If It Doesn't Get Its Vaccines*, Wash. Post (Jan. 26, 2021), https://www.washingtonpost.com/world/europe/european-union-astrazeneca-pfizer-vaccine-exports/2021/01/26/2840444e-5fc7-11eb-a177-7765f29a9524_story.html [https://perma.cc/Z84V-DBG6]; Angela Dewan, *A Fight Between the EU and UK Reveals the Ugly Truth About Vaccine Nationalism*, CNN (Jan. 30, 2021), https://edition.cnn.com/2021/01/30/europe/uk-eu-astrazeneca-vaccine-nationalism-gbr-intl/index.html [https://perma.cc/Q6GD-HJW8]; Jonathan Stearns, Alberto Nardelli & Nikos Chrysoloras, *Faced With Vaccine Shortages, EU Set to Impose Export Controls*, Bloomberg (Jan. 28,

has left less developed countries with weaker economies far behind. Competition for scarce, life-saving vaccines has transformed a public health crisis into an urgent political and legal dilemma.

This nationalistic response to the COVID-19 pandemic is incredibly short-sighted. We are seeing more and more variants of the SARS-CoV-2 virus that causes COVID-19, and many of these variants are both more infectious and more deadly. The longer the virus continues to infect new hosts, the more these variants will emerge and potentially become more virulent. As the novel coronavirus itself has demonstrated, the world is now so interconnected that attempting to stop viral spread at national borders is impossible.[6] It is, therefore, imperative that the continued expansion of the SARS-CoV-2 virus be stopped worldwide.[7] Yet, distribution inequities and market failures undermine the interest of all countries in speedy, universal inoculation. While the world's richest countries expect to have their populations vaccinated by the summer of 2021, developing countries are not projected to reach that goal until early 2022 or later, leaving them to become "potential breeding grounds for variants" impervious to these vaccines.[8] To solve this problem, we need not only the capacity to produce vaccines at affordable prices, but also to do so very quickly and globally. While the race to develop vaccines has yielded results in record time, ensuring widespread access to affordable vaccines remains a major challenge. Cooperation among the world's nations is key.

Nevertheless, there has been no unified global effort to ensure equitable and large-scale access to COVID-19 vaccines. Although pharmaceutical manufacturers such as the Bangladeshi firm Incepta could help boost vaccine production, they sit idle.[9] The reasons why are complex but boil down to the market-driven approach to pharmaceuticals and shortages and high prices to which it leads.[10] We, therefore, offer a groundbreaking scheme for global funding, technology transfer, and procurement that will be both exclusive and mandatory for all countries during infectious pandemics.

2021), https://www.bloomberg.com/news/articles/2021-01-28/europe-opens-door-to-vaccine-export-ban-risking-global-backlash [https://perma.cc/6QAN-TS3K].

6. Carman, *supra* note 4.

7. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 184; *Why Is No One Safe Until Everyone Is Safe in a Pandemic?*, GAVI (Sept. 14, 2020), https://www.gavi.org/vaccineswork/why-no-one-safe-until-everyone-safe-during-pandemic [https://perma.cc/4N4V-7QKL].

8. Lynsey Chutel & Marc Santora, *As Virus Variants Spread, 'No One Is Safe Until Everyone Is Safe'*, N.Y. TIMES (Jan. 21, 2021), https://www.nytimes.com/2021/01/31/world/africa/coronavirus-south-africa-variant.html [https://perma.cc/5Q3C-KYWP].

9. Christopher Rowland, et al., *Drug Companies Defend Vaccine Monopolies in Face of Global Outcry*, WASH. POST (Mar. 20, 2021), https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/ [https://perma.cc/3QSJ-WWP5].

10. Anna Marriot & Alex Maitland, *The Great Vaccine Robbery*, THE PEOPLE'S VACCINE ALLIANCE 1, 12 (2021), https://reliefweb.int/sites/reliefweb.int/files/resources/The%20Great%20Vaccine%20Robbery%20Policy%20Brief%20final.pdf [https://perma.cc/UE7E-9577].

First, and most importantly, this centralized global plan will allow compulsory licensing of not only any patents but also any trade secrets and rights of reference to safety and efficacy data necessary to allow the multiple manufacturing sites to meet worldwide demand. The most commonly cited obstacles are intellectual property rights and other rights of exclusivity over not only the vaccines themselves but also over the specialized equipment and raw materials needed for their production.[11] Rights of exclusivity thus affect both vaccine prices and ability of others to alleviate the vaccine shortage by contributing to their manufacture. Compulsory licensing schemes, including those contemplated by the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), are an oft-cited tool for mitigating such access concerns in the context of emergencies such as the current pandemic.

Second, the plan would provide funding and other support for retrofitting and operating facilities for manufacturing as well. Patents and other exclusivities aside, manufacturers lack not only sufficient facilities but also often the expertise and specially trained workforce needed to produce complex biologics such as vaccines. A centralized structure to coordinate funding for facilities modifications, training, and sharing of tacit knowledge would help build an infrastructure that can produce enough vaccines to meet the world's needs.

Third, our proposal features a centrally administered, differentiated pricing scheme and equitable distribution mechanism. A differentiated pricing scheme affords countries across the economic and development spectrum the ability to access vaccine supplies by spreading the cost across all nations, effectively cross-subsidizing vaccine procurement in a way that guarantees vaccine developers appropriate enough of the social value they have created and thus earn enough return on their investments to incentivize future vaccine development.

Indeed, in many ways, our proposal expands and, more importantly, strengthens and solidifies the WHO's initiatives into a permanent, government-supported institution. The WHO has launched a number of initiatives such as their C-TAP patent pool and the COVID-19 Vaccine Global Access Facility (COVAX) procurement initiative.[12] Unlike the WHO's rather diffuse efforts, however, an essential feature of our proposed scheme is its mandatory nature. It is premised on the understanding that cooperation of all countries is required and that opting out is impossible and can be sanctioned.[13] We propose incorporating this regime as an addendum to the TRIPS Agreement, affording it the benefit of effective enforcement measures under the World Trade Organization's (WTO) framework. The proposal also introduces a more powerful enforcement mechanism that would

11. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 177–78.

12. Grace Ren, *Progress On COVID-19 Technology Pool Inches Along as Sister Initiative to Pool Vaccine Procurement Accelerates*, HEALTH POL'Y WATCH (Sept. 25, 2020), https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/ [https://perma.cc/C7JM-AD4L].

13. *See* Part II, *infra*, discussing the normative framework.

leverage contracts with vaccine developers and manufacturers to make it difficult for nations to procure supplies outside of our centralized, global scheme. These requirements are necessary to address the market failure that results from nationalistic domestic approaches.

While the current COVID-19 crisis may have abated before our proposal becomes operative, there is little doubt that future pandemics await. Our proposal offers a solution to the vaccine pricing and distribution issues that are sure to arise.

The Article proceeds as follows. Part I provides an explanation of how vaccine nationalism resulted from both the shortage of vaccine supplies and the often prohibitive cost of providing vaccines. These factors in turn stem from the unique nature of vaccine development, the economic incentives involved, and its dependence on patent protections, as well as the equally important role of trade secrecy, tacit knowledge, testing data, and raw materials in manufacturing and distribution of vaccines. In Part II we present our novel global compulsory licensing and procurement scheme for pandemics and its unique features: its mandatory, global nature; its aggregated pricing and royalty structure for not only patents but also trade secrecy, data, and tacit knowledge; and its inherent cross-subsidy system for manufacturing and distribution. We also explain why the TRIPS Agreement provides the right platform for the proposed centralized scheme, its likely impact, and how the scheme is designed to abide by principles of economic and distributive justice. In Part III, we compare our model to other models offered to cope with the COVID-19 pandemic, such as government incentives, voluntary licensing schemes, and other changes to patent law and policy. We discuss the advantages and drawbacks of each of these alternatives and explain why our proposed model offers a more coherent, broad, and consistent solution for providing equitable, worldwide access to vaccines while preserving the pharmaceutical companies' development incentives. Part III also addresses possible challenges to our model.

I. Vaccine Nationalism

As modalities for preventing communicable diseases, vaccines are usually given to the entire susceptible population. Worldwide mass vaccination can help control pandemics and prevent their continued spread. Indeed, mass vaccination campaigns have largely eliminated once-deadly diseases such as measles, hepatitis B, and polio.[14] Mass vaccination during pandemics can not only save lives but also ameliorate the economic instability and other social costs associated with pandemics.[15] And because pandemics can spread so quickly, particularly in the highly mobile modern world, vaccinating the world's entire population is essen-

14. Vaccine Timeline, IMMUNIZATION ACTION COAL. (Aug. 27, 2021), https://www.immunize.org/timeline/ [https://perma.cc/47FX-XVPE].

15. Charlene C. Rodrigues & Stanley A. Plotkin, *Impact of Vaccines; Health, Economic and Social Perspectives*, 11 FRONTIERS IN MICROBIOLOGY 1, 8–11 (2020).

tial. The speed with which COVID-19 has spread around the world demonstrates that in the 21st century pandemics must be addressed globally. Moreover, the rapid emergence of more contagious and deadly variants of the coronavirus means that immediate and simultaneous global vaccination is critical. It is thus in every country's best interest to enable universal vaccination as quickly as possible—"no one is safe until everyone is safe."[16]

The need for equitable global access to vaccines calls into question the traditional incentive scheme for pharmaceutical companies to develop new vaccines, however. Despite developing COVID-19 vaccines in record time, actual production has been achingly slow. This has led to vaccine shortages, which in turn have spurred wealthy countries to buy up supplies before they are even available.[17] A 2020 report by the Organisation for Economic Co-operation and Development (OECD) noted two major obstacles to equitable global access: first, ensuring rapid mass production of the vaccines; and second, lack of international agreement on how to address intellectual property rights (IPRs) and other limits on mass production so as to "avoid bidding wars between countries and high prices, which could prevent the most vulnerable from having access."[18] The report further stressed that public funding "should be tied to conditions for accessibility and affordability" as well as need.[19]

No binding international agreement for allocating public funding has taken form, however, and an international procurement race has taken its place. To guarantee themselves supplies of vaccines sufficient for their own peoples, the developed world has negotiated a number of advance purchasing agreements with vaccine developers. These efforts at securing preferential access have exacerbated the scarcity of vaccines, at least in the near term, and as a result, vaccine prices have soared. This further disenfranchises less wealthy countries, which is the very definition of vaccine nationalism.[20]

As the OECD report suggests, only a centrally organized, institutionally structured, and worldwide system for managing the global flow of vaccines during pandemics can counter the market effects of unrestrained vaccine nationalism and fully address the challenges we face in the current COVID-19 global health crisis.[21] The question is how best to achieve this end: continued use of a free-market pricing scheme or a scheme tailored

16. GAVI, *supra* note 7.
17. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 183–84.
18. OECD, *supra* note 1, at 2.
19. *Id.*
20. *See* Raf Casret, *Delay in Pfizer Vaccine Shipments Frustrate Europe, Canada*, CP24 (Jan. 20, 2021), https://www.cp24.com/world/delay-in-pfizer-vaccine-shipments-frustrate-europe-canada-1.5275035 [https://perma.cc/VM5J-49X7]; *Rich Countries Will Get Access to Coronavirus Vaccines Earlier Than Others*, EIU UPDATE (Dec. 18, 2020), https://www.eiu.com/n/rich-countries-will-get-access-to-coronavirus-vaccines-earlier-than-others/ [https://perma.cc/R7NB-F2PK]. For updated data concerning vaccination rates around the globe, see *Coronavirus (COVID-19) Vaccinations*, OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations [https://perma.cc/EU6S-YZ96].
21. OECD, *supra* note 1, at 20–21.

exactly for pandemics? Clearly the latter approach should prevail, but the complex nature of vaccine development means that tailoring is not a simple thing.

A. Vaccine Development

Vaccines are just one of many public health and health care concerns that pandemics raise. Treating novel infectious diseases requires development of diagnostic tests, treatment protocols, screening and prevention protocols, medications, and hospital beds and equipment.[22] This Article focuses only on vaccines, however, as they raise particularly complex issues, not only in terms of patents and other exclusivities but also in terms of research and development (R&D), returns on investment, manufacturing, reproduction by others, and so on.

Like pharmaceutical development, vaccine development is quite risky, with only 7% of candidates likely to be worth testing in clinical trials and only 15–20% of those proving to be safe and effective enough for regulatory marketing approval.[23] Unlike the small-molecule pharmaceuticals that have been the focus of R&D for many decades, moreover, vaccines fall within the new generation of complex biologic agents, which typically require the use of living organisms such as animal, bacterial, or yeast cell cultures.[24] Vaccines and other biologics are, therefore, poorly understood, more difficult to develop, harder to store, and more onerous to administer as compared to small-molecule drugs. Vaccine development is inherently risky, as most early vaccine candidates fail.[25] Like most biologics, vaccines involve very large, complex molecules comprising component parts whose interactions are often unpredictable. The human immune system itself likewise is often unpredictable in its responses to various stimuli and difficult to model.[26] As a result, development of new vaccines is believed to cost an average of $600 million to $800 million in R&D alone,[27] and typically requires twelve to fourteen years to complete.[28]

The fact that developed countries have hedged their bets by arranging advance purchase agreements with a wide variety of pharmaceutical companies, before their vaccines have even been developed, much less approved for marketing, shows how difficult and unpredictable vaccine development can be. Those vaccines that are successful are likely to proceed through development at different rates, moreover, with some becoming available

22. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 172.

23. *See* Nick Jackson, *Why We Need a "Portfolio Approach" to COVID-19 Vaccine Development*, GAVI (Oct. 20, 2020), https://www.gavi.org/vaccineswork/why-we-need-portfolio-approach-COVID-19-vaccine-development [https://perma.cc/Z4B6-3QRY].

24. Aurelia Nguyen & Nina Schwalbe, *Apples and Oranges? Can Second Generation Vaccines Become as Low Cost as Generic Medicines?*, 37 VACCINE 2910, 2911 (2019).

25. R. Gordon Douglas & Vijay B. Samant, *The Vaccine Industry*, *in* PLOTKIN'S VACCINES 41, 41 (7th ed., 2018).

26. *Id.*

27. *Id.* at 43.

28. Tony D'Amore & Yan-ping Yang, *Advances and Challenges in Vaccine Development and Manufacture*, 17 BIOPROCESS INT'L 44, 46 (2019).

more quickly than others, while at the same time varying in efficacy, ease of distribution and use, and so on. By pursuing a "portfolio approach" that includes multiple vaccine candidates, wealthy nations mitigate the risk of failure, delay, and issues of supply and distribution.

Moreover, vaccines are generally viewed as less profitable than therapeutic drugs,[29] and the market for vaccines suffers from underinvestment.[30] This is in part because, while small-molecule and biologic therapeutical drugs can often be used for a variety of indications and on an ongoing basis, especially for chronic conditions, vaccines are designed for very specific diseases and are unlikely to be a recurring need.[31] The market for vaccines is thus comparatively small and less attractive for investment. This phenomenon has been termed the "vaccine development paradox" because the undervalued market for vaccines does not reflect their public health significance.[32]

True, governments and, to a lesser extent, charitable organizations typically fund large part of vaccine R&D because of the significant social value they provide, as well as the national security issues raised by the threat of biologic warfare.[33] Governments also buy the largest part of vaccine supplies for the public.[34] Both the lack of profitability and dependence on government and charitable support, however, show that market forces are insufficient to drive vaccine development and distribution.

Indeed, it takes crises like COVID-19 to alter pharmaceutical R&D priorities, with over 150 vaccine candidates in development in just months.[35] Research on potential COVID-19 vaccines has also been quite unusual in the degree of collaboration between erstwhile competitors and the speed with which those collaborative efforts arose. The role of market forces in these efforts must thus be questioned.

B. Patents

Against this background on the economics of vaccine development is the role of the patent system. Because pharmaceutical development is so risky and expensive, pharmaceutical companies rely on patent protections to maximize their abilities to recoup their investments in R&D. Patents confer exclusive rights to make, use, offer for sale, sell, and import the

29. Lisa Larrimore Ouellette & Q. Claire Xue, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCES 1, 5 (2020); Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2.

30. Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs*, J.L. & BIOSCIENCES 1, 8 (2020); Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. 170, 172, 176 [hereinafter Rutschman, *The Intellectual Property of Vaccines*].

31. Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 756 (2019).

32. *Id.* at 752.

33. Douglas & Samant, *supra* note 25, at 46.

34. *Id.* at 49; Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 762–63.

35. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 171.

product, as well as the right to license, assign, or transfer all or part of these rights.[36] The patent system is thus designed to incentivize risky investments in innovation by providing the inventor with a set of exclusive rights for a limited time, enabling her to recoup her investment and earn a profit while benefitting society as a whole.[37] Indeed, pharmaceuticals are thought to be one industry in which patents actually work, although this analysis relates mainly to small-molecule drugs.

Newly developed vaccines are generally eligible for patent protection, and to date, all pharmaceutical companies have applied for patents on their vaccines. Patenting pharmaceutical products is a relatively new phenomenon that emerged in the 1970s and 80s, when the pharmaceutical industry grew significantly and started relying heavily on patent protection. The pharmaceutical industry in the highly developed "Northern Countries" began to exert political pressure on the frequently less developed "Southern Countries" to begin allowing pharmaceutical patents where pharmaceuticals had previously been ineligible.[38] This major change contributed to the 1995 adoption of the TRIPS Agreement under the auspices of the WTO. In fact, one of the major reasons for integrating intellectual property issues into the WTO trade regime through the TRIPS Agreement was the Northern Countries' wish to expand pharmaceutical patents to Southern Countries.[39] The TRIPS Agreement established a gradual process, which concluded in 2005, requiring all member countries to adopt certain standards of protection for intellectual property, including patent protection for pharmaceuticals.[40]

The TRIPS Agreement thus now requires that signatories make patents available for inventions in any field of technology without discrimination as to the place of invention or production, provided the inventions meet the requirements of novelty, non-obviousness or inventive step, and utility or industrial application, among other criteria.[41] The term of protection available under the TRIPS Agreement is a minimum of twenty years from the filing date.[42] One allowed exception to patent eligibility is for inventions that are contrary to *ordre public* or morality; this explicitly includes inventions that are dangerous to human, animal, or plant life or health or that are seriously prejudicial to the environment.[43] The second exception is that member states may exclude from patentability diagnostic, therapeu-

36. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 28, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS].

37. For a general discussion, see WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 294–310 (Harvard Univ. Press, 2009); *see also* John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37, 52 (2004).

38. Kenneth C. Shadlen et al., *Patents, Trade and Medicines: Past, Present and Future*, 27 REV. INT'L POL. ECON., 75, 77–80 (2020) (reviewing the history of pharmaceutical patents).

39. *Id.* at 80.

40. *Id.*

41. TRIPS, *supra* note 36, art. 27.1.

42. *Id.*, art. 33.

43. *Id.*, art. 27.2.

tic, and surgical methods for the treatment of humans or animals.[44] The third is that member states may exclude plants and animals other than micro-organisms, as well as biological processes for the production of plants or animals other than non-biological and microbiological processes.[45] Only the *ordre public* exception would apply to vaccines, but no country to date has used this exception to bar patents on vaccines or other pharmaceuticals. In fact, vaccine patenting has increased in countries such as India, China, and Brazil.[46]

Patents on biologics such as vaccines often cover only parts of the overall invention, however. Gardasil, the vaccine for the human papilloma virus that can cause cervical and other cancers, is covered by at least eighty patents.[47] New vaccines, particularly pioneering vaccines like the mRNA vaccines invented by Pfizer and Moderna, are covered by a large number of patents.[48] A sizeable portion of vaccine-related patents also cover the complicated manufacturing processes and equipment necessary for production.[49] To the extent that those patent rights are held by separate entities, they can lead to anticommons or other hold-up problems.[50] For example, Moderna is in the midst of a dispute over Arbutus' patents on the lipid nanoparticles that Moderna needs for its mRNA vaccine.[51] These kinds of disputes can delay or even derail vaccine rollout.

That being said, for most existing vaccines, patent exclusivities are not necessarily the most critical barrier. First, diffuse ownership of patent rights in biologics makes it less likely for any one patent owner to acquire significant market power. Just as patent protections are insufficient to inspire investment in vaccine development,[52] limiting patent protections would be insufficient to guarantee access to vaccines. A number of other barriers serve to keep follow-on vaccines off of the market, including manufacturing esoterica, the difficulties of reproducing vaccines and other biologics, and the need for safety and efficacy testing.

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44. *Id.*, art. 27.3(a).

45. *Id.*, art. 27.3(b).

46. *Innovation Perseveres: International Patent Filings Via WIPO Continued to Grow in 2020 Despite COVID-19 Pandemic*, World Intellectual Property Organization [WIPO] (Mar. 2, 2021), https://www.wipo.int/pressroom/en/articles/2021/article_0002.html [https://perma.cc/3TDW-P8SX].

47. Mario Songane & Volker Grossmann, *The Patent Buyout Price for Human Papilloma Virus (HPV) Vaccine and the Ratio of R&D Costs to the Patent Value*, PLOS One (Jan. 11, 2021), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0244722 [https://perma.cc/XZ3Y-3K8D].

48. Jorge L. Contreras, *Patent Pledges*, 47 Ariz. St. L.J. 543 (2015).

49. Nguyen & Schwalbe, *supra* note 24.

50. Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 760–61.

51. Daniel Shores, *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?*, IPWATCHDOG (Nov. 11, 2020), https://www.ipwatchdog.com/2020/11/11/breaking-modernas-COVID-19-patent-pledge/id=127224/ [https://perma.cc/3LKH-LL69].

52. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2.

C. Manufacturing and Regulatory Approval

As noted in the previous section, difficulties in manufacturing adequate supplies are also a significant determinant of vaccine availability, particularly for an acute need such as a pandemic. In point of fact, Pfizer, Moderna, Johnson & Johnson, and AstraZeneca have all reported concerns about meeting their promised deliveries on time due to difficulties in scaling up manufacturing.[53] Estimates suggest that, at the time the COVID vaccines were being developed, the world had only twenty-five percent of the manufacturing capacity necessary to vaccinate the world's population.[54]

These manufacturing related shortages stem in large part from the simple fact that investment in vaccine development usually begins only after a particular disease strain has been identified as a significant threat.[55] The emergence of dangerous and fast-spreading new infectious diseases is relatively infrequent, however, so pandemic vaccine preparedness in particular tends not to be a priority. By the point a pandemic such as COVID-19 does occur, it is in many ways too late because the necessary infrastructure for rapid development, testing, manufacturing, and distribution is not in place, setting the stage for vaccine nationalism.[56]

The lack of infrastructure also stems from its sheer cost as well. As noted above, vaccines are a type of biologic agent, and biologics are expensive to manufacture, ship, and administer.[57] Manufacturing facilities cost from $50 million to $500 million to construct, depending on the complexity of the vaccine and the output required.[58] Ongoing maintenance of facilities that meet the regulatory standards for sterility and good manufacturing practices mean that operation costs are high as well. Production of some types of vaccines are not scalable, moreover, so that there are no economies of scale to lower the per-dose cost.[59]

In the case of small-molecule drugs, patient costs are reduced by allowing generic manufacturers to make and sell copies of drugs once any exclusivities on them have expired. Vaccines and other biologics cannot be copied so easily, however. Indeed, the U.S. statutory scheme for biologics (the Biologics Price Competition and Innovation Act, or BPCIA) explicitly

53. Madeleine Hoecklin, *EU Protests AstraZeneca Vaccine Delays– Could Block UK-Bound Exports*, HEALTH POL'Y WATCH (Jan. 28, 2021), https://healthpolicy-watch.news/81767-2/ [https://perma.cc/D2F7-V5A4]; Matthew Perrone & Lauran Neergaard, *Drug Executives: Big Jump in COVID Vaccine Supply Is Coming Soon*, ABC 27 NEWS (Feb. 23, 2021), https://www.abc27.com/news/health/coronavirus/vaccination-frustration/drug-executives-big-jump-in-covid-vaccine-supply-is-coming-soon/ [https://perma.cc/725N-6F5J].

54. Jennifer Brant, Mark Schultz & Peter Brown, *Unprecedented: The Rapid Innovation Response to COVID-19 and the Role of IP* (Innovation Council, Geneva, Switzerland, 2021) (forthcoming).

55. Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1200 (2018).

56. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2.

57. Rutschman, *The Intellectual Property of Vaccines*, *supra* note 30.

58. Nguyen & Schwalbe, *supra* note 24.

59. Douglas & Samant, *supra* note 25.

contemplates that exact copies of biologic therapeutics will be rare and instead allows "biosimilars" to be approved as substitutes of a sort for a reference biologic.[60] For the same reasons, proving that a biosimilar is in fact similar enough to its reference biologic to substitute for it requires a significant amount of testing.[61] Vaccines are no different, requiring extensive immune studies to prove sufficient similarity.[62] Given the investments necessary to reproduce, test, and produce another's vaccine, the risks of failing to prove similarity are enough to deter many a would-be manufacturer.[63]

These multiple obstacles to vaccine reproduction and approval often act as much more significant barriers to market entry by new manufacturers than patents do.[64] Not surprisingly, vaccine prices tend not to change much over time.[65] Even "generic" vaccines generally yield less in cost savings than generic small-molecule drugs do.[66]

That being said, several commentators argue that available vaccine manufacturing capacity exists but that vaccine developers resist sharing intellectual property rights, expertise, and other manufacturing assets that stand in the way of transferring the technology necessary to expand vaccine production.[67] Trade secrets and tacit knowledge about the highly complex process of producing vaccines and other biologics can create natural exclusivities that are daunting to overcome.[68] For example, other manufacturers need to be able to refer to the clinical trials data demonstrating that the vaccine is safe and effective. The reference vaccine manufacturer generally holds this data as a trade secret.[69] Regulatory agencies in many countries such as the United States and those in the EU nonetheless allow follow-on manufacturers rights of reference to the data (although not access to the data itself), but only when that data has already been submitted to the respective agency by the reference drug manufacturer and only

60. *Biologics & Biosimilars*, PhRMA, https://www.phrma.org/policy-issues/Research-Development/Biologics-Biosimilars [https://perma.cc/9G3A-6PY3].

61. Jacob Bell, *Why Be a Vaccine Company?*, BioPharma Dive (June 25, 2018), https://www.biopharmadive.com/news/spotlight-vaccine-manufacturing-business-development-decisions/526150/ [https://perma.cc/37DT-VYCT].

62. Nguyen & Schwalbe, *supra* note 24.

63. Douglas & Samant, *supra* note 265.

64. *Id.*; Nguyen & Schwalbe, *supra* note 24.

65. Douglas & Samant, *supra* note 25.

66. Nguyen & Schwalbe, *supra* note 24.

67. *See* Ravelo, *supra* note 3.

68. *See generally* Michael R. Darby & Lynne G. Zucker, *Grilichesian Breakthroughs: Inventions of Methods of Inventing and Firm Entry in Nanotechnology* 19 (Nat'l Bureau of Econ. Research, Working Paper No. 9825, 2003), http://www.nber.org/papers/w9825 [https://perma.cc/6MC7-AEPZ]; Frank T. Rothaermel & Marie Thursby, *Incubator Firm Failure or Graduation? The Role of University Linkages*, 34 Res. Pol'y 833 (2005).

69. Nguyen & Schwalbe, *supra* note 24. Article 39(3) to the TRIPS Agreement protects undisclosed data provided to the authorities in the course of obtaining use permits, yet when a compulsory license is issued, in some countries, it includes such information while, in others, it does not. *See* Ellen F. M. 't Hoen, Pascale Boulet & Brook K. Baker, *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 J. Pharm Pol'y Prac., 19, 20 (2017).

after a multi-year period of delay under various regulatory exclusivities.[70]

For another thing, tacit knowledge encompasses the kinds of skills and knowledge that are difficult to communicate without extensive personal practice, experience, and interaction and is common in less predictable fields like biotechnology.[71] This kind of tacit knowledge and expertise is a "critical variable" in vaccine manufacturing, which, unlike small-molecule drug manufacturing, is difficult to automate fully because it is very labor-intensive and requires a highly skilled work force.[72] As a result, the capacity for successful vaccine reproduction may depend on access to personnel with the requisite specialized skills.

Likewise, reproduction of some types of vaccines may require access to specialized manufacturing equipment, cell cultures, and raw materials.[73] A unique type of lipid nanoparticle (specifically, ionizable cationic lipid) is critical for delivery and protection of the mRNA in Pfizer's and Moderna's vaccines, for example.[74] These lipid nanoparticles were not widely used before COVID-19 hit and are incredibly laborious to make. And while they are also covered by patents or other exclusivities, the main factor holding up production of these materials is the fact that very few facilities are currently equipped to manufacture ionizable cationic lipids and other requisite materials in large enough quantities. Like vaccine production facilities, it is difficult for lipid nanoparticle and other raw material facilities to scale up their operations, and retrofitting other facilities to begin production could take months because of the need for specialized manufacturing equipment (which themselves are often covered by patents) and building adaptations.[75] Other shortages involve securing unusually large numbers of vials in which to store vaccines and syringes and needles with which to administer them. Distribution issues also contribute to the problems of both availability and price. The cost of transport, shipping economies of scale, and other costs may increase the per-dose price patients must pay as well.[76]

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70. Hoen et al., *supra* note 69.

71. Darby & Zucker, *supra* note 68, at 19; Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240, 245 (2001); Rothaermel & Thursby, *supra* note 68, at 833, 846–47.

72. Nguyen & Schwalbe, *supra* note 24.

73. Contreras, *supra* note 48.

74. Ryan Cross, *Without These Lipid Shells, There Would Be No mRNA Vaccines for COVID-19*, C&EN (Mar. 6, 2021), https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8 [https://perma.cc/5F6U-UL9N].

75. Rebecca Heilweil, *The Key Ingredient That Could Hold Back Vaccine Manufacturing*, VOX: RECODE (Mar. 3, 2021), https://www.vox.com/22311268/covid-vaccine-shortage-moderna-pfizer-lipid-nanoparticles [https://perma.cc/52RT-TLNZ]; Charles Schmidt, *New COVID Vaccines Need Absurd Amounts of Material and Labor*, SCI. AM. (Jan. 24, 2021), https://www.scientificamerican.com/article/new-covid-vaccines-need-absurd-amounts-of-material-and-labor1/ [https://perma.cc/BK7G-72FY].

76. Esther Nakkazi, *Uganda Defends Price Paid for AstraZeneca COVID19 Vaccine; New Study Suggests Vaccine Could Cut Transmission by Two-Thirds*, HEALTH POL'Y WATCH (Mar. 2, 2021), https://healthpolicy-watch.news/uganda-defends-astrazeneca-price-says-its-not-higher-than-other-countries/ [https://perma.cc/T6FX-7Q4G].

II. An Innovative Model for a Global, Centralized Vaccine Regime for Pandemics

The science behind pandemic response efforts reveals two essential features of successful vaccine campaigns: they must cover the largest possible portion of the world's population, and they must be conducted in all regions simultaneously, with minimal time gaps.[77] These two principles should thus serve as the backbone of any legal framework designed to regulate the global COVID-19 inoculation effort, which requires a systemic, well-organized, and well-administered global scheme. All of these supply issues described in the previous Part, however, lead to COVID-19 vaccine shortages and concomitant vaccine nationalism.

This Article therefore offers a unique scheme to contend with vaccine nationalism during pandemics. The basic economic rationale for the proposed scheme acknowledges that the current patchwork of nationalistic efforts at vaccine procurement, undertaken independently by each nation, fails to create the economic incentives necessary to achieve immediate, universal inoculation of the world's population. Only a joint and globally coordinated operation can achieve efficient and equitable vaccine access. To that end, the proposed model is based on two interrelated key elements: a global procurement scheme coupled with a global compulsory licensing scheme for any relevant intellectual property. These combined elements are necessary to leverage the global market power to purchase and distribute vaccines in the universal and equitable manner required to suppress global pandemics effectively. These combined features are also necessary to guarantee the successful cooperation of all stakeholders by providing a legal framework for enforcement. While the global procurement plan compels the participation of the international community, the global compulsory license encourages the cooperation of the pharmaceutical industry.

This framework, under the auspices of the WTO, would provide a centralized and structured regime for rapid and equitable distribution of safe and effective vaccines during pandemics while at the same time protecting the economic interests of the pharmaceutical industry. First, the centralized mechanism would be designed to function as a global procurement scheme, in which all WTO member states would have to participate to act collectively as a single buyer, enhancing the bargaining leverage of negotiating countries vis-à-vis developers of COVID-19 vaccines. Thus, the proposed scheme would regulate the manufacture, distribution, and pricing of all pandemic vaccines on a global scale while also assisting in the research and development of such vaccines.

Second, the mandatory and exclusive nature of this centralized scheme would entail an obligation for all countries to fund the initiative in proportion to their respective population sizes and economic status. This

77. Thomas J. Bollyky & Stewart M. Patrick, *Improving Pandemic Preparedness: Lessons From COVID-19*, COUNCIL ON FOREIGN RELATIONS [CFR], Independent Task Force Report No. 78 (Oct. 2020), https://www.cfr.org/report/pandemic-preparedness-lessons-covid-19 [https://perma.cc/5WWC-CDWT].

funding would then be used both to subsidize vaccine research and development and to compensate developers for supplying the vaccine to ensure adequate incentives for the pharmaceutical industry. The funding scheme in this way would structure vaccine pricing in a way that wealthy nations effectively subsidize poorer ones.

Moreover, by consolidating countries' buying power into a single, centralized purchasing authority, the proposed global coalition would have the power not only to negotiate the lowest reasonable prices but also to coordinate widespread manufacture of the vaccines. To the extent that patents, trade secrecy, and other exclusivities over newly developed vaccines are a major hurdle to their immediate, large-scale distribution, the scheme would allow a global compulsory license to be issued by the collective authority, which would become effective in all member countries, should a vaccine developer refuse to allow others to practice any patents necessary to produce their vaccine. Based on the existing compulsory licensing scheme in the TRIPS Agreement, we propose to incorporate an addendum that introduces such a global compulsory licensing mechanism for not just any patents, but also any trade secrets, safety and efficacy data, tacit knowledge, cell lines, or other resources necessary for successful and safe vaccine manufacture. Production then could be conducted by both the patent owner as well as follow-on manufacturers to scale up supply as quickly and widely as possible. The proposed addendum to the TRIPS Agreement will set forth the conditions under which its terms are triggered, such as the WHO's declaration of a global pandemic, and the criteria by which those vaccines will be priced and allocated.

Because a global coalition of all nations is essential to ensure rapid and fair distribution of affordable COVID-19 vaccines, participation in our proposed scheme would be *mandatory* and *exclusive* of any outside agreements. Anchoring it to the WTO's existing infrastructure by way of an addendum to the TRIPS Agreement offers multiple advantages. In particular, adherence to the terms of the scheme can be enforced through the TRIPS Agreement's existing mechanisms to ensure compliance with member states' international obligations. For example, member states that attempt to avoid participating in the scheme by contracting directly with a vaccine supplier can be subject to sanctions. Moreover, by aggregating the bargaining power of such a global bloc and by providing funding and other assistance to those developing pandemic vaccines, the proposed centralized authority would also have the ability to contract with vaccine developers not to deal with nonparticipants in or defectors from the regime.

Together, these basic elements of the proposed global compulsory license scheme offer a novel framework for addressing the specific need for widespread, simultaneous, and equitable vaccine distribution during pandemics, while also ensuring fair returns for pharmaceutical companies on their risky vaccine investments.

A. Compulsory Licenses

One of the most important features of the proposed global procurement scheme is the ability to impose compulsory licenses when reasonable licensing agreements cannot be reached. Compulsory licenses are generally viewed as ways to allow other manufacturers to reproduce another's innovation. For example, compulsory licenses issued under Article 31*bis* of the TRIPS Agreement, described below, allow countries with mass production capacity to engage in manufacturing to meet the pressing demand.[78] Compulsory licensing in pharmaceuticals often addresses only patent rights, however.[79] As the next section explains, we, therefore, also propose that compulsory licensing under our centralized scheme also include rights of access to a variety of other elements necessary to produce pharmaceuticals, such as trade secrets and tacit knowledge regarding nuances of manufacturing or storage; clinical trials data on safety and efficacy required for regulatory approval; and even raw materials, such as cell lines.

1. Compulsory Licenses Under the TRIPS Agreement

The intersection between patents and public health has been discussed extensively, and access to medicine stands at the heart of many global controversies.[80] Pharmaceutical companies use patent rights as the primary means of recovering their investments in the risky research and development required to create new vaccines. The power to control access to one's invention is the basic *quid pro quo* underlying the patent system, which, in normal times, is expected to create the proper incentive structure for innovation. While patent protection is thus widely regarded as necessary to incentivize such innovation, it also allows the patentee to charge supracompetitive prices for their products, leading to deadweight losses. In the case of vaccines and life-saving medicines, however, these deadweight losses are more than just an economic loss—they are in fact deadly.[81]

In times of global public health crises, the ordinary principles of patent protection must give way to the pressing need for immediate, widely available solutions so that less developed countries will not be priced out

78. Eduardo Urias & Shyama V. Ramani, *Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of The Existing Evidence*, 3 JIBP 367, 369 (2020).

79. Hoen et al., *supra* note 69, at 19–20 (noting that many compulsory licenses in pharma do not include access to clinical trials data); *see also* Caroline Southey, *Dummy's Guide to How Trade Rules Affect Access to COVID-19 Vaccines*, THE CONVERSATION (Jan. 9, 2021), https://theconversation.com/dummys-guide-to-how-trade-rules-affect-access-to-COVID-19-vaccines-152897 [https://perma.cc/5MUF-E4DJ] (noting that TRIPS's compulsory licensing provisions do not include trade secrecy, cell lines, and so on).

80. A HANDBOOK ON THE WTO TRIPS AGREEMENT 198–199 (Antony Taubman, Hannu Wager & Jayashree Watal eds., 2020).

81. Yugank Goyal, *Economic and Procedural Constraints of Compulsory Licenses for Medicines*, *in* COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD 438 (Reto M. Hilty & Kung-Chung Liu eds., 2015).

of access.[82] Recognizing the need for flexibility in the administration of intellectual property rights in times of emergency, the TRIPS Agreement introduced limited exceptions to these exclusive rights, provided that the exceptions do not unreasonably conflict with the normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner or third parties.[83] One such exception is a compulsory patent licensing framework.

TRIPS's compulsory licensing framework enables member states to issue such licenses authorizing use of a patented invention without the patentee's permission.[84] Specifically, Article 30 of the Agreement recognizes that member states may, in certain circumstances, "provide limited exceptions to the exclusive rights conferred by a patent," including for the furtherance of public health goals.[85] Article 31 of the TRIPS Agreement outlines most of the conditions for issuing compulsory licenses.[86] These include the general rule that such licenses be granted only after an unsuccessful attempt has been made to acquire a voluntary license on reasonable terms and within a reasonable period of time, although this requirement can be waived in cases of national emergency, extreme urgency, or noncommercial use.[87] In any event, the patentee must be given "adequate remuneration."[88] Many countries have proposed the introduction of domestic legislation in accordance with this provision.[89]

Article 31(f) limits the use of compulsory licenses under these circumstances to domestic product distribution, however.[90] Because less developed countries often lack manufacturing capacities, the WTO Doha Declaration on Public Health amended the TRIPS Agreement in 2003 to provide more flexibility for compulsory licensing of pharmaceutical products.[91] Article 31*bis* of the TRIPS Agreement now provides that a compulsory license can be issued for nondomestic manufacture of medicines,

82. Jean E. Akl, *Patent Exceptions in the Time of a Pandemic*, 55(3) LES NOUV 1 (2020).

83. TRIPS, *supra* note 36, art. 30.

84. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/9LMX-WN4K].

85. Burton Ong, *Compulsory Licenses of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines?*, *in* COMPULSORY LICENSING, *supra* note 81, at 239.

86. TRIPS, *supra* note 36, art. 31.

87. *Id.*

88. Benjamin Tham & Mark Finlay, COVID-19 Vaccine Research, Development, Regulation and Access 18 (Sing. Mgmt. Univ. Centre for AI & Data Governance (Research Paper No. 2020/03, June 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3640153 [https://perma.cc/H9BS-RDTP].

89. Daniel Crosby et al., *Update on the Proposed TRIPS Waiver at the WTO: Where is it Headed, and What to Expect*, JD SUPRA (June 8, 2021), https://www.jdsupra.com/legalnews/update-on-the-proposed-trips-waiver-at-8411942/ [https://perma.cc/ZKT6-6QXE].

90. TRIPS, *supra* note 36, art. 31.

91. World Trade Organization [WTO], Ministerial Declaration of 14 Nov. 2001, WT/MIN(01)/DEC/2 (2001); Art. 31bis(5) of the Protocol Amending the TRIPS Agreement; Ong, *supra* note 85, at 244.

effectively permitting countries that have the manufacturing capacities to export patented products without the patentee's authorization.[92] In their application to the TRIPS Council, importing and exporting countries must specify the name and expected quantity of the patented drug they wish to import.[93] Importing members are urged to prevent the re-exportation of products after their importation.[94] In this way compulsory licenses may be used to increase access to medicines in times of public health crises.[95]

That being said, Article 31(k) of the TRIPS Agreement also explicitly authorizes compulsory licenses for use under domestic competition laws as a remedy for patent holders' "anti-competitive" conduct, although the Agreement does not specifically define "anti-competitive" behavior.[96] Compulsory licenses under this section are not subject to the Article 31(f) no-export limitation,[97] and member states issuing compulsory licenses under Article 31(k) are exempt from preliminary negotiations with patent holders and from paying them "adequate"—and, in some cases, any—renumeration.[98] Commentators have expressed differing views on the feasibility of increasing access to pharmaceuticals by granting compulsory licenses under Article 31(k).[99]

In practice, however, countries rarely invoke these provisions to issue compulsory licenses. For example, some have criticized the Article 31*bis* system for the administrative burden it places on exporting countries.[100] Additionally, importing countries may be reluctant to disclose their importation of licensed products to the TRIPS Council, as this information might make patent-holding firms wary of making future investments in their countries.[101] Finally, the strict limitations placed on production and dis-

92. O ng, *supra* note 85, at 244; Tham & Finlay, *supra* note 88. While the least developed countries are assumed to lack this infrastructure, the TRIPS Council must deem developing countries "incapable of domestic production" before they receive importing rights. Appendix to the TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

93. TRIPS, *supra* note 36, art. 57.

94. *Id.*, art. 59.

95. Jerome H. Reichman & Fredrick M. Abbott, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT. ECON. LAW 921, 935, 957–58 (2007); Ong, *supra* note 85, at 246; *see also* Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT. ECON. L. 73, 89 (2004).

96. *See* Thomas Cottier, *The Doha Waiver and Its Effect on the Nature of the TRIPS-System and on Competition Law: The Impact of Human Rights*, *in* INTELLECTUAL PROPERTY, PUBLIC POLICY AND INTERNATIONAL TRADE 173 (Inge Govaere & Hanns Ullrich eds., 2007); Ong, *supra* note 85, at 237.

97. Ong, *supra* note 85, at 239.

98. *Id.* at 246.

99. Cottier, *supra* note 96; Joerg Baten, Nicola Bianchi & Petra Moser, *Compulsory Licensing and Innovation—Historical Evidence from German Patents after WWI*, 126 J. DEV. ECON. 231, 232 (2017); Shyama V. Ramani & Eduardo Urias, *When Access to Drugs Meets Catch-Up: Insights from the Use of CL Threats to Improve Access to ARV Drugs in Brazil*, 47 RES. POL'Y 1538 (2018).

100. Ong, *supra* note 85, at 245.

101. *Id.*

tribution of follow-on pharmaceuticals manufactured under a compulsory license disincentivize exportation by manufacturers.[102] Perhaps for these reasons, the Article 31*bis* mechanism has been used only once in practice.[103]

2. Compulsory Licenses Under Domestic Law

Provisions that allow for compulsory licensing-like powers also exist on the national level. Two such examples in the United States include the government's "march-in" rights under the so-called Bayh-Dole Act.[104] Although the United States has historically been adamantly opposed to compulsory patent licensing, the competing interests of patent enforcement on the one hand and antitrust enforcement on the other ebbed and flowed, as did governmental support for R&D and innovation.[105] In general, periods characterized by comparatively weak patent protection and strong antitrust enforcement corresponded to an increase in efforts to pass compulsory licensing legislation.[106] During these periods, federal antitrust bodies also implemented compulsory licensing indirectly through litigation and consent decrees to dismantle monopolies and re-engineer markets.[107] Between 1941–1959, for example, compulsory licensing orders in antitrust actions affected an estimated 40,000–50,000 patents (8% of all unexpired patents at the time).[108] In addition to compulsory licensing, government funding for research and development also weakened intellectual property rights. In return for government support, firms forfeited certain patenting abilities.[109]

This all changed with the passage of the Bayh-Dole and the Stevenson-Wydler Acts, however, which allow, and in fact encourage, recipients of federal government funding or assistance to hold patent rights over their research.[110] In exchange for these new patenting rights, however, the Bayh-Dole Act also granted the government "march-in" rights for patents on research at least partly government-funded—one of the Act's most con-

102. *Neither Expeditious, nor a Solution: The WTO August 30th Decision is Unworkable*, MEDECINS SANS FRONTIERES (Aug. 29, 2006), https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable [https://perma.cc/B43D-3FQK].

103. Rwanda, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/N/9/RWA/1, 19 July 2007; Canada, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/N/10/CAN/1, 8 November 2007.

104. JONATHAN M. BARNETT, THE GREAT PATENT GRAB 1 (Stephen H. Haber & Naomi R. Lamoreaux, Oxford Univ. Press, 2021).

105. *Id.*

106. *Id.*

107. *Id. See also* United States v. Aluminum Co. of America, 148 F.2d 416 (2d Cir. 1945); United States v. United Shoe Machinery Corp., 110 F. Supp. 295 (D. Mass. 1953); In re Xerox Corp., 86 F.T.C. 364 (1975).

108. BARNETT, *supra* note 104.

109. *Id.*

110. Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision*, 7 J.L. & BIOSCIENCES 1, 5–8 (2020).

tentious provisions.[111] This provision allows the funding agency, on its own initiative or at the request of a third party, in effect to ignore the exclusivity of a patent subject to the Act and to grant additional licenses to other "reasonable applicants."[112] Moderna's mRNA vaccine, for example, was developed largely by dint of U.S. government funding and, therefore, has been the subject of frequent calls for the United States to grant third-party licenses to the vaccine.[113] The march-in right is strictly limited, however, and can be exercised only if the agency determines, following an investigation, that certain criteria are met. The most important of these is a failure by the funded contractor to take "effective steps to achieve practical application of the subject invention" or a failure to satisfy the "health and safety needs" of consumers.[114] Thus far, the U.S. government has never exercised its march-in rights in any context despite repeated calls to do so,[115] perhaps because of the political ramifications of compulsorily licensing technology that might eventually fail.[116]

A third path for implementing implicit compulsory licenses in the United States is through the denial of injunctive relief in patent litigation. The American Patent Act indicates that courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."[117] In the seminal 2006 case of *eBay Inc. v. MercExchange, L.L.C.*,[118] the Supreme Court held that permanent injunctions against patent infringers should not be granted automatically.[119] The refusal to grant a permanent injunction results with the user having to pay monetary damages in a way akin to a *de facto* compulsory license.[120]

In sharp contrast, the European Union's Regulation 816/2006, adopted in May of 2006, explicitly authorizes the compulsory licensing of patents relating to the manufacture of pharmaceuticals for export to countries facing public health challenges.[121] This legislation reflects a 2003

111. 35 U.S.C. § 203.
112. *Id.*
113. Paradise, *supra* note 110.
114. 35 U.S.C. § 203.
115. Paradise, *supra* note 110.
116. David S. Bloch, *Alternatives to March-in Rights*, 18 VAND. J. ENT. & TECH. L. 247, 260 (2016).
117. 35 U.S.C. § 283.
118. Ebay v. MercExchange, L.L.C., 547 U.S. 388 (2006).
119. *See* John M. Golden, *Injunctions as More (or Less) than "Off Switches": Patent-Infringement Injunctions' Scope*, 90 TEX. L. REV. 1399, 1424–25 (2012); Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After* eBay, 101 IOWA L. REV. 1949, 1988–89 (2016).
120. Jaideep Venkatesan, *Compulsory Licensing on Nonpracticing Patentees after* eBay v. MercExchange, 14 VA. J.L. & TECH. 26, 39 (2009); P. Andrew Riley & Scott A. Allen, *The Public Interest Inquiry for Permanent Injunctions or Exclusion Orders: Shedding the Myopic Lens*, 17 VAND. J. ENT. & TECH. L. 751, 756 (2015). *See also*, Hybritech, Inc. v. Abbott Laboratories, 849 F.2d, 1458 (1988).
121. 2006 O.J. (L 157) 1; Jakob Cornides, *European Union Adopts Regulation on Compulsory Licensing of Pharmaceutical Products for Export*, 10(1) J. WORLD INTELL. PROP. 70 (2007).

decision by the WTO[122] and was intended to improve less developed countries' access to medical relief.[123]

3. The Compulsory Licensing Dilemma

While compulsory licensing seems, at first blush, like a promising mechanism for achieving greater access and fair pricing of vaccines, it has notable disadvantages. For example, the issuance of compulsory licenses requires an administrative procedure and sometimes legislative action.[124] Compulsory licensing also has little value when licensees are inefficient and unable to manufacture products at meaningfully lower prices than their licensors.[125]

Perhaps the most salient concern about compulsory licenses is that they could have a chilling effect on vaccine development. Global patent filing is costly, and if companies filing for a patent on a COVID-19 vaccine fear global compulsory licenses await their inventions, they may hesitate to invest in vaccine development.[126] Moreover, given the nationalistic approach many countries have taken to cope with the COVID-19 pandemic, some—especially developing and least developed countries—may consider issuing compulsory licenses to facilitate mass production of vaccines for an affordable price in an effort to meet urgent local demands.[127] This possibility raises similar concerns about preserving adequate incentives for the pharmaceutical industry to engage in risky and expensive vaccine research and development.[128]

A number of scholars have questioned the wisdom of compulsory patent licensing and its effect on innovation and investment in research and development. For example, some have surmised that, given pharma's high research and development cost and the relatively few products from which it earns significant profit, compulsory patent licensing must necessarily have a negative economic impact on the pharmaceutical industry.[129] A study by Bird and Cahoy finds that compulsory licensing has led to reduced foreign direct investment (FDI) in pharmaceuticals in countries

122. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (2003).

123. Cornides, *supra* note 121, at 75.

124. CARLOS M. CORREA, GUIDE FOR THE APPLICATION AND GRANTING OF COMPULSORY LICENSES AND AUTHORIZATION OF GOVERNMENT USE OF PHARMACEUTICAL PATENTS (2009).

125. Richard J. Gilbert & Carl Shapiro, *An Economic Analysis of Unilateral Refusals to License Intellectual?Property*, 93(23) PROC. NAT'L ACAD. SCI. U.S.A. 12749, 12753–54 (1996).

126. Akl, *supra* note 82, at 2.

127. It should be noted that developed countries, such as Germany and Canada, have also threatened to override patents if necessary. *See* Cynthia Koons, *The Vaccine Scramble Is Also a Scramble for Patents*, BLOOMBERG (Aug. 12, 2020), https://www.bloomberg.com/features/2020-COVID-vaccine-patent-price/ [https://perma.cc/UJ55-DVNP].

128. *See* Part II.A, *supra*, discussing compulsory licenses.

129. Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unreasonable Problem*, 34 JURIMETRICS 295, 312–13 (1994).

granting such licenses.[130] More to the point, a recent empirical study by Jonathan Barnett of the shifting trends in the tension between patent protection and antitrust enforcement in the United States since the late nineteenth century appears to confirm this.[131] Barnett's study noted that periods of strong patent protection and weak antitrust enforcement yielded a surge in R&D investment.[132] During periods in which antitrust law seemed to take the fore, on the other hand, indirect compulsory licensing through antitrust litigation became common, as noted above, leading to a significant decline in patenting rates by U.S. inventors.[133] The rush of litigation-related compulsory licensing during the 1940s and 1950s also led to investment, and innovation remained concentrated among several large, established firms, which are less likely to produce breakthrough inventions. By the mid-1960s, innovation amongst even those firms began to decline as government funding fell.[134] It was only after courts began to strengthen patent protections that smaller firms eventually began to increase their innovative output.[135] Based on these observations, Barnett concluded that without a strong intellectual property system, innovation will falter with time, especially in industries that require substantial investment capital, such as pharmaceuticals.[136]

On the other hand, a number of scholars emphasize the positive effects of compulsory patent licensing. For one thing, compulsory licensing of patents from other countries often leads to an upturn in domestic innovation. A study by Moser and Voena, for example, found that under the Trading with the Enemy Act passed during World War I, compulsory licensing of German patents by American firms led to a 20% increase in American innovation.[137] Stephanie Lee found a similar positive correlation post-World War II between compulsory licensing of German, Japanese, and Italian patents and US domestic innovation.[138] Like eminent domain, compulsory licensing also has the virtue of lowering transaction costs and avoiding hold-out problems in situations where patent rights are held by multiple owners.[139] Furthermore, monopolies, such as through patents, can allow the use of price discrimination in ways that ameliorate the deadweight losses that might otherwise occur.[140] Pharmaceutical companies, for example, often price their products at lower levels in less developed countries than in the United States and other more developed states. Importantly, some studies of the impact of compulsory licensing on R&D

130. Robert Bird & Daniel H. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L. REV. 283 (2008).
131. BARNETT, *supra* note 104.
132. *Id.*
133. *Id.*
134. *Id.*
135. *Id.*
136. *Id.* at 2.
137. Petra Moser & Alessandra Voena, *Compulsory Licensing: Evidence from the Trading with the Enemy Act*, 102(1) AM. ECON. REV. 396, 404 (2012).
138. Goyal, *supra* note 81, at 439.
139. Bird & Cahoy, *supra* note 130, at 290.
140. Gilbert & Shapiro, *supra* note 125, at 12750.

actually find a positive correlation between the two. For instance, a one-year, 1977 study by F.M. Scherer found that the forty-two companies that were subject to compulsory licenses at that time, including pharmaceuticals, actually spent *more* on R&D than others.[141] Similarly, although some found that Canada's seventy-year venture with compulsory licensing for pharmaceutical patents led to a decline in R&D, others found that the impact on global pharmaceutical distribution was minimal, possibly because the Canadian market was relatively small.[142]

Indeed, more nuanced analyses suggest that the ultimate effect of compulsory patent licensing on incentives to innovate depends on the form of the license and on the relationship between the licensor and licensee.[143] First and most obviously, the more reasonable the royalty or fee paid to the licensor, the less likely the compulsory license is to dampen incentives.[144] Studies by Goyal and Chien also suggest that compulsory licensing's repercussions on innovation depend primarily on the size and importance of the licensed market.[145] If the licensed market is very small or one that the licensor is unlikely to exploit, the impact on their incentives obviously will be negligible.[146] Similarly, compulsory patent licensing can reduce the flow of foreign direct investment (FDI) into countries, but this, again, depends on whether the compulsory license affects markets in which the licensor has a vested interest.[147] A final determinant of impact is the length, frequency, and foreseeability of compulsory licensing. Studies by Scherer and Chien suggest that antitrust litigation-imposed compulsory patent licenses had little effect on incentives to innovate in the United States because they were all rather brief (only a year or so in duration) and unexpected and sporadic.[148]

Regardless of their effect on incentives to innovate, however, the problem with existing compulsory licensing practices in the context of a global pandemic is that patent law is territorial in nature.[149] This means that the administration of vaccine patent rights—including licensing regimes, whether voluntary or compulsory—occurs at the domestic level. Under current law, a compulsory license issued in a particular country in accor-

141. Goyal, *supra* note 81, at 439.

142. Donald G. McFetridge, *Intellectual property, Technology Diffusion, and Growth in the Canadian Economy*, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE BASED ECONOMY 64 (Robert D. Anderson & Nancy T. Gallini eds., 1998); Goyal, *supra* note 81, at 438–39.

143. Gilbert & Shapiro, *supra* note 125, at 12753–54; Colleen V. Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 891–92 (2003).

144. Goyal, *supra* note 81.

145. Chien, *supra* note 143.

146. Gilbert & Shapiro, *supra* note 125; Chien, *supra* note 143.

147. Goyal, *supra* note 81, at 439.

148. Chien, *supra* note 143; *see also* F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting*, 27 WORLD ECON. 1127, 1140 (2004).

149. GRAEME DINWOODIE, WILLIAM HENNESSEY & SHIRA PERLMUTTER, INTERNATIONAL AND COMPARATIVE LAW §1.03, 30 (2d ed. 2002) ("[P]atent laws operate territorially, and patent rights are thus national in scope.").

dance with the TRIPS Agreement can authorize the use of a particular vaccine only in the issuing country's territory.[150] Similar territorial restrictions apply to other domestic measures available to national governments in times of emergency, such as the issuance of special governmental orders allowing the use of a patented technology in return for adequate remuneration.[151]

Yet, "nationalist" approaches to vaccine distribution undermine international efforts to distribute vaccines effectively in the context of a global pandemic.[152] For example, if some countries employ territorial exceptions to patents but others do not, some nations will receive vaccines at below market prices,[153] potentially driving prices up in other countries, including those that may lack the resources to pay. In a similar vein, efforts by individual countries to gain preferential access to vaccines by entering into early agreements with pharmaceutical companies to guarantee the earliest supply for their populations generates competition among states, which may likewise leave poorer countries unable to afford the vaccines. Market-driven differential pricing is highly problematic when it comes to pandemic vaccines because pricing some countries out of the market creates an inoculation gap that jeopardizes the ability of all countries to overcome the outbreak.

In summary, the use of compulsory licenses issued under domestic laws can offer greater access and better pricing of vaccines all over the world. The exceptions provided in the TRIPS Agreement's general commitment to guaranteeing of patent protection reflect the underlying intention

150. Caranina Colpaert, *Compulsory Licensing for Pharmaceuticals in the EU: A Reality Check*, BILL OF HEALTH (Oct. 21, 2020), https://blog.petrieflom.law.harvard.edu/2020/10/21/compulsory-licensing-eu-pharma/ [https://perma.cc/BHX9-7JRK].

151. *See, e.g.*, Christopher Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE L.J. 1, 43–45 (2020) (discussing 28 U.S.C. § 1498 under U.S. law); Thiru, *Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 3, 2020), https://www.keionline.org/32503 [https://perma.cc/43MC-C5KU] (discussing Chapter Six, Article Three of the Patents Law 5727-1967 under Israeli law); *Decree No. 3.201 of October 6, 1999* (*Compulsory Licenses in Cases of National Emergency and Public Interest*), WIPO, http://www.wipo.int/wipolex/en/details.jsp?id=516 [https://perma.cc/7NJW-H2HJ] (describing example of compulsory licensing under Brazilian law). For the view that in emergency times the defense of necessity in tort law should allow relaxation of intellectual property rights, *see* Heled et al.*, supra* note 30.

152. *See*, *e.g.*, Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT'L AFF. ONLINE, (July 3, 2020); Ana Santos Rutschman, *The Intellectual Property of COVID-19*, *in* OUTSMARTING PANDEMICS (Elizabeth Kirley & Deborah Porter eds., 2021) (forthcoming), https://ssrn.com/abstract=3691239 [https://perma.cc/UP5R-FNKJ] [hereinafter Rutschman, *The Intellectual Property of COVID-19*].

153. It was noted that, in the United States, the compensation paid under the exception stipulated in § 1498 reflects the market price of the patented product. *See* Morten & Duan, *supra* note 151, at 44 ("[S]urveys of past § 1498 cases confirm that reasonable royalty awards under § 1498 are 'generally provided at a market rate,' such that the reasonable royalty paid for government patent use is similar to compensation for private infringement calculated using the standard factors of *Georgia-Pacific Corp. v. U.S. Plywood Corp.*").

of member states to allow flexibility in rare and unique circumstances.[154] However, negative perceptions of this measure—even if unwarranted—frequently generate resistance on the part of governments, which may be reluctant to use it. Moreover, under certain conditions, compulsory licenses tend to stifle innovation, which can have devastating consequences for vaccine development. A carefully tailored global compulsory license scheme, by contrast, preserves R&D incentives while carefully rewarding vaccine inventors. Therefore, a scheme to regulate the national self-help "impulse" or "instinct"[155] by offering a better framework for all countries is not only consistent with moral imperatives, but also more efficient.

4. The Proposed Compulsory Licensing Scheme

Our centralized compulsory licensing and procurement proposal provides exactly such careful tailoring. Expanding upon existing compulsory licensing frameworks, our proposed scheme shows how, far from being anathema, a centrally organized but careful use of compulsory licensing provisions can help provide pandemic vaccines in not only an efficient manner but an equitable and mutually agreeable one as well.

While it is easy to see how compulsory licensing of COVID-19 vaccine patents benefits the general population, it is less clear how it could benefit vaccine patentees, at least at first blush. The market size for COVID-19 vaccines clearly spans the entire world, including highly developed, developing, and least developed countries, ranging from the quite affluent to the impoverished. Most vaccine developers are assumed to want to market to not only the wealthiest countries but also developing and less developed countries, leaving only the least developed countries to be supplied through nonmarket means such as charitable donation. And while the COVID-19 pandemic was certainly acute in onset, health officials around the world have expressed uncertainty as to how long the pandemic may last and, more importantly, as to whether it will require ongoing or annual vaccination programs such as those seen for the flu. Vaccine developers could, therefore, fear that compulsory licensing of their patents may be both frequent and extended in duration. And of course, if our proposal were implemented, compulsory licensing of vaccines for infectious diseases causing pandemics would be entirely foreseeable. All these features of our

154. "Self-help" is a fuzzy term used in legal literature to describe "the act of redressing or preventing wrongs by one's own action, without recourse to legal process." David E. Pozen, *Self-Help and the Separation of Powers*, 124 YALE L.J. 2, 11 (2014). Richard Epstein adhered to a slightly different definition according to which self-help is "legally permissible conduct that individuals undertake absent the compulsion of law and without the assistance of a government official in efforts to prevent or remedy a legal wrong." Richard A. Epstein, *The Theory and Practice of Self-Help*, 1 J.L. ECON. & POL'Y 1, 2 (2005). The legal aspects of self-help are discussed from various points of view, including constitutional law, public international law, tort law, criminal law, and more. *See* Adam B. Badawi, *Self-Help and the Rules of Engagement*, 29 YALE J. REG. 1 (2012); Pozen, *supra*; Epstein, *supra*.

155. For the perception of "self-help" measures as preservation of basic human behaviors, see Epstein, *supra* note 154, at 15–17.

proposal suggest that compulsory licensing of patents on pandemic vaccines could be particularly detrimental to incentives to invest in vaccine development. This is particularly true given the already existing difficulties in incentivizing investments in vaccine development. For all of these reasons, vaccine developers could be justifiably concerned about the effect of compulsory licensing.

Yet, the mere threat of a compulsory license often results in consensual purchase agreements covering all aspects of pricing and production, which may be conducted either by the patentee or under his license. However, when the threat of a compulsory license is exercised on a global scale, and the patentee has only a single centralized buyer, the patentee is effectively required to cooperate.[156] In other words, under the proposed global compulsory scheme, the pharmaceutical industry would have no choice but to cooperate with the global procurement plan on favorable terms to the buyer. Nevertheless, the proposed global compulsory license scheme can be used where a satisfactory agreement is not reached, and production by additional follow-on manufacturers is necessary to meet pressing global demand and to provide equitable vaccine access. This scheme will allow for issuance of a compulsory license in all countries simultaneously, thus enabling a global response to vaccine shortage.

More importantly, the compulsory licensing scheme that we propose here would make use of its uniquely centralized and mandatory nature not only to guarantee a global market for vaccine developers but also to secure reasonable payment for them. The scheme thus would address both pricing and distribution of vaccines. Because all countries would pay royalties under the licenses, aggregate royalties could be taken into account in pricing the vaccines to enable pharmaceutical companies to recoup their investment costs and possibly gain additional profits, thus maintaining an adequate incentive structure. Royalty rates and vaccine pricing would be set in accordance with each country's economic strength, such that developed countries effectively subsidize developing and least developing countries. (In fact, many patented drug manufacturers already designate a portion of their supply for distribution in developing countries at what are effectively subsidized lower prices.)[157] In this way, the proposed scheme would both promote the goal of distributive justice goals and maintain efficient allocation of resources. In essence, our proposal would function as a centralized vaccine procurement scheme to control the prices of vaccines internationally.

Because purchasing countries would operate collectively as a single buyer, it is likely that the patentee would prefer to negotiate the vaccine

156. For a similar argument that developing countries should cooperate to exert greater joint pressure to force patent owners to grant licenses and to threaten that they will issue compulsory licenses pursuant to the TRIPS Agreement otherwise, see Frederick M. Abbot & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 1, 17 (2020).

157. Cornides, *supra* note 121, at 75.

price rather than risk having a multitude of compulsory licenses issued against her. Indeed, unlike procurement initiatives based on free market negotiations, the proposed scheme gives the negotiating collective a major bargaining leverage—the threat of compulsory licenses—thus improving all countries' position vis-à-vis the patentee. It is quite likely that merely the threat of compulsory licensing, coupled with the buying power of our proposed centralized authority and its emphasis on price discrimination and reasonable royalties, will be enough to motivate patentees to negotiate voluntarily.[158] A study by Beall and Kuhn reviewed twenty-four instances in which compulsory licensing was considered between 1995–2011, most of which were for HIV/AIDS treatments, and found that in almost half of the cases, the mere specter of a compulsory license produced price reductions or a voluntary licensing agreement.[159] Indeed, as an effective monopsony, our proposed global coalition would have great bargaining power, even without the threat of compulsory licensing, simply by virtue of the size of the market it represents. The larger the market, the more bargaining power a buyer has.[160]

B. Coordinated Licensing and Funding Beyond Patents

As explained above, a successful global plan to provide pandemic vaccines will require not only the threat of compulsory patent licensing, but also access to tacit knowledge, equipment, cell lines, rights of reference to safety and efficacy data, and other resources. Again, patents may play only a partial role in determining vaccine availability, as lack of access to these other factors are often significant barriers to entry for follow-on manufacturers. The proposed centralized, global scheme will, therefore, need to coordinate not only vaccine procurement (and compulsory licensing if necessary) but also licensing of trade secrets and rights of reference to data and procurement of equipment and raw and other materials.

First, the proposed centralized scheme could license or simply grant rights of reference outright to the clinical trials data needed to gain regulatory approval. This is very similar to what the COVID-19 Technology Access Pool (C-TAP), launched by WHO in partnership with a number of state co-sponsors, is doing in asking vaccine developers to share a wide range of resources relevant to fighting COVID-19.[161] Although self-described as a "patent" pool, C-TAP's call is to pool *any* "IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-

158. *Id.* at 70 (stating that critics miss that "the value of compulsory licensing rules . . . [springs from] the pressure such provisions exert on patentees to make their product available at a reasonable price.").

159. Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9(1) PLoS Med. 3 (2012).

160. Nakkazi, *supra* note 76 (noting that larger countries have more power to bargain down vaccine pricing).

161. *COVID-19 Technology Access Pool*, WHO (Mar. 17, 2021), https://www.who.int/initiatives/covid-19-technology-access-pool [https://perma.cc/UAZ2-Y37A] [hereinafter *COVID-19 Technology Access Pool*, WHO].

how.'"[162] The United Nations supported Medicines Patent Pool (MPP) also request waivers of data exclusivity rights where they exist.[163] Unlike C-TAP and MPP, however, which ask only that vaccine developers and others voluntarily share their data, the proposed scheme would require it but would also compensate for it.[164]

In many countries, regulatory exclusivities effectively prevent follow-on manufacturers from reproducing pharmaceuticals even after they are no longer covered by patent protections. Regulatory exclusivities require that follow-on manufacturers wait for some period of years before being allowed to rely on a right of reference to the originator's clinical trials data for a drug.[165] Licensing an immediate right of reference, by contrast, would allow immediate follow-on market entry, an absolute necessity if the COVID-19 virus and its variants is to be eradicated.

Furthermore, merely granting waivers of data exclusivity and allowing immediate rights of reference is not enough to make vaccines globally accessible. Many countries will not grant regulatory approval for generic and other follow-on pharmaceuticals based simply on the fact that the reference pharmaceutical was approved elsewhere. Instead, they require that the originator submit their clinical trials data directly to their regulatory agency. Thus, the proposed regime would require that originators submit their clinical trials data to agencies in any country in which a follow-on manufacturer might be located, as well as to waive any resulting data exclusivities. Both the originator and follow-on manufacturers would then be approved to market in that country. Note, however, that the vaccine originator would not lose their trade secrecy rights over their clinical trials data, in keeping with Article 39(3) of TRIPS, which requires member states to protect such data against disclosure.[166] As with the licensing of patent rights discussed above, the proposed scheme will include a mechanism for allocating reasonable revenues for originator vaccine developers, not only for their patent rights but also for their clinical trials data.

In addition, distributed production of pandemic vaccines will depend on access to the kinds of tacit knowledge, expertise, raw materials, and equipment necessary for their mass manufacture, especially in the case of pioneering vaccines like the mRNA vaccines. Again, biologics are complex to produce and often unpredictable and difficult to copy, and successful technology transfer entails licensing not only of patents but also anything else needed to practice those patents. This is why public-private partnerships like the WHO's C-TAP initiative call for research organizations to share their "relevant knowledge, IP and data to enable widescale and worldwide production, distribution, and use of [technologies to fight COVID-19]

162. *Id.*

163. *Medicines Patent Pool Announces First Licensing Agreement with a Pharmaceutical Company*, MEDICINES PATENT POOL (June 12, 2011), https://medicinespatentpool.org/news-publications-post/medicines-patent-pool-announces-first-licensing-agreement-with-a-pharmaceutical-company/ [https://perma.cc/5L75-6S6C].

164. *Cf.* Colpaert, *supra* note 150.

165. Hoen et al., *supra* note 69, at 10.

166. TRIPS, *supra* note 36, art. 39(3).

and necessary raw materials . . . ."[167] Even more on point, the Brazilian Senate passed a Compulsory Licensing Bill on August 11, 2021, to provide for not only compulsory patent licensing in national or international emergencies but also disclosure of "necessary and sufficient information for the effective reproduction of the [patented] subject matter . . . and the other technical aspects applicable to the specific case, as well as the results of tests and other data necessary for the granting of its registration by the competent authorities" as well as provision of any biological materials necessary to practice the patented invention.[168] Brazilian President Bolsonaro vetoed the latter two parts of the Bill, however, on September 2, 2021.[169]

Successful tech transfer thus requires licenses (whether compulsory or voluntary) on the patents on vaccines themselves, on their methods of manufacture, on any specialized equipment for manufacturing the vaccines, and on any requisite raw materials, such as lipid nanoparticles. It also requires transferring necessary trade secrets (with accompanying nondisclosure agreements) and tacit knowledge. The latter may mean that technicians and other employees from follow-on manufacturers will have to be physically present at originators' facilities to learn directly from the originators. In fact, because of the large size of the market and the need for immediate, large-scale production beyond the capacity of manufacturers, some developers of COVID-19 vaccines have demonstrated a surprising willingness to share their know-how with others. For example, vaccine developer Johnson & Johnson has voluntarily teamed up with rival Merck to use their respective facilities to manufacture and package Johnson & Johnson's recently approved COVID-19 vaccine.[170] Likewise, AstraZeneca has contracted with the Serum Institute in India to supply vaccines to a number of countries,[171] and Pfizer has continued to search for potential manufacturing partners with whom it can share the proprietary knowledge necessary to produce the Pfizer vaccine.[172]

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167. *Operationalising the COVID-19 Technology Access Pool (C-TAP)*, WHO (Oct. 27, 2020), https://www.who.int/publications/m/item/c-tap-a-concept-paper [https://perma.cc/FF2Q-7X5Y] [hereinafter *Operationalising*, WHO].

168. Lisa. L. Mueller, *Compulsory Licensing in Brazil: Updates and Perspectives*, LEXOLOGY (Aug. 17, 3021), https://www.lexology.com/library/detail.aspx?g=4adf38aa-3a49-4230-b129-82b3f750993e [https://perma.cc/65EY-RHMB].

169. 169. Gabriel Francisco Leonardos, *The COVID-19 Pandemic Triggered the Issuance of New Compulsory License Rules for Patents in Brazil*, KASZNAR LEONARDOS (Sept. 3, 2021), https://www.kasznarleonardos.com/news-and-publications/newsletters/the-covid-19-pandemic-triggered-the-issuance-of-new-compulsory-license-rules-for-patents-in-brazil [https://perma.cc/5TDL-BZR3].

170. Tamara Keith, *How the White House Got 2 Pharma Rivals to Work Together on COVID-19 Vaccine*, NPR (Mar. 3, 2021), https://www.npr.org/2021/03/03/973117712/how-the-white-house-got-2-pharma-foes-to-work-together-on-COVID-19-vaccine [https://perma.cc/M4HK-QKFZ].

171. Douglas & Samant, *supra* note 25; Nakkazi, *supra* note 76.

172. Jared S. Hopkins, *Pfizer's Global Covid-19 Vaccine Rollout Depends on Two Expert Staffers*, WALL ST. J (Aug. 20, 2021), https://www.wsj.com/articles/pfizers-global-covid-19-vaccine-rollout-depends-on-two-expert-staffers-11629464010?page=1 [https://perma.cc/7XQM-7AMF].

Like COVAX, our proposed centralized organization would also provide financial assistance in building or retrofitting manufacturing facilities.[173] Given the urgency of the pandemic, both tech transfer and retrofitting need to happen as early as possible.[174] Both vaccine developers and follow-on manufacturers are normally averse to investing in constructing or adapting manufacturing facilities until the vaccine has been approved for marketing (or the follow-on manufacturer has been approved for market entry). This would greatly slow worldwide vaccine roll-out, which is why COVAX has committed to funding preparations for manufacturing.[175]

Indeed, a centralized source of funding for vaccine development and manufacturing is paramount to provide not only adequate compensation for vaccine developers *ex post,* but also to provide some of the necessary resources up front for R&D, clinical trials, and manufacturing facilities. The proposed scheme would provide this funding, in much the same way that many governments and public-private partnerships are already doing now. The United States' "Operation Warp Speed," for example, granted Moderna nearly $1 billion for clinical trials and application for regulatory approval.[176] Even outside of pandemics, vaccine development relies heavily on government funding for both R&D and testing. Plus, the availability of funding will also give vaccine developers yet more incentives to pre-commit to the proposed centralized system. It also will afford the proposed centralized authority bargaining chips with which to demand global licensing of IP and other know-how, in much the same way that the US government retains "march-in" rights to patented technologies that it helped fund. The C-TAP initiative requests similar provisions for access in its funding agreements with pharmaceutical developers.[177] Under the proposed scheme, moreover, vaccine developers will know up front that they will be adequately compensated and, therefore, will be much more inclined to share not only patented technologies but also other information right from the start of the development process.

C. Procurement and Enforcement

As described above, the proposed scheme would create a global authority, based on a coalition of all countries, to centralize coordination of all aspects of production, procurement, distribution, and pricing of the emergency vaccines. Multinational procurement schemes have been used

173. *See Working for Global Equitable Access to COVID-19 Vaccines*, WHO https://www.who.int/initiatives/act-accelerator/covax [https://perma.cc/53SS-XTEX] (last visited Oct. 4, 2022).

174. Ravelo, *supra* note 3.

175. Seth Berkeley, *COVAX Explained*, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained [https://perma.cc/ECV6-LQRN].

176. Kiersten Fowler & Andrew Wasson, *When the "States" Come Marching-In: The Bayh-Dole Act's Effect on IP Rights of COVID-Related Patents and Knowledge Ecology International's Involvement*, JD SUPRA (Sept. 18, 2020), https://www.jdsupra.com/legalnews/when-the-states-come-marching-in-the-85133/ [https://perma.cc/8SDH-BFA3].

177. WHO, *supra* note 167.

for many years in the pharmaceutical sector. Within such frameworks, several countries maintain a high level of integration, with tendering, contracting, and payment performed centrally.[178] For example, the EU operates a procurement scheme that aims to secure equitable access to medical products and obtain "balanced prices."[179]

The EU procurement scheme is operated on a voluntary basis, however, and the participating countries are free to contract individually with suppliers and opt out of the scheme at any stage.[180] While this and other multinational procurement schemes can amplify the bargaining power of their participating countries,[181] in emergency situations, such schemes can successfully overcome market failures only when they are mandatory for all countries. The scheme proposed here, therefore, also includes incentive and enforcement mechanisms that encourage participation and discourage defection. Both the procurement and enforcement measures are detailed below.

1. Procurement and Pricing

The proposed combined global scheme, whether based on voluntary negotiation or full-fledged compulsory licensing, not only serves the interest of global access to vaccines but also meets the industry's need for adequate incentives. A central issue under the proposed procurement plan relates to the pricing of vaccines bought pursuant to the scheme. Because the pricing of all vaccines would be set under a centralized framework in which all countries act as a single buyer, the need to guarantee sufficient incentives for all vaccine developers would be met.

In this way pharmaceutical companies would not consider the proposed framework to be less desirable than a free-market model because it guarantees royalty payments by all countries. Under the scheme, each country would pay its proportionate share based on its ability to pay, effectively creating a price differentiation scheme. The centralized nature of the scheme provides significant leverage to the joint global effort as compared to the leverage of individual buyers in a free-market model, yet it also guarantees sufficient revenues to incentivize the industry. Therefore, this scheme advances global distributive goals as well as health goals,[182] increases efficiency and certainty regarding royalty payments and equita-

178. For example, the Pan American Health Organization established a procurement scheme for vaccines. *See Immunization*, PAHO, https://www.paho.org/immunization-toolkit/?page_id=25 [https://perma.cc/K4L8-5YXC].

179. *See Preparedness and Response Planning*, EUR. COMM'N, https://ec.europa.eu/health/security/preparedness_response_en [https://perma.cc/GJQ5-G5D8].

180. *See id.* (explaining that the "agreement provides for a voluntary mechanism enabling participating EU countries and the EU institutions to purchase jointly medical countermeasures for different categories of cross-border health threats including vaccines, antivirals and other treatments").

181. Abbot & Reichman, *supra* note 156, at 20.

182. For example, under the proposed scheme, in case of a global pandemic disproportionately affecting the elderly, the global elderly community would be vaccinated first and would have preferential access to vaccines, thus avoiding the experience of the current COVID-19 pandemic, in which whoever is able buy vaccines can be vaccinated

ble distribution of vaccines,[183] while also avoiding the business risks associated with individual nations' invocation of exceptions to patent enforcement, opportunistic behavior of states, and differing bargaining powers.[184]

Even where a full-fledged compulsory license is issued, the royalties paid for the use of patented vaccines would be collected from all follow-on manufacturers, with all countries subsidizing the payment of these licenses. The royalties could be based on the well-established Fair, Reasonable, And Non-Discriminatory (FRAND) licensing practices used for standard-essential patents.[185] The expected revenues from these royalties will maintain the proper incentives for the pharmaceutical industry to develop vaccines, even as follow-on manufacturers also engage in production, leading to lower prices.

Another prominent advantage of the global compulsory license scheme is that it is designed on a cross-subsidies basis to ensure fair access to vaccines globally. The scheme contemplates setting an average price for vaccines, which may then serve as the baseline price. The prices for each country would be differentiated in a manner that would ensure countries pay prices that reflect their economic power. Thus, developing and least developed countries would pay less than high-income countries. Pricing can be further fine-tuned based on additional factors. The end result is that while each country would contribute royalties in accordance with its economic power, vaccines would be distributed equally to all nations.[186]

Cross-subsidies generate a proportionate economic burden on each country and are justified by notions of distributive justice.[187] There have been growing calls to achieve distributive justice goals via intellectual property laws.[188] Some prominent examples of this trend include the 2013

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first irrespective of medical considerations. These results cannot be achieved pursuant to a patchwork of nationalistic approaches.

183. The predictable flow of revenues stemming from a certain asset is a central element in the value of the asset. *See* YORAM BARZEL, ECONOMIC ANALYSIS OF PROPERTY RIGHT 4–7 (1989).

184. Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 766.

185. *See* Yann Ménière, *JRC Science and Policy Report: Fair, Reasonable and Non-Discriminatory (FRAND) Licensing Terms* at 10, EUR. COMM'N (2015).

186. For a similar stance calling for a cross-subsidies policy pursuant to which support of strong patent rights throughout the world should be conditioned on the pharmaceutical industry's commitment to devote twenty percent of its R&D budget to diseases specific to less-developed countries, see Scherer, *supra* note 148, at 1140.

187. Under a distributive justice approach as conceptualized by John Rawls, in the absence of prior knowledge regarding the advantages of one's own status or social position and while acting under the veil of ignorance, policy makers should adopt norms and rules of fairness and equality. *See generally* JOHN RAWLS, A THEORY OF JUSTICE (1971); *see also* Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 998–99 (2012).

188. *See, e.g.*, Peter S. Menell, *Intellectual Property: General Theories*, *in* ENCYCLOPEDIA OF LAW AND ECONOMICS 129, 160 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000); Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2905–07 (2006); Kapczynski, *supra* note 187, at 993–1006; Oren Bracha Talha Syed, *Beyond Efficiency: Consequence-Sensitive Theories of Copyright*, 29 BERKELEY TECH. L.J. 229 (2014); Shlomit Yanisky-Ravid, *The Hidden though Flourishing Justification of*

WIPO Marrakesh Treaty, which stipulates special mandatory exceptions to copyright to facilitate access to works for the benefit of visually impaired persons.[189] Another example is the Doha Amendment to the TRIPS Agreement concerning compulsory licensing, discussed above, which was intended to foster distributive justice by differentiating among least developed countries (LDCs), developing countries, and developed countries, and relaxing the territorial production requirement of Article 31(f) with respect to LDCs.[190]

An organized, compulsory distribution framework is necessary, however, to offset trends such as the one observed during the 2009 influenza pandemic, when countries stockpiled vaccines in excess of their need.[191] Indeed, in times of pandemic, countries are likely to behave irrationally and over-prepare to the extent of their capacity.[192] This tendency results in a purchasing race,[193] exacerbating vaccine shortages that exist regardless of their pricing[194] when demand outpaces supply. A mandatory global scheme that controls all aspects of the vaccine market would minimize the risk of irrational purchasing behavior and ensure that all nations gain access to vaccines at prices they can afford, while at the same time protecting the financial incentives pharmaceutical companies need to develop them.

This model could be enhanced even further by encouraging competition among all vaccine developers by bidding on the global demand for their vaccines, thus incentivizing them to offer the best prices for consumers. In light of the public interest in encouraging the development of multiple vaccines, *i.e.*, the "portfolio approach," the proposed scheme should cover all approved vaccines in the market, not merely a single "leading" one. The structured and centralized nature of the procurement plan would also avoid risk and provide certainty by tailoring the price of each vaccine after a preliminary market survey during which each country would commit to purchasing certain amounts of the vaccines in the portfolio. This survey would provide a clear picture of the global demand for each vaccine and would allow fair pricing, taking into account the supply capacity of the

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Intellectual Property Laws: Distributive Justice, National versus International Approaches, 21 LEWIS & CLARK L. REV. 1 (2017).

189. *See* Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled, WIPO, June 27, 2013, VIP/DC/8 REV; *see also* Yanisky-Ravid, *supra* note 188, at 29.

190. *See Amendment of the TRIPS Agreement*, WTO (Dec. 8, 2005), https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [https://perma.cc/6PN9-67PD].

191. OECD, *supra* note 1, at 20–21.

192. Heled et al., *supra* note 30, at 6.

193. *Id.*

194. In the early days of the COVID-19 outbreak, a similar trend was documented concerning the purchase of ventilators in the open market. *See* Joshua Resnik, *The Ventilator Shortage is Here. The Medication Shortage is Next*, WASH. POST (Apr. 9, 2020), https://www.washingtonpost.com/opinions/2020/04/09/ventilator-shortage-is-here-medication-shortage-is-next/ [https://perma.cc/KPB4-6J5Y]. A race among countries raised ventilators prices, which after a short time were in shortage. *See id.* Some countries had purchased an immense number of ventilators—much beyond their need—while other countries were struggling with shortages of ventilators. *See id.*

vaccine developers.[195] Such a framework would provide a large pool of vaccines at different prices that could be distributed equitably among all countries based on their buying power. In that respect, it should be noted that the available vaccines might not be perfectly interchangeable, and that countries could buy a mixed package of vaccines for their populations based not only on pricing but also on medical considerations.[196]

2. *Carrots and Sticks*

How to convince all the parties involved—both national governments and vaccine developers—to adhere to the proposed scheme would, of course, be of paramount importance to its success. On the one hand, eliciting vaccine developer fidelity to the scheme could be (relatively) straightforward, as there are a number of carrots that could be dangled in front of them to show how cooperation would be in their best interests. Incentivizing nation states, on the other hand, and in particular the wealthier, more developed countries to cooperate, could require more forceful measures.

One of the main but largely underutilized incentives for vaccine developers to share their technologies is funding agreements. Indeed, a frequent criticism of vaccine developers such as Moderna is that they have received billions of dollars in funding from various governmental and nongovernmental entities and yet none of these funding entities has thus far shown a willingness to capitalize on the agreements to pressure developers into sharing the fruits of that funding more widely. The U.S. government, for example, could exercise its march-in rights or, where applicable, its joint ownership rights to COVID-19 vaccine technologies that it has funded, but the United States has not even broached the subject, possibly because it has little incentive to help others outside of the United States. Although the WHO's C-TAP initiative exhorts the funders also to include vaccine accessibility provisions in their funding agreements,[197] C-TAP has little or no

195. This mechanism should not be confused with national regulation of prices in the pharmaceutical sector, which is a common practice in many countries. *See, e.g.*, Difei Geng & Kamal Saggi, *Optimal Price Regulations in International Pharmaceutical Markets with Generic Competition*, 71 J. HEALTH ECON., 1 (2020) (discussing two different pharmaceutical price regulation models common in EU countries). Regulation of prices in the pharmaceutical sector has long been criticized for disincentivizing innovation and for failing to achieve greater access to medicines. *See, e.g.*, Carmelo Giaccotto, Rexford E. Santerre & John A. Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195 (2005); Emma Boswell Dean, *Who Benefits from Pharmaceutical Price Controls? Evidence from India* (CGD Working Paper No. 509, 2019), https://www.cgdev.org/publication/who-benefits-pharmaceutical-pricecontrols-evidence-india [https://perma.cc/DX98-LNZH]. In contrast, the proposed scheme regulates vaccines prices but is based on global revenues and is aimed at incentivizing the industry; its primary goal is to encourage affordable access to vaccines in all countries through its centralized global structure.

196. Vaccines may vary in their compatibility with different user profiles, considering various factors such as side effects, pre-existing diseases, effectiveness in different age groups, and more.

197. WHO, *supra* note 167, at 2; *COVID-19: Countries Support 'Once-Stop Shop' to Share Science and Research*, UN NEWS (May 29, 2020), https://news.un.org/en/story/2020/05/1065132 [https://perma.cc/H674-XY5R].

power to mandate such provisions, much less enforce them. Perhaps more importantly, neither national governments nor public-private partnerships have the power to control global vaccine pricing or other measures to guarantee adequate returns on vaccine R&D. Commercial vaccine developers, therefore, undoubtedly balk funding provisions mandating that they share intellectual property or other know-how.

The centralized authority in our proposal, by contrast, will have power to differentially price vaccine supplies according to not only each country's capacity to pay but also according to what would yield adequate returns for each vaccine developer. Vaccine developers accordingly will be much less hesitant to work with the proposed authority. And because the proposed scheme would be a permanent fixture within the WTO and the TRIPS Agreement, organized well ahead of time and ready to spring into action immediately upon the WHO's declaration of a global pandemic, all potential vaccine developers will know that they can seek funding and other assistance from the authority and will know exactly on what terms they can do so. Structuring a pandemic response authority well ahead of any need will also reduce transaction costs and save precious time. This early and public establishment of structure is important, as recognized by the WHO.[198] Most importantly, the centralized authority would have the sole power to negotiate funding and technology transfer agreements with vaccine developers, which would include provisions requiring tech transfer. And with global vaccine access as its sole mission, unlike national governments, the authority would have no other potentially conflicting interests to prevent it from negotiating and enforcing such agreements.[199]

While vaccine developers would thus have numerous reasons to work willingly with the proposed scheme, individual nation states would admittedly be more difficult to entice, despite the obvious advantages of protecting themselves from the emergence of potentially more virulent variants of a pandemic's infectious agent. The global scheme offered here, therefore, would by necessity include some punitive measures to discourage violation of or defection from the scheme's stipulations. One of the most obvious of these would be the WTO's existing enforcement mechanisms.

By placing the proposed global procurement vaccination initiative within the WTO, the scheme can take advantage of the fact that the WTO is one of the strongest global players with a similarly strong scheme to enforce its agreements. The WTO's system for binding third-party adjudication of disputes between sovereign states, adopted in 1994, is considered one of the most important pillars of the multilateral trading system, and a very effective one at that.[200] The WTO dispute settlement process is man-

198. WHO, *supra* note 167, at 3.

199. Selam Gebrekidan & Matt Apozzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. TIMES (Mar. 21, 2021), https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html [https://perma.cc/U5B9-AY2C].

200. Arie Reich, *The Effectiveness of the WTO Dispute Settlement Mechanism: A Statistical Analysis*, in TRANSNATIONAL COMMERCIAL AND CONSUMER LAW: CURRENT TRENDS IN BUSINESS LAW (Arie Reich, Mary Hiscock & Toshiyuko Kono eds., 2018).

aged by its Dispute Settlement Body (DSB), which appoints panels for each dispute, and compliance with DSB-recommended resolution of these disputes is around 80%.[201] Like our proposed vaccine procurement scheme, the WTO's dispute resolution process is both exclusive and compulsory.

However, the WTO's dispute settlement mechanism would, by itself, be insufficient for the proposed global vaccine scheme. The only penalties for failure to comply are suspension of WTO concessions and economic retaliation by the complaining member state. Moreover, the timetable set by the agreement establishing dispute resolution procedures runs from twelve to fifteen months, and in practice these periods average closer to two years. However, a recent empirical study showed that the most developed countries tended to be the most common parties to dispute resolutions, both as complainants and respondents. Least developed countries may not be able to afford the expense of the process or may fear the political reprisals of availing themselves of it.

An even more effective enforcement mechanism specific to our proposal, however, would leverage the centralized coalition's monopsony power to deter defection from the scheme. To wit, because our centralized system will sign pre-commit agreements with as many vaccine development projects as have a reasonable likelihood of success, it can corner the market, so to speak, on global supplies of vaccines. Rather than using this market power to raise vaccine prices, the proposed vaccine authority can instead include exclusivity provisions in its agreements with vaccine developers, prohibiting them from selling to any buyers outside of the proposed system. Countries that defect from our proposed global regime would have to negotiate procurement on their own but would face great difficulties in doing so because our centralized system would already have contracts with most vaccine developers.

III. Potential Criticisms of the Model and Comparison with Alternatives

The proposed vaccine procurement scheme is admittedly an ambitious one. Developed and wealthy countries may well object to the scheme and to its compulsory licensing provisions in particular; even if they did not, the power differentials between countries and unforeseen consequences could all reduce the scheme's effectiveness. Existing alternatives such as patent pools and public-private partnerships may seem more viable ways of rectifying the vaccine shortage. This section addresses these criticisms and shows that the proposed scheme would be much more effective in both incentivizing vaccine development and production and in assuring equitable and affordable access to them.

201. *Id.* at 22.

A. Potential Criticisms

1. Resistance to the Concept of Compulsory Licensing

To create the proposed global scheme and to amend TRIPS accordingly would require support of three-fourths of the WTO Members.[202] Garnering such support could face significant obstacles, however.

For one thing, compulsory licenses have rarely been employed in pharmaceutical contexts,[203] due largely to the fact that compulsory license applications are frequently subject to heavy resistance domestically and internationally. For example, Thailand's use of compulsory license in the pharmaceutical sector met with heavy opposition from different players,[204] even though Thailand appears to have acted within the parameters of the TRIPS Agreement. Moreover, while some countries have stated that they would use the Article 31*bis* exception in national emergencies or other circumstances of extreme urgency, some developed countries have committed not to invoke Article 31*bis* to import patented products, potentially undermining the fundamental objective of Article 31*bis* to level the playing field among countries of vastly different economic means.[205] For example, although India is often thought of as the generic manufacturer for the world and, therefore, the country most likely to avail itself of compulsory licenses, India's Patent Controller has repeatedly denied compulsory license applications to enable the exportation of patented drugs to develop-

202. Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 154, at art. IX (1994).

203. Colpaert, *supra* note 150.

204. Kevin Outterson, *Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31*bis, *in* RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES 673 (Carlos M. Correa, ed., 2010); *see* Editorial, *Bangkok's Drug War Goes Global*, WALL ST. J. (Mar. 7, 2007), https://www.wsj.com/articles/SB117322181443628799 [https://perma.cc/WU5P-93U4]; Martin Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, INTELL. PROP. WATCH (Mar. 19, 2007), https://www.ip-watch.org/2007/03/19/in-clash-with-activists-critics-charge-thailand-violation-of-trade-rules [https://perma.cc/6VC6-LLZU]; *Abbott To Stop Launching New Drugs in Thailand in Response to Country's Compulsory License for Antiretroviral Kaletra*, KAISER HEALTH NEWS (Mar. 14, 2007), https://khn.org/morning-breakout/dr00043558/ [https://perma.cc/2NTB-VF9E]; Amy Kazmin & Andrew Jack, *Thai Government to Break Drug Patents*, FIN. TIMES (Jan. 25, 2007), https://www.ft.com/content/6889bbbc-ac98-11db-9318-0000779e2340 [https://perma.cc/YNF4-T93A]; Apiradee Treerutkuarkul, *Talks with Pharma-Giants Collapse, CL Seems a Certainty*, BANGKOK POST (Dec. 18, 2007); Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition*, 48 VA. J. INT'L L. 211 (2007); Kevin E. Noonan, *Worldwide Drug Pricing Regime in Chaos*, PATENT DOCS BLOG (May 9, 2007); Kevin E. Noonan, *The Law of Unintended Consequences Arises in Applying TRIPS to Patented Drug Protection in Developing Countries*, PATENT DOCS BLOG (May 1, 2007); Kevin Outterson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines in Developing Countries*, 27 HEALTH AFF. 130, 133–34 (2008). *See also* Press Release, Médecins Sans Frontières, Abbott Should Reconsider its Unacceptable Decision to Not Sell New Medicines in Thailand (Mar. 23, 2007), https://msfaccess.org/abbott-should-reconsider-its-unacceptable-decision-not-sell-new-medicines-thailand [https://perma.cc/FV3E-ADZC].

205. *Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, WTO, https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm [https://perma.cc/88MB-4AGJ].

ing countries.[206] Because of this opposition, implementation of compulsory license legislation has been slow in both affluent, exporting countries and economically disadvantaged, importing countries.[207]

To make matters worse, the United States—a prominent exporter of medicines and other products protected by intellectual property—and the EU have pursued a policy of negotiating bilateral agreements that require protections in excess of the TRIPS standards, thus termed "TRIPS-plus" agreements.[208] These TRIPS-plus standards are of a particular concern for Southern Countries because they may prevent use of TRIPS flexibilities for tackling health crises[209] or lead to a rise in medicine prices.[210] Some of these TRIPS-plus agreements include restrictions on the use of compulsory licenses.[211] Even within its own borders, moreover, the U.S. government has thus far refused to exercise its own march-in rights. This reluctance attests to the strength of the pharmaceutical industry lobby in the United States and its influence over both domestic and foreign trade negotiations.

As COVID-19 has shown, however, pandemics are just different. The enormous size of the market, the urgent need for immediate large-scale production, and the inability of individual pharma companies to meet that need mean that the commercial pharmaceutical industry has much more to gain from cooperation and coordination than from dogmatic assertion of proprietary rights. This can be seen from the willingness of companies such AstraZeneca and Johnson & Johnson to license their respective vaccine technologies to follow-on manufacturers.[212] And if they could be assured of reasonable returns on their vaccine R&D, commercial pharmaceutical industries might be even less resistant to the idea of a global licens-

206. Miriam Marcowitz-Bitton & Yotam Kaplan, *Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution*, U.C. IRVINE L. REV. at 36 (forthcoming 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3855033 [https://perma.cc/H6MR-JSAC]; C.H. Unnikrishnan, *Natco Withdraws Plea on Making Patented Cancer Drugs*, MINT (Sept. 11, 2008), https://www.livemint.com/Companies/ptTTNsQ4InCP8Y8avJ305J/Natco-withdraws-plea-on-making-patented-cancer-drugs.html [https://perma.cc/J22Q-CXZC].

207. Cornides, *supra* note 1211, at 75.

208. *See, e.g.*, Henning Grosse Ruse-Khan, *The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?*, 18 J. INTELL. PROP. L. 325, 330 (2011) (discussing TRIPS-plus standards). For a thorough review of bilateral "TRIPS-plus" agreements, see Jean-Frédéric Morin & Jenny Surbeck, *Mapping the New Frontier of International IP Law: Introducing a TRIPs-plus Dataset*, WORLD TRADE REV. 1–3 (Jan. 10, 2020), https://ssrn.com/abstract=3517290 [https://perma.cc/3R3A-7YBS]; Shadlen et al., *supra* note 38, at 75–81.

209. Charles T. Collins-Chase, *The Case against TRIPS-Plus Protection in Developing Countries Facing Aids Epidemics*, 29 U. PA. J. INT'L L. 763, 783–85 (2008) (discussing the case against TRIPS-plus standards for developing countries facing epidemics such as HIV).

210. Shadlen et al., *supra* note 38, at 81–85 (discussing the effect of TRIPS-plus agreement on the prices of medicines in developing countries).

211. *Id.* at 83–84 (reviewing thirteen bilateral agreements initiated by the United States, three of which [with Australia, Jordan, and Singapore] contained some restrictive measures that "substantially circumscribe countries' ability to use" the compulsory license tool).

212. Keith, *supra* note 170.

ing structure in times of global pandemics. They, therefore, may refrain from lobbying against participation by economic superpowers such as the United States and the EU.

2. Reluctance to Commit to International Coordination

A second obstacle is that a global agreement of any kind is an ambitious objective, and national governments—particularly those of developed nations likely to perceive themselves as certain "winners" in any vaccine race—may be reluctant to commit to a regime that requires them to subsidize poorer nations for fear of compromising their own national interests. In fact, both wealthy and middle-income countries refused to take part in early negotiations over vaccines.[213] Recent developments in the WTO likewise highlight the North-South divide. On October 2, 2020, India and South Africa sent a proposal to the WTO, asking for a waiver of intellectual property rights, including not only to patents but also to trade secrecy, cell lines, and other proprietary resources to address COVID-19.[214] Although this proposal could not be enforceable in any sense, the United States and other developed countries opposed it.[215]

As explained above, however, "vaccine nationalism" is ultimately short-sighted, as inoculation gaps anywhere in the world jeopardize the ability of all nations to protect their citizens. Indeed, the current pandemic exemplifies the futility of nationalistic pandemic responses based on narrow, short-term economic interests. Moreover, the COVID-19 vaccine shortages observed in the United States and the EU illustrate that even the developed world is not well-served by the current approach. Countries like Australia and Canada have highly developed economies, but they are importers rather than exporters of pharmaceutical products. Scientific and experiential evidence confirming that a global approach best serves the interests of all countries may encourage the international community to overcome disagreements, bridge conflicting interests, and generate a global platform for handling the next health crisis.

We already see evidence of this happening. Over seventy-eight of the wealthiest countries had joined COVAX by September of 2020,[216] and in a

213. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 185.

214. Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from India and South Africa*, WTO Doc. IP/C/W/669 (Oct. 2, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W669.pdf&Open=true [https://perma.cc/226M-X2NK] [hereinafter Council for Trade-Related Aspects of Intellectual Property Rights, *India and South Africa*]; *see also* Southey, *supra* note 79; Ellen 't Hoen, *COVID-19 Crisis and WTO: Why India and South Africa's Proposal on Intellectual Property is Important*, THE WIRE (Oct. 12, 2020), https://thewire.in/law/COVID-19-crisis-wto-intellectual-property-vaccine-public-health [https://perma.cc/8RQT-QN8D].

215. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Advance Minutes of Agenda Item 15 of the Meeting Held in the Centre William Rappard on 15-16 October 2020* at ¶¶ 19, 21, WTO Doc. JOB/IP/41 (Nov. 5, 2020), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/Jobs/IP/41.pdf&Open=true [https://perma.cc/8JX4-VP6N]; Gebrekidan & Apozzo, *supra* note 199.

216. Berkeley, *supra* note 175.

movement toward "vaccine diplomacy," several countries have separately promised to provide either vaccines or funding for other countries.[217] At the 2021 Quadrilateral Security Dialogue summit, the Biden administration from the United States, along with leaders from Australia, India, and Japan, have vowed to supply more than one billion vaccines to poorer countries throughout Asia and the Pacific by the end of 2022 and to expand vaccine production through India's Biological E manufacturing company.[218] Given the growing awareness of the developed world that pandemics require global solutions and their recent willingness to overcome their nationalistic instincts, an attempt now to implement the kind of centralized vaccine scheme proposed here might well succeed.

3. Bargaining Asymmetries

One significant potential drawback to the proposed centralized regime is that the bargaining power of WTO and TRIPS member states differs significantly, with developed, wealthy countries dominating negotiations and terms of agreements. The negotiation history of the TRIPS Agreement exemplifies this point. During the negotiations, developed countries, such as the United States, Canada, and Japan, as well as the European Communities (EC), advanced their own objectives, including provisions requiring that pharmaceuticals be patentable, despite the fact that countries such as China and India were not at the time allowing patents on pharmaceutical products.[219] The United States also insisted on protecting clinical trials and other regulatory data from disclosure.[220]

The most contested issue during the TRIPS negotiations was the intense North-South debate on compulsory licenses. Developing countries wanted to secure the use of these licenses.[221] The United States, the EC, Japan, and Switzerland, among others, proffered a transparent process regarding the issuance of a compulsory license, with recourse to judicial review of that decision available to the patentee, and payment of appropriate remuneration.[222] Limitations on the use, scope, and duration of compulsory licenses also had strong support. After considerable discussion, negotiators were able to propose conditions on compulsory licensing involving concepts of "national emergency," "circumstances of extreme urgency," and "public noncommercial use" to provide flexibility and serve as the basis for a waiver of the requirement for prior negotiations on a

217. Gebrekidan & Apozzo, *supra* note 199.

218. Fact Sheet: Quad Summit, WHITE HOUSE (Mar. 12, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/12/fact-sheet-quad-summit/ [https://perma.cc/73VP-KN6C].

219. Piragibe dos Santos Tarragô, *Negotiating for Brazil*, *in* THE MAKING OF THE TRIPS AGREEMENT: PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS 239, 243 (Jayashree Watal & Antony Taubman eds., 2015).

220. Catherine Field, *Negotiating for the United States*, *in* THE MAKING OF THE TRIPS AGREEMENT, *supra* note 219, at 129, 140–44

221. Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, *in* COMPULSORY LICENSING, *supra* note 81, at 43, 47.

222. Field, *supra* note 220, at 143.

voluntary license.[223]

Many scholars, however, argued that the TRIPS negotiations were essentially a North-South negotiation, in which the South was for the most part the weaker party and ineffective in advancing its goals.[224] In many cases the North presented a united front in the negotiations.[225] And as reflected in the many "TRIPS-plus" and free-trade agreements that the United States and others have negotiated since the TRIPS Agreement, the pattern of developed countries dominating negotiations with less developed countries to the detriment of the latter has continued. The effects of these bargaining asymmetries could heighten during a global emergency such as a pandemic and could imperil how equitably our proposed central authority decides not only differentiated funding from countries but also optimal distribution of limited vaccine supplies.

Yet, developing countries have had some success in pushing back against the developed world. When developing countries were united during TRIPS negotiations, for example, they managed to achieve their goals to some extent.[226] For one thing, the very fact that compulsory licensing provisions were included in TRIPS was something of a concession for the United States and other developed countries in what they saw as a trade-off for strengthened patent rights in other ways.[227] Similarly, developing countries managed to push for exceptions to patent eligibility for *ordre public* and diagnostic, therapeutic, and surgical methods and other "flexibilities."[228] And after the TRIPS negotiations, developing countries have been able to guarantee themselves some continued flexibilities in subsequent trade agreements.[229] Thus, although inequality in bargaining power will undoubtedly play a role in the proposed global vaccine scheme, developing and less developed countries will have some power to protect their interests, particularly if they negotiate *en bloc*. Perhaps more importantly, even if developed countries would continue to dominate the proposed vaccine scheme in much the same way that they have dominated other international agreements, the result would unquestionably be better than the vaccine nationalism that we see now.

4. The Wisdom of Implementing Technology-Specific Laws

Technology-specific approaches to law are often criticized for their administration costs, the issues of public notice and clarity that they raise, and their vulnerability to rent-seeking and other unforeseen consequences.[230] As noted in the previous section, the global vaccine scheme

223. *Id.*
224. Jayashree Watal, *Patents: An Indian Perspective*, *in* THE MAKING OF THE TRIPS AGREEMENT, *supra* note 219, at 295, 301.
225. *Id.*
226. *Id.* at 300.
227. Field, *supra* note 220, at 140.
228. *Id.* at 144.
229. Emily Michiko Morris, *Much Ado About the TPP's Effect on Pharmaceuticals*, 20 SMU SCI. & TECH. L. REV. 135, 163 (symposium issue) (2017).
230. Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 763–64.

proposed here could be subject to bargaining asymmetries, agency capture, and consequent "rent-seeking" in the form of nationalistic self-serving. Disputes could erupt over differential funding and price burdens, what would constitute adequate returns on respective developers' investments in vaccine R&D, safeguards against continued exploitation of licensed rights after the pandemic ends, the composition of the centralized authority, and so on.

Others have called for similar technology-specific licensing schemes for vaccines, however, and such pharmaceutical-specific modifications of intellectual property rights have become *de rigueur* in the last four decades.[231] While attractive in its uniformity, treating all technologies the same creates several obvious problems because not all technologies are the same. The patent system in the United States, for example, has long been described as a "one-size-fits-all" system that measures all technologies by the same standards of patentability and grants them all the same duration and scope of protection, regardless of how pioneering or minor or how costly or inexpensive they were to develop. The consequent lack of tailored incentives means that some technologies are "over-incentivized" in that wastefully inefficient resources are invested in innovations of little additional social value. At the same time, other technologies are so under-incentivized that sorely needed technologies such as new antibiotics—or new vaccines—will receive little investment because they simply are not profitable enough under the current patent system.

Perhaps more to the point, it is not clear that any problems, foreseen or unforeseen, that might arise from the proposed scheme would be nearly as deleterious as what we have now with unchecked vaccine nationalism. A comprehensive global partnership, whatever disagreements or strategic gamesmanship it may engender, would surely be a vast improvement over the naked nationalistic self-interest that now limits and controls vaccine supplies.

B. Comparison to Other Proposals

1. Existing TRIPS or Domestic Compulsory Licensing Provisions

In the COVID-19 vaccine race, pharmaceutical companies will likely exploit patents to price their vaccines profitably, and vaccines may not be accessible and affordable to developing and least developed countries as a result.[232] Thus, it is equally foreseeable that many countries will issue compulsory licenses to overcome this challenge. In some ways this is very similar to the approach proposed here.

However, the current procedures for compulsory licensing under the TRIPS Agreement or under existing domestic laws are both burdensome and time-consuming. Most require some level of negotiation with the IP rights holder before a compulsory license can be imposed, and the transaction costs of negotiating licenses for every country that might need one

231. *Id.* at 762.
232. Akl, *supra* note 82, at 204.

would be prohibitive. It bears recalling that for all these reasons, scattered use of compulsory licensing on a domestic level runs counter to the universal interest in widespread, equitable vaccine distribution needed for a pandemic. Global emergencies require a tailored scheme that can cover *all* countries, regardless of any other existing agreements. The proposed global compulsory licensing scheme will not only serve LDCs by effectively providing cross-subsidies, but it will also serve developed countries by fixing a price lower than the price they would have paid under free market conditions. In this way, the proposed model promotes equitable access to vaccines in all countries.[233]

2. Patent Pledges

Another alternative mechanism to make COVID-19 vaccines more broadly available is voluntary patent pledges. Moderna, for example, has declared that it will not enforce its patent rights, although it remains to be seen whether it will uphold this commitment.[234] A similar initiative is the Open COVID-19 Pledge, launched in March 2020, which encourages "commitments made voluntarily by patent holders to limit the enforcement or other exploitation of their patents."[235] A number of influential companies including Facebook, Amazon, Intel, IBM, Microsoft, Hewlett Packard, and the Sandia National Laboratories, have joined the Pledge.[236] The initiative offers standard licenses of three different types that Pledgors can use to address the essential contractual areas for technology licensing.[237] These licenses cover patent rights, copyright rights, or both.[238] Patent holders can choose the specific terms of their license to best serve their interests.[239] While the term of some standard licenses is "until one year after WHO declares the COVID-19 pandemic to have ended,"[240] others will terminate on "January 1, 2023, unless otherwise extended by the Pledgor."[241]

Both types of pledges are unique because they allow patent holders to maintain ownership of their interest while relinquishing some of their rights for a limited time and a limited purpose, demonstrating that altering

233. For a similar stance, see Scherer, *supra* note 148, at 1141 (concluding that "global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than in rich nations.").

234. Shores, *supra* note 51.

235. Contreras, *supra* note 48, at 546; *see also* Rutschman, *The Intellectual Property of COVID-19*, *supra* note 152, at 17.

236. *Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19*, Open Covid Pledge, https://openCOVIDpledge.org [https://perma.cc/7B6A-8EJ9] (last visited Oct. 3, 2022).

237. *About the Licenses*, Open Covid Pledge, https://opencovidpledge.org/licenses/ [https://perma.cc/38XK-RXKJ] (last visited Oct. 3, 2022).

238. *Id.*

239. Rutschman, *The Intellectual Property of COVID-19*, *supra* note 152, at 19.

240. *See, e.g.*, *OCL-PC v1.0*, Open Covid Pledge (Mar. 31, 2020), https://openCOVIDpledge.org/v1-0/ [https://perma.cc/8DBC-CRCW].

241. *See, e.g.*, *OCL-PC v1.1*, Open Covid Pledge (Apr. 17, 2020), https://openCOVIDpledge.org/v1-1-ocl-pc/ [https://perma.cc/UKT2-HWJQ].

licensing protocols can promote technology transfer for the improvement of public health *within* the dynamics of intellectual property.[242] Some philanthropic groups have advocated this approach,[243] for which there is some precedent.[244] China's president also has pledged to make a potential Chinese COVID-19 vaccine a global public good.[245]

Nevertheless, the major drawback of all these initiatives is that they are voluntary. The ability to contend with public health emergencies should not depend on the altruism of individual IP owners, as access to safe and effective vaccines by all countries should not be subject to the vicissitudes of private philanthropy.[246] Only two players in the vaccine industry—Moderna and the open-source vaccine group RaDVaC—have taken the pledges.[247] In addition, such pledges promise only to license patent and copyright rights and do not include the trade secrets, tacit knowledge, rights of reference to data, and other resources necessary to produce complex inventions like vaccines.[248] As such, patent pledges do not offer the kind of organized, consistent, and reliable framework capable of addressing the persistent challenges of ensuring equitable and affordable access to vaccines. Our model offers a more promising, stable, and consistent way to address these concerns globally.

3. *Patent Pools*

Licensing pools such as Unitaid's "Medicines Patent Pool," a "one-stop-shop where licenses for multiple products are available for interested generic manufacturers,"[249] represent another type of voluntary initiative that could be used to stabilize vaccine supply and reduce prices. The WHO defines a patent pool as "an agreement between two or more patent owners to license one or more of their patents to one another or to third

242. Rutschman, *The Intellectual Property of COVID-19*, *supra* note 152, at 19.

243. *COVID 19 Action for Access Campaign*, MEDECINS SANS FRONTIERES (May 20, 2020), https://msfaccess.org/COVID-19-action [https://perma.cc/RRF7-D9XF]; Tung Thanh Le et al., *The COVID-19 Vaccine Development Landscape*, 19 NAT. REV.: DRUG DISCOVERY 305–06 (2020), https://www.nature.com/articles/d41573-020-00073-5 [https://perma.cc/ZC5K-7JRP].

244. *See, e.g.*, Eric Wesoff, *Tesla's Elon Musk Declares 'All Our Patent Are Belong to You'*, GREENTECH MEDIA (June 13, 2014), https://www.greentechmedia.com/articles/read/teslas-elon-musk-declares-all-our-patent-are-belong-to-you [https://perma.cc/WSZ2-FVUC].

245. Xinhua, *China's COVID-19 Vaccine to Become Global Public Good When Available: Xi*, XINHUANET (May 18, 2020), http://www.xinhuanet.com/english/2020-05/18/c_139066851.htm [https://perma.cc/LW6L-UZFX].

246. Joshua D. Sarnoff, *COVID-19 Highlights Need for Rights to Repair and Produce in Emergencies* 2 (May 19, 2020), https://ssrn.com/abstract=3636551 [https://perma.cc/K69K-283J], http://dx.doi.org/10.2139/ssrn.3636551 [https://perma.cc/B8DY-M8EZ].

247. Jorge Contreras, *Deconstructing Moderna's COVID-19 Patent Pledge*, BILL OF HEALTH (OCT. 21, 2020), https://blog.petrieflom.law.harvard.edu/2020/10/21/moderna-covid19-patent-pledge/ [https://perma.cc/MF62-J4WM].

248. *Id.*; Jorge Contreras et al., *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUS. L. REV. 61, 82–83 (2019).

249. *Unitaid's Approach to Intellectual Property*, UNITAID (Dec. 2016), http://unitaid.org/assets/Unitaids-approach-to-intellectual-property.pdf [https://perma.cc/3V79-EF5J].

parties."[250] Under negotiated terms and conditions, patent owners may permit certain follow-on manufacturers to produce and sell their vaccines in poorer countries that would otherwise face shortages due to the high prices of patent-protected vaccines.[251]

The WHO's COVID-19 Technology Access Pool (C-TAP), formed in May 2020, includes thirty-five countries and several international organizations to date.[252] Although commonly referred to as "patent pools," as noted above, C-TAP covers much more than just patent rights. C-TAP promotes public disclosure of clinical trial data as well as gene sequencing research; agreements that mandate equitable distribution of treatments and vaccines; licensing to a range of manufacturers and distributors and "open innovation models and technology transfer that increase local manufacturing and supply capacity; and expediting R&D by signaling to scientists, leaders, and funders early on that a patent committed to the pool indicates that the underlying technology or method can be licensed.[253] And although the United States has generally opted not to join international collaborative frameworks,[254] the Patent and Trademark Office has created a voluntary program—Patents 4 Partnerships[255]—to facilitate the licensing of patented technologies relevant to treating COVID-19, as well as a searchable platform—the IP Marketplace Platform[256]—that provides access to a centralized list of patents and patents applications. These

250. *Patent Pools and Antitrust—A Comparative Analysis*, WORLD INTELL. PROP. ORG (2014), https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf [https://perma.cc/VF65-2ZT8]; *see also* Ryan Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry*, 70 J. ECON. HIST. 898, 898 (2010); 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 124, 129 (Rochelle C. Dreyfuss et al., eds., 2010); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in INNOVATION POLICY AND THE ECONOMY 119, 123 (Adam Jaffe et al., eds., 2001); Michael J. Madison et al., *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657, 660–61, 681–90, 700–06 (2010); Jean Tirole & Josh Lerner, *Efficient Patent Pools* 2 (Nat'l Bureau of Econ. Res., Working Paper No. 9175, 2002); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM, 141, 216–20 (2004).

251. Tham & Finlay, *supra* note 88, at 22–23.

252. *COVID-19 Technology Access Pool*, WHO, *supra* note 161; UN NEWS, *supra* note 197.

253. *WHO Director-General's opening remarks at the media briefing on COVID-19*, WHO (May 29, 2020); *see also* Muhammad Zaheer Abbas, *Treatment of the Novel COVID-19: Why Costa Rica's Proposal for the Creation of a Global Pooling Mechanism Deserves Serious Consideration?*, 7 J.L. & BIOSCIENCE 1, 2 (2020); *see also* 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 371, 381–82 (Rochelle C. Dreyfuss et al., eds. 2010).

254. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 181.

255. *Patents 4 Partnerships: Inventions*, U.S. PAT. & TRADEMARK OFF., https://developer.uspto.gov/ipmarketplace/search/patents [https://perma.cc/K7WT-JMEX] (last visited Oct. 3, 2022).

256. *IP Marketplace Platform*, U.S. PAT. & TRADEMARK OFF., https://developer.uspto.gov/ipmarketplace/search/patents [https://perma.cc/6S3H-WYB6] (last visited Oct. 3, 2022).

resources are intended to reduce transaction costs and expedite R&D. To date, there are over 300 patents listed as available for licensing.[257]

Inventors may also volunteer to join a FRAND (Fair, Reasonable and Non-Discriminatory) group to be deemed an "essential" company by a standard-setting organization.[258] In return, these inventors commit to making their patents available on fair terms.[259] Currently, these licensing systems include only telecommunication companies. Extending this system to cover medical technologies such as vaccines for use in global emergencies would obviate the need for governments to intervene by issuing compulsory licenses. Moreover, this approach could draw on authoritative and independently produced lists of essential medical technologies—such as the WHO's List of Essential Medicines[260]—to determine which patents should be deemed "essential."[261]

Through these measures, patent pooling arrangements undoubtedly facilitate access to emerging vaccines. Nevertheless, they are an incomplete solution to problems of supply and distribution inequalities. Again, as with patent pledges, participation in patent pools is voluntary, which limits their magnitude and diversity.[262] To date no vaccine developer has joined C-TAP, and developed countries have ignored C-TAP's call to include equitable distribution clauses in their contracts with developers.[263] Key players in pharmaceutical R&D, such as the International Federation of Pharmaceutical Manufacturers & Association, also have been reluctant to join a voluntary COVID-19 product pool.[264]

4. Waivers of Intellectual Property Rights

India and South Africa proposed that the WTO ask for waivers from certain provisions of the TRIPS Agreement for the "prevention, contain-

257. *About the Platform*, U.S. PAT. & TRADEMARK OFF., https://developer.uspto.gov/ipmarketplace/search/platform [https://perma.cc/M84L-SC6E] (last visited Oct. 3, 2022).

258. Justine Pila, *Reflections on a Post-Pandemic European Patent System*, EIPR 15–16 (forthcoming 2021).

259. *See* Case C-170/13, Huawei Technologies Co. Ltd. v. ZTE Corp., ECLI:EU:C:2015:477 (July 16, 2015).

260. *See WHO Model Lists of Essential Medicines*, WHO, http://www.who.int/medicines/publications/essentialmedicines/en/ [https://perma.cc/MY25-TRHT] (last visited Oct. 3, 2022).

261. Pila, *supra* note 258, at 18.

262. *See* Contreras, *supra* note 48, at 546.

263. *See* Gebrekidan & Apozzo, *supra* note 199; Rutschman, *The Intellectual Property of COVID-19*, *supra* note 152, at 15.

264. Chris Dall, *Pharma Execs Say Several COVID Vaccine Options Needed*, CIDRAP NEWS (May 29, 2020), https://www.cidrap.umn.edu/news-perspective/2020/05/pharma-execs-say-several-covid-vaccine-options-needed [https://perma.cc/W86C-ZKDP]; *see also* Ed Silverman, *The WHO Launched a Voluntary COVID-19 Product Pool. What Happens Next?*, STAT (May 20, 2020), https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/ [https://perma.cc/G8VQ-SP4E] (noting that "the pharmaceutical industry has dismissed the notion [of the patent pool], which underlies concerns that such a project is unlikely to succeed without widespread involvement.").

ment or treatment of COVID-19."[265] The proposed waiver would apply not only to patents but also to trade secrecy, cell lines, and other proprietary resources and would remain in effect until the world's population has developed immunity to the virus.[266] They explained that institutional and legal hurdles prevented developing countries from taking advantage of the flexibilities contemplated by the TRIPS Agreement, particularly the cumbersome and lengthy compulsory license process in Article 31*bis*. They argued that it is urgent that immediate responses for handling COVID-19 "can be put in place on a real time basis."[267] Many developing and least developed countries asked to join this proposal as well, reflecting the despair of these countries over the pandemic.[268] The WHO has subsequently indicated its support for this request.[269]

A number of developed countries, including the United States and those in the EU, have opposed this proposal, however.[270] This is not surprising, given that a waiver of IP rights is equivalent to a royalty-free license. Thus, while the Southern Countries stressed their need for immediate affordable treatment and vaccines, the Northern Countries stressed the need to incentivize the pharmaceutical industry. Nonetheless, considering the growing pressure to adopt a tailored solution to handle the COVID-19 pandemic, it is apparent that developed countries consider global schemes as a sensible solution.

5. Government Incentives and Agreements

Another way to incentivize vaccine development while addressing pricing and access concerns is by using government-issued nonpatent incentives. Nonpatent incentives are critical to vaccine development for several reasons.[271] As noted above, vaccine development typically suffers from

265. Council for Trade-Related Aspects of Intellectual Property Rights, *India and South Africa*, *supra* note 214, ¶ 12.

266. *Id.*; *see also* Hoen, *supra* note 214; Southey, *supra* note 79.

267. Council for Trade-Related Aspects of Intellectual Property Rights, *India and South Africa*, *supra* note 214, ¶¶ 10–11.

268. These include countries such as Jordan, Pakistan, Bolivia, and Egypt. *See* Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa, IP/C/W/669/Rev.1/Add.1 (Aug. 9, 2021); *see* Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa, IP/C/W/669/Add.3 (Nov. 20, 2020); *see* Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa, IP/C/W/669/Add.4 (Dec. 8, 2020); *see* Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa, IP/C/W/669/Add.8 (Jan. 9, 2021); *see also* Hoen, *supra* note 214.

269. Daniel Merino & Gemma Ware, *How Patent Laws Get in the Way of the Global Coronavirus Vaccine Rollout*, THE CONVERSATION (Feb. 18, 2021), https://theconversation.com/how-patent-laws-get-in-the-way-of-the-global-coronavirus-vaccine-rollout-155494 [https://perma.cc/R5GF-49UL].

270. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 215, ¶¶ 19, 21

271. Rutschman, *IP Preparedness for Outbreak Diseases*, *supra* note 55; Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 169, 173; Qiwei Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCE 1, 1 (2020).

underinvestment from the private sector.[272] Government grants, subsidies, tax incentives, annuity exemptions, and prizes are, therefore, regularly used to offset the lack of market incentives for vaccine development.[273]

A similar nonpatent mechanism governments may use to encourage innovation generally, and to speed development of vaccines in particular, is to fund R&D either in return for joint ownership in the intellectual property rights in the resulting innovation or in exchange for preferential use of the innovation.[274] Indeed, one of first COVID-19 vaccines approved for use is the mRNA-1273 vaccine developed by Moderna, following an early-stage research collaboration with the National Institutes of Health (NIH) and later stage government funding of Moderna's clinical trials.[275] Current evidence suggests that the United States government thus might have retained some rights over the vaccine.[276] If so, U.S. patent law would allow the NIH to produce and distribute vaccine doses with a focus on public health rather than profit and could do so without a duty of accounting to Moderna.[277] And even if the NIH does not have joint ownership in the Moderna vaccine, the federal government may still retain "march-in" rights to compel non-exclusive licenses in favor of other manufacturers if Moderna were unable or unwilling to produce sufficient vaccine doses at affordable prices.[278] Nonpatent incentives such as these could also be used to secure commitments to make vaccine-related inventions openly available to the public for use in response to global pandemics such as COVID-19[279] while still allowing them to monetize the inventions in other

272. Rutschman, *IP Preparedness for Outbreak Diseases*, *supra* note 55, at 120; Ouellette & Xue, *supra* note 29, at 1.

273. Doug Lichtman, *The Central Assumptions of Patent Law: A Response to Ana Santos Rutschman's IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV 1268, 1268 (2018); Ouellette & Xue, *supra* note 29, at 1.

274. *See* 15 U.S.C. § 3710(a) (allowing federal agencies to enter into "cooperative research and development agreements"); *see also* 15 U.S.C. § 3710(a)(d)(1) (defining these agreements as "between one or more Federal laboratories and one or more non-Federal parties").

275. Christopher Rowland & Carolyn Y. Johnson, *A Coronavirus Vaccine Rooted in a Government Partnership is Fueling Financial Rewards for Company Executives*, WASH. POST (July 2, 2020), https://www.washingtonpost.com/business/2020/07/02/coronavirus-vaccine-moderna-rna/ [https://perma.cc/UX7U-2Y3J].

276. *See* Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 169, 173; Ed Silverman, *NIH May Own Patents for the Moderna COVID-19 Vaccine; ICER Boosts Recommended Price for Remdesivir*, STAT (June 25, 2020), https://www.statnews.com/pharmalot/2020/06/25/nih-covid19-coronavirus-vaccine-gilead-remdesivir/ [https://perma.cc/6R2R-P5FX].

277. 35 U.S.C. § 262; Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31, at 169, 173.

278. 35 U.S.C. § 203. Moderna has stated that it is on track to produce between 500 million and 1 billion doses annually, however. *See, e.g.*, Eric Sagonowsky, *Moderna Has Started Turning Out COVID-19 Vaccine Doses for Quick Shipment if Approved: CEO*, FIERCE PHARMA (July 15, 2020), https://www.fiercepharma.com/pharma/moderna-has-started-producing-commercial-covid-19-vaccines-at-risk-ceo [https://perma.cc/A2NK-GUDS].

279. OPEN COVID PLEDGE, *supra* note 236.

fields.[280]

Yet, while nonpatent alternatives avoid the problems associated with the monopolistic pricing of patented products, they introduce their own problems. As noted above, this latter mechanism resembles compulsory licensing, but it would require federal intervention of a kind the U.S. government has historically been reluctant to implement.[281] There is also broad agreement that prize and reward systems would present thorny problems of administration.[282] Because a system that rewards inventors with prizes would be susceptible to political influence and agency capture, some mechanism would be required to ensure that prizes are based on the value of the invention to society, rather than on external factors. At the same time, unless offered by a centralized, global authority, prizes and rewards would do little to combat vaccine nationalism. Indeed, it is in part because of the use of government-issued grants and subsidies that developed countries have been able to engage vaccine nationalism. For example, even if the U.S. government has ownership or other rights in Moderna's vaccine, the United States will receive millions of first-preference doses, leaving the rest of the world without recourse.[283]

As the foregoing discussion illustrates, governments can use a variety of non-patent incentives to support innovation, several of which may help to ensure an adequate domestic supply of vaccines for use in times of a global pandemic. Nevertheless, these solutions fail to address, and even exacerbate, inequities among the world's nations, all of which must have access to effective and affordable vaccines given the global reach of the current crisis. Our proposed global compulsory license model, by contrast, encourages innovation while confronting both access and pricing challenges by setting reasonable caps on the profits a patentee can earn.

6. Modifications to Patent Law

Some scholars have proposed amending the patent laws to accommodate them to the imperatives of a global pandemic. The proposed changes range from incentivizing information sharing or narrowing the patent scope for vaccines to denying patent protection for vaccines altogether.

To incentivize information sharing, for example, patent law could allow an extension of the current range of non-prejudicial disclosures, allowing inventors to make their inventions available to the public for a limited period *without sacrificing their novelty*. This proposal has been made with regards to the European Patent system,[284] suggesting that the European Patent Convention 2000 (EPC), Art. 55, will be changed in a way

280. Jorge L. Contreras, *Expanding Access to Patents for COVID-19*, *in* ASSESSING LEGAL RESPONSES TO COVID-19 158 (Scott Burris et al. eds., 2020).

281. *See generally* Ryan Whalen, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015); Rutschman, *The Vaccine Race in the 21st Century*, *supra* note 31.

282. Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1405–06 (2011).

283. *Id.*

284. Pila, *supra* note 258, at 4–5.

that allows inventors to make their inventions available to the public for a limited period without sacrificing their novelty.[285]

Another proposal that has been made is to make the patenting process itself attentive to moral considerations. Under the current system, patent offices around the world determine the patentability of medical technologies (as they do with all inventions) without serious inquiry into the negative distributive effects and adverse humanitarian consequences that patent protection is certain to cause.[286] While under Article 53(a) of the EPC, any member of the public may oppose a grant of a patent on grounds of morality or *ordre public*,[287] the EPO will deny a patent under that section only for inventions universally regarded as immoral.[288] One scholar has proposed expanding the *ordre public* ground for rejecting a patent application to reflect humanitarian considerations.[289] This could be achieved by lowering the burden for establishing an Article 53(a) objection,[290] taking into account the patent's economic and distributive effects when assessing the implications of granting it,[291] and instituting a mechanism for assessing the likely social and humanitarian implications of commercializing an emerging technology.[292] One measure along these lines might be to require applicants to disclose potential disadvantages or negative social consequences of their inventions as part of the application process.[293] Some suggest that patent offices could also deny a manufacturer's patent application by strictly interpreting the application requirements while implicitly preferring more open market access.[294]

These proposals introduce their own challenges. Bringing about legislative changes involving the patentability criteria for vaccines at various regional and international levels is a challenging task and may lead to vigorous opposition in countries with strong pharmaceutical industries. Additionally, incorporating humanitarian considerations into the patenting process, while perhaps a laudable objective, is ill-suited as an approach to addressing the needs of a global pandemic, given that patent offices and patent grants are ill-suited to address immediate needs, and in any event, such a proposal would require the agreement of all nations to modify their patent examination standards. More importantly, these proposals could potentially have a devastating effect on innovation and R&D in the context

285. *Id.* at 4.
286. *Id.* at 13.
287. Convention on the Grant of European Patents, 13 ILM 268, art. 53(a) (2000).
288. T 0272/95 (Relaxin/Howard Florey Institute) of 23.10.2002, EUR. PATENT OFF. (Oct. 23, 2002), https://www.epo.org/law-practice/case-law-appeals/recent/t950272eu2.html [https://perma.cc/X7V5-2L6H]; T 0356/93 (Plant cells) of 21.2.1995, EUR. PATENT OFF. (Feb. 21, 1995), https://www.epo.org/law-practice/case-law-appeals/recent/t930356ex1.html [https://perma.cc/2VBA-CDW2].
289. Pila, *supra* note 258, at 13.
290. *Id.*
291. *Id.*
292. Justine Pila, *Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies*, 38 NAT. BIOTECH. 555 (2020).
293. *See* Pila, *supra* note 258, at 15.
294. *Id.*

of vaccines. For these reasons, a carefully crafted global compulsory license model is a more promising route to ensuring adequate incentives to innovate life-saving pharmaceuticals while minimizing the obstacles patent protection creates to their widespread access.

7. *Public-Private Partnerships*

Public-private partnerships are another voluntary mechanism that may help to speed access to *emerging* vaccines.[295] Through such partnerships, non-profit organizations can provide funding for product development, grant underprivileged populations access to products by purchasing them from manufacturers, or act as negotiators between funders, country-level purchasers, and manufacturers.[296] Several such initiatives have emerged in the context of COVID-19. The Coalition for Epidemic Preparedness Innovations (CEPI) is an initiative funded by several countries and philanthropists that has raised $1.4 billion in support of COVID-19 vaccine R&D.[297] If a CEPI-sponsored vaccine receives market approval, CEPI and its partners project having two to three vaccine manufacturing plants per vaccine, and eight to ten regional distribution sites, for an estimated production capacity of at least two billion doses of vaccine by late 2021.[298] CEPI emphasizes the importance of international collaboration—and the need for expanded modes of international governance—in the development and production of new vaccines.[299]

COVAX, another public-private partnership, is an initiative organized by the WHO[300] in partnership with the World Vaccines Alliance (GAVI).[301] COVAX is integrated into a broader structure known as the "vaccines pillar" of the Access to COVID-19 Tools (ACT) Accelerator, in which CEPI and the WHO play separate but complementary roles. CEPI coordinates vaccine "development and manufacturing," while the WHO oversees "policy and allocation" issues, and COVAX (under Gavi) is

295. *See generally* MARGRET CHON ET AL., CAMBRIDGE HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT (2018); Jon F. Merz, *Intellectual Property and Product Development Public/Private Partnerships*, WHO (May 16, 2005) (focusing on product development partnerships).

296. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 187.

297. *CEPI Enters Into Funding Agreement with Gritstone Bio to Develop COVID-19 Variant Vaccine*, CEPI (Sept. 17, 2021), https://cepi.net/news_cepi/cepi-enters-into-funding-agreement-with-gritstone-bio-to-develop-covid-19-variant-vaccine/ [https://perma.cc/TM8Z-QR77].

298. Julie Steenhuysen, *Vaccine Alliance Finds Manufacturing Capacity for 4 Billion Doses of Coronavirus Vaccines*, REUTERS (June 24, 2020), https://www.reuters.com/article/us-health-coronavirus-cepi-vaccines-excl/exclusivevaccine-alliance-finds-manufacturing-capacity-for-4-billion-doses-of-coronavirus-vaccines-idUSKBN23V3D0 [https://perma.cc/52CK-E7H2].

299. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 181.

300. *See COVAX*, WHO (Sept. 17, 2021), https://www.who.int/initiatives/act-accelerator/covax [https://perma.cc/K2Q3-JNZD].

301. *See COVAX*, GAVI (Sept. 17, 2021), https://www.gavi.org/covax-facility [https://perma.cc/9ANG-2VVH].

responsible for "procurement and delivery at-scale."[302] COVAX offers participants the possibility of placing advance commitment orders for doses of COVID-19 vaccine in exchange for a financial contribution.[303] This provides pharmaceutical companies with an incentive to engage in risky R&D, and countries that have joined COVAX will receive a share of available doses.[304] Mass orders make the vaccine more affordable to countries in COVAX than to countries that choose to negotiate directly with manufacturers.[305] COVAX works with multiple vaccine manufacturers simultaneously,[306] which mitigates the "all the eggs in one basket" problem that is particularly acute in poor countries.[307] Like nationalist approaches, this model relies on advance commitment agreements between governments and manufacturers, but in the case of COVAX, these negotiations are mediated by international third-parties.[308]

These models offer promising results; yet they, too, have disadvantages. While ACT and its components may boost COVID-19 vaccine innovation, it is unknown whether they will outlast the current pandemic. Future outbreaks should be tackled with permanent mechanisms instead of hastily crafted solutions.[309] Indeed, information related to intellectual property developed by these ad hoc partnerships is often "vague."[310] Moreover, despite the success of CEPI, many public-private partnerships—especially those relying on philanthropy—will likely suffer from donor fatigue.[311] There are also numerous asymmetries between the public and the private players.[312] A large breadth of players may also lead to coordination inefficiencies.[313] New collaborative relationships may lead some of the participants to underestimate or miscalculate transaction costs.[314]

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302. *Access to COVID-19 Tools (ACT) Accelerator: Commitment and Call to Action*, WHO (Apr. 24, 2020), https://www.who.int/publications/m/item/access-to-COVID-19-tools-(act)-accelerator [https://perma.cc/4ACM-MYE4] (noting that the collaboration is comprised of "an initial group of global health actors [BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO] and private sector partners and other stakeholders").

303. *An Investment Opportunity*, GAVI (Sept. 17, 2021), https://www.gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf [https://perma.cc/YWQ9-UK5M].

304. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 190.

305. *COVAX Factory Explainer*, GAVI (Sept. 17, 2021), https://www.gavi.org/sites/default/files/2020-06/Gavi-COVAX-AMC-IO.pdf [https://perma.cc/AJJ5-8GJ2].

306. *Id.*

307. Rutschman, *The COVID-19 Vaccine Race*, *supra* note 2, at 191–92.

308. *Id.* at 193.

309. *Id.* at 194.

310. Hilde Stevens et al., *Intellectual Property Policies in Early-Phase Research in Public-Private Partnerships*, 34 NAT. BIOTECH. 504 (2016), https://www.nature.com/articles/nbt.3562?proof=true [https://perma.cc/YF5V-SBJ8].

311. Merz, *supra* note 295.

312. *See generally* NAT'L ACADEMIES OF SCIENCES, THE ROLE OF PUBLIC-PRIVATE PARTNERSHIPS IN HEALTH SYSTEMS STRENGTHENING: WORKSHOP SUMMARY (National Academies Press, 2016); *see also* Liza Vertinsky, *Boundary-Spanning Collaboration and the Limits of Joint Inventorship Doctrine*, 55 HOUS. L. REV. 401, 416 (2017) (describing over-rewarding of private-sector players).

313. NAT'L ACADEMIES OF SCIENCES, supra note 312.

314. Jens K. Roehrich et al., *Are Public-Private Partnerships a Healthy Option? A Systematic Literature Review*, 113 SOC. SCI. & MED. 110, 113 (2014).

It is worth emphasizing that these partnerships are taking on roles that historically have belonged to international organizations and national governments, and the outcome of their novel and ambitious efforts is unknown.[315] Additionally, despite COVAX's professed aim of promoting "equitable access" to vaccines for populations in both developing and developed countries,[316] its current allocation policy distinguishes between self-funding countries, which will receive a sufficient supply of an emerging vaccine for only 20% of their populations, and funded countries, which will receive doses allocated by the WHO.[317] Finally, self-funded countries are encouraged to donate vaccines if they have more than they need,[318] which runs counter to the goal of making vaccines affordable internationally.

Moreover, COVAX is hampered by vaccine nationalism, particularly lack of financial support from and vaccine hoarding by developed nations,[319] and general lack of participation. Of the 136 countries signed up to receive distributions from COVAX, very few of those are among countries with the largest national economies.[320] Because it is not mandatory, it is seen by developed nations as merely a charitable effort on behalf of less developed countries, not a unified effort on behalf of entire world.[321] Lack of authority or power also hampers COVAX's ability to get vaccine manufacturers to commit to supply contracts with COVAX, despite the fact that COVAX provided a good deal of funding to developers such as Moderna.[322] COVAX's lack of compulsory licensing power makes it dependent on the vagaries of developed nations' beneficence.[323]

Conclusion

While "vaccine nationalism" is understandable from the perspective of individual countries desperate to stem the tide of social and economic disaster, national efforts to control the pandemic are senseless from a global perspective. Because COVID-19 knows no political boundaries, short-term, domestic solutions must give way to a long-term, global approach that addresses the universal interest in immediate and affordable access to vaccines.[324] Indeed, the recent emergence of variants to the COVID-19

315. *See, e.g.*, Kenny Bruno & Joshua Karliner, *Tangled Up in Blue: Corporate Partnerships at the United Nations*, CorpWatch (Sept. 1, 2000), https://corpwatch.org/article/tangled-blue [https://perma.cc/3VE8-L652].

316. *COVID-19 Vaccine Global Access (COVAX) Facility: Preliminary Technical Design: Discussion Document* 2, GAVI (June 11, 2020).

317. *World Leaders Make Historic Commitments to Provide Equal Access to Vaccines for All*, GAVI (Sept. 17, 2021), https://www.gavi.org/news/media-room/world-leaders-make-historic-commitments-provide-equal-access-vaccinesall [https://perma.cc/DC49-9FBF].

318. *Id.* at 4.

319. Ravelo, *supra* note 3.

320. Nakkazi, *supra* note 76.

321. Ravelo, *supra* note 3.

322. *Id.*

323. *Id.*

324. OECD, *supra* note 1.

virus underscores the urgency of speedy global action. A simultaneous worldwide effort is imperative.[325]

It can be argued that past experience with international health crises suggests that it is very hard to mobilize the western world to address the health needs of the developing world. Nevertheless, the international community had to take the needs of developing nations into account in return for their joining the TRIPS Agreement. When developing and least developed countries joined the TRIPS Agreements, they undertook major commitments to protect intellectual property rights, including the provision of patent protection to medicines. In return for those commitments, these countries received the benefit of the TRIPS Agreement's different mechanisms addressing public health crises, including compulsory licensing schemes intended to serve those countries interests. In practice, however, whenever those countries wanted to issue compulsory licenses, they were subject to heavy pressure and opposition from the pharmaceutical sector and nations with strong economies such as the United States.

Nevertheless, history has shown us that differentiated pricing schemes can offer more affordable pricing to the developing world while at the same time protecting incentives to innovate. Greater access to medicines can ultimately be achieved by expanding on the flexibilities provided in the TRIPS Agreement framework. The case for inserting provisions to address global pandemic responses within this framework is even stronger because failure to address the needs of the developing world in this context has a direct impact on all nations. These special circumstances make global cooperation more likely.

Whatever the negative perceptions of compulsory licensing or centralized price setting in many developed countries, emergencies such as a global pandemic and public health imperatives require a different balancing of interests, as most countries currently struggling with the pandemic seem to realize. A mandatory global vaccine scheme offers promise as an effective regime for making vaccines affordable and available worldwide. Moreover, experience reveals that compulsory licenses do not necessarily lead to negative effects on research and development, or on foreign direct investment, and that when negative effects are observed, they last only for a short period and do not have long-term effects on innovation. With countries struggling to get access to vaccines worldwide, it is apparent that only a global mandatory compulsory license scheme and a procurement plan can achieve the stated goals of effectively fighting the pandemic.

325. Rutschman, *The COVID-19 Vaccine Race*, supra note 2, at 194.