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# Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution

Miriam Marcowitz-Bitton\* & Yotam Kaplan\*\*

*A safe and effective COVID-19 vaccine is the holy grail of our generation, necessary to resurrect our societies, save millions of lives, and protect our economies from collapse. Patent protection is the primary legal mechanism for ensuring timely development of such a vaccine. The patent system is designed to create the necessary incentives for private parties to invest in developing the vaccine, knowing they will enjoy the fruits of their success. Indeed, patent protection is necessary to promote human knowledge generally as well as a quick, safe, and effective COVID-19 vaccine.*

*Yet in reality, patent law may be obstructing the very goal it is intended to achieve. Patent law grants exclusive rights to inventors, enabling them to charge supracompetitive prices, delaying the distribution and dissemination of emerging technologies. In the context of the COVID-19 vaccine, patent protection means that vaccines will be financially out of reach for many. This produces a paradoxical result: rather than promote technological advancement for the public good, patent protection impedes it. Since universal immunity is necessary in the fight against the pandemic, delays in vaccine distribution can be catastrophic, costing millions of lives and carrying devastating economic consequences.*

*This Article therefore proposes a novel, alternative patent regime, designed to overcome this paradox at the heart of patent law. We propose a mechanism that will eliminate the problem of overprotection of patent rights that exists under current patent law, while still providing sufficient incentive for inventors to invest in innovative efforts. Under our proposed regime, the developer of a new vaccine will be granted a patent protecting its invention, but*

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*this patent will expire once the patentee has recouped its investment, plus a handsome profit. This regime, which we term "recoupment patent," ensures that inventors are rewarded appropriately—but not excessively—for their innovative efforts. The result is a structure that encourages innovation while minimizing the time it takes for life-saving inventions to reach the public domain. We compare the proposed regime with other suggestions for reforming the patent system, including compulsory licensing; government incentives such as grants, subsidies, and prizes; and altruistic initiatives such as private-public partnerships, patent pools, and patent pledges. We highlight the recoupment patent model's advantages over these alternatives.*

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#### INTRODUCTION

As additional doses of the new COVID-19 vaccine are being circulated, we must consider the effects of patent law on our long-term ability to overcome this global crisis. Effective COVID-19 vaccines are at hand, yet to eliminate the pandemic, these vaccines must be swiftly and universally distributed. Quick and effective distribution depends on vaccine prices, which depend in turn on the degree of legal protection provided to inventors and to patent-holders. Control over the vaccines is currently held by a small number of pharmaceutical firms that own the patent rights to them.<sup>1</sup> This narrow control, if not properly managed, could spell a long road to full victory over the COVID-19 pandemic. If patent owners are free to demand supracompetitive prices, this can render the vaccines inaccessible for many, thus critically delaying full population immunity.<sup>2</sup>

Patent law offers inventors a legal monopoly in their inventions,<sup>3</sup> offering them exclusive property rights to use and sell those inventions for a period of twenty

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1. See Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic* 10–11, (LSE L., Soc’y & Econ. Working Paper, Paper No. 06, 2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3851737](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737) [<https://perma.cc/FCY7-W6PE>].

2. *Id.*

3. 35 U.S.C. § 271(a) (stating that once a patent is granted, the patent holder enjoys exclusive rights to make, use, sell, offer for sale, or import the claimed invention).

years.<sup>4</sup> This protection is necessary to incentivize innovation.<sup>5</sup> Indeed, absent protection for their inventions, the pharmaceutical companies that developed the COVID-19 vaccines would have had insufficient incentive to invest in the research and devote the resources necessary to produce these new therapies so quickly. Without patent protection, anyone could copy these efforts, and companies such as Moderna, Pfizer, and AstraZeneca would have no way of securing the fruits of their labor.<sup>6</sup> Thus, on the one hand, the patent system grants a necessary incentive to innovation; on the other, this incentive can come with a heavy price.<sup>7</sup> As pharmaceutical companies now hold a legally sanctioned monopoly over their respective vaccines, they are free to extract high prices from buyers and users, making it difficult for many consumers to purchase those vaccines.<sup>8</sup> This is not to say that patent holders act maliciously; they merely attempt to maximize their profits. Unfortunately, this often means that new drugs are beyond the reach of those who need them the most.

Global health crises such as the COVID-19 pandemic bring into sharp relief the need to calibrate patent law to incentivize effective and welfare-enhancing innovation, while ensuring maximal access to inventive efforts once they are created.<sup>9</sup> As the unrelenting, deadly outbreaks around the world have made clear, time is of the essence; any delay in innovation or distribution is immensely costly to societies worldwide. Current conditions demand patent protections that are optimally calibrated to maximize the public good—and fast.

If patent rights are too weak, pharmaceutical companies lack sufficient incentives to invest in developing a cure or a vaccine. This is not merely a theoretical

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4. The term of patent protection begins on the date the patent is granted and ends on the date twenty years from the date the application was filed, with special extensions available if prosecution of the patent was unreasonably delayed or if regulatory approval of a drug consumed a portion of the patent term. 35 U.S.C. §§ 154(a)(2), 154(b), 156; see also Maayan Perel, *From Non-Practicing Entities (NPEs) to Non-Practiced Patents (NPPs): A Proposal for a Patent Working Requirement*, 83 U. CIN. L. REV. 747, 754 (2015).

5. See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 609 (1962) (explaining the rationales for patent protection).

6. See Christopher A. Cotropia, “*After-Arising*” *Technologies and Tailoring Patent Scope*, 61 N.Y.U. ANN. SURV. AM. L. 151, 168–71 (2005) (explaining the goals of patents protection in terms of offering incentives for innovation); Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129–30 (2004) (highlighting the role of intellectual property rights in protecting investment by innovators).

7. Miriam Marcowitz-Bitton, Yotam Kaplan & Maayan Perel, *Recoupment Patent*, 98 N.C. L. REV. 481, 491–92 (2020) (highlighting the effects of patents in inflicting deadweight loss on society); WILLIAM A. MCEACHERN, *ECONOMICS: A CONTEMPORARY INTRODUCTION* 204–05 (7th ed. 2006).

8. Marcowitz-Bitton et al., *supra* note 7, at 492 (showing how prices can rise under patent protection).

9. *Id.* at 488 (explaining the need to recalibrate patent protection to better serve the goals of technological advancement and the encouragement of innovation).

concern but a very real and very common problem in the pharmaceutical industry.<sup>10</sup> The cost of developing a new drug (including multiple stages of clinical trials) is often estimated in the billions of dollars.<sup>11</sup> When innovation is so costly, the standard patent protection offering a twenty-year monopoly<sup>12</sup> may be too weak.<sup>13</sup> That is, the investment required to develop a specific drug may be so large that a twenty-year patent will not suffice for the inventors to recoup their investment.<sup>14</sup> When that is the case, inventors cannot invest in the necessary research and development (R&D), and the public is left without a much needed cure.

On the other hand, patent protection must not be too strong. A company with absolute control over a patented drug can set high prices that will make the drug unavailable to many. This result is especially unacceptable in the case of the COVID-19 vaccine since widespread immunity is essential to quell the pandemic. Past failures in this connection are all too real, and their consequences all too tragic. A prominent example is the high price of PrEP, an effective HIV treatment.<sup>15</sup> PrEP is a pill that when taken daily is up to ninety-nine percent effective at preventing HIV infection.<sup>16</sup> This is a remarkable success rate,<sup>17</sup> comparable to that of the vaccines that have wiped out formerly deadly diseases like polio or smallpox. Yet, the price of PrEP remains prohibitively high in many places.<sup>18</sup> A monthly supply of PrEP can cost over \$1,600 in the United States—despite production costs of only six dollars.<sup>19</sup> The reason for this shocking discrepancy is that U.S. patent law currently grants one firm, Gilead Sciences, a total monopoly over PrEP, allowing it to extract extremely high rents.<sup>20</sup> In 2018, Gilead made \$3 billion in profits from PrEP sales.<sup>21</sup> These high prices leave PrEP outside the reach of those who need it

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10. See DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 3–4 (2009) (showing that under the existing patent system, pharmaceutical companies often lack sufficient incentive to invest in medical research).

11. See *Research & Development Policy Framework*, PHRMA, <https://www.phrma.org/policy-issues/research-development> [<https://perma.cc/T7G7-6H2E>] (Sept. 30, 2021) (“On average, it takes 10-15 years and costs \$2.6 billion to develop one new medicine, including the cost of the many failures.”).

12. 35 U.S.C. § 154(a)(2).

13. BURK & LEMLEY, *supra* note 10, at 3–4, 136–37.

14. See generally *id.*

15. James Krellenstein, Aaron Lord & Peter Staley, Opinion, *Why Don't More Americans Use PrEP?*, N.Y. TIMES (July 16, 2018), <https://www.nytimes.com/2018/07/16/opinion/prep-hiv-aids-drug.html> [<https://perma.cc/62SZ-NB9G>].

16. *Id.*

17. *Id.*

18. Lenny Bernstein, *This HIV Pill Saves Lives. So Why Is It So Hard to Get in the Deep South?*, WASH. POST (Mar. 11, 2019), [https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a\\_story.html](https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a_story.html) [<https://perma.cc/A5GA-WCNY>].

19. *Id.*

20. Christopher Rowland, *Taxpayers Funded This HIV Research. The Government Patented It. Now a Company Profits*, L.A. TIMES (Mar. 27, 2019, 3:05 PM), <https://www.latimes.com/business/la-fi-gilead-sciences-truvada-hiv-prep-20190327-story.html> [<https://perma.cc/L8F5-87H5>].

21. *Id.*

the most. In the American South, where U.S. infections of HIV are the highest, the use of PrEP is half what it is in the comparatively wealthy Northeast, and its use in Black and Hispanic populations across the United States is a fraction of that among white populations.<sup>22</sup> Thus, despite the availability of a simple HIV preventive, twenty thousand new cases of HIV were diagnosed in the American South in 2017.<sup>23</sup> Patent protection is the crux of the problem: because the patent holder enjoys total control over the drug, it can command prices that generate profits exponentially greater than its investment in R&D.

Unfortunately, if appropriate steps are not taken in advance, and soon, we are likely to find ourselves with a similar problem with respect to COVID-19 treatments and vaccinations. Gilead—the very company that holds the patent for PrEP—also holds the patent rights to Remdesivir, a drug that has shown some promise in treating COVID-19.<sup>24</sup> Now that COVID-19 vaccines are available, it is absolutely crucial that pricing is fair and will allow widespread immunization on a global scale to achieve population immunity as soon as possible. Unfortunately, as we know from the PrEP experience, this is not a given: HIV remains a very real threat in the world's poorer regions, despite the fact that effective medical solutions have existed for years.<sup>25</sup>

This problem has already begun to emerge in the context of COVID-19 vaccines, mainly in the form of “vaccine nationalism,”<sup>26</sup> in which nations compete for maximal access to scarce supplies for their own citizens.<sup>27</sup> On the national level, such efforts are understandable—even admirable—as each government is responsible above all else for the welfare of its own citizens. Yet from a global perspective, these efforts foretell calamity. Vaccine nationalism represents competition over scarce resources, a bidding war among countries fueled by the knowledge that each vaccine is monopolistically held by one inventor, which controls the vaccine's purchase price. Bidding wars necessarily drive prices up, making the vaccine widely available in nations with developed economies but not in developing nations. Given the pandemic's global reach, only global and universal distribution can end it. As things currently stand, the patent system's tendency to offer excessive returns on pharmaceutical companies' investments is likely to prolong the crisis.

The more general nature of the problem is the extreme rigidity of the patent system, which operates on a one-size-fits-all basis. Patent protection allows pharmaceutical companies absolute control over the drugs they develop, allowing

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22. Bernstein, *supra* note 18.

23. *Id.*

24. See Erin K. McCreary & Derek C. Angus, Opinion, *Efficacy of Remdesivir in Covid-19*, 324 JAMA 1041, 1041 (2020).

25. Bernstein, *supra* note 18.

26. Ana Santos Rutschman, *The Covid-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J.L. & POL'Y, 167, 183–87 (2021) (describing the phenomenon of vaccine nationalism in the context of the COVID-19 pandemic).

27. *Id.*

them to extract rents far beyond what is necessary to incentivize investment in innovation *ex ante*.<sup>28</sup> Current patent law includes no safeguards that can effectively guarantee that pharmaceutical companies are offered a fair reward for their efforts—but no more. This level of private control is especially enraging as applied to COVID-19 vaccines, considering the unprecedentedly high levels of public investment in COVID-19 vaccine research<sup>29</sup> and the vaccine’s critical importance to human welfare and socio-economic stability.

Against this backdrop, we propose a recalibration of the patent system and advocate reforms that will better tailor patent protection to the needs of the COVID-19 pandemic (and similar global health challenges that are sure to arise in the future). In particular, based on our previous theoretical work,<sup>30</sup> we propose a novel patent regime that will tailor the duration of patent protection to the level of investment required to create the protected vaccine. This means that COVID-19 vaccines will be patent protected but that those patents will expire once the patent holder recoups its investment and a handsome—but not excessive—profit.

This form of patent allows a precise fit between the level of patent protection and the need to incentivize innovation—a fit that is impossible to devise under current law. Currently, patent protection is a one-size-only product: a twenty-year monopoly right for any and all inventions.<sup>31</sup> Under such a rigid, one-size-fits-all regime, it is inevitable that patent protection will be sometimes too strong and sometimes too weak. Under our proposal, by contrast, the level of patent protection is tailored precisely to the level of investment, plus a measure of profit sufficient to encourage innovation. This regime guarantees that the inventor profits off its investment, but once it has done so, the public’s interest in quick and effective distribution takes over and monopoly protection ceases to exist.<sup>32</sup> This framework can offset problems such as the PrEP disaster described above, where the patentee’s monopoly delays medical advancement far beyond what is necessary to incentivize innovation—and deprives people of life-saving medications in the meantime.

This proposed solution can mitigate many of the problems under current patent law, while maintaining the fundamental features of the patent regime. Our proposed reform is subtler, and therefore more realistically obtainable, than other reform suggestions. Some scholars have proposed partially or completely abolishing the current patent system in favor of a system of state forfeiture, together with

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28. Thambisetty et al., *supra* note 1, at 10 (“The present IP system allows for monopoly power in pricing . . . [which] potentially results in a perverse incentive for COVID-19 vaccine manufacturers, one that does not necessarily favour achieving global equitable access to vaccines.”).

29. *Id.* (reporting a global public sector investment of €85.6 billion in COVID-19 vaccine development and stating that “during the pandemic unprecedented amounts of public funding have gone into vaccine research”).

30. See generally Marcowitz-Bitton et al., *supra* note 7.

31. 35 U.S.C. § 154(a)(2).

32. Marcowitz-Bitton et al., *supra* note 7.

prizes or rewards.<sup>33</sup> The advantage of such a system is that it can offer the inventor a tailored incentive level to ensure that there is ample incentive to invest in medical innovation, without later allowing the inventor to demand high prices from consumers. Yet, because such far-reaching proposals represent a complete overhaul of the existing patent system, they suffer significant disadvantages. Our proposal avoids many of these problems, since it does not suggest abolishing patent protection, but simply tailoring it more accurately to specific cases.

This Article proceeds as follows. Part II provides the scientific background by describing the current race to find a COVID-19 vaccine. This Part explains the patent paradox: patents are granted to induce innovation but at the same time hinder widespread distribution and use of innovation. Part III then offers our novel reform proposal, based on the recoupment model. We explain in detail the operation and application of patent law under this regime, including the different safeguards necessary for its operation. Part IV compares our proposed regime with other reform proposals and highlights the advantages of the recoupment model. We identify other initiatives that have been advanced in the past years and highlight their advantages and drawbacks, grouping them into four major categories as follows: *first* and foremost, compulsory licenses, which are widely perceived as a key solution for addressing access and price challenges in times of pandemics; *second*, government agreements and incentives, such as advance commitment agreements, and various types of government support for vaccine R&D; *third*, voluntary initiatives to enhance vaccine access and affordable pricing, such as patent pools, patent pledges, public-private partnerships, commitments not to seek or enforce patents, and information sharing platforms; and *fourth*, other reforms to patent law and policy. We show that while each of these initiatives can have salutary effects on vaccine pricing and access, they all suffer from drawbacks that compromise their potential to offer stable and consistent means to ensure widespread, equitable distribution of vaccines in times of a global pandemic. Some introduce a high tax on innovation, thus disincentivizing R&D, while others depend on private altruism, thus lacking reliability. We demonstrate that a recoupment patent model avoids these pitfalls and offers a more promising, long-term alternative for what is sure to be a recurring problem in our increasingly globalized world. The Article ends with a short conclusion.

#### I. BACKGROUND: PATENTS IN THE AGE OF COVID-19

This Part provides the background for our proposal by explaining the basic facts of the race to patent a COVID-19 vaccine. We start by providing the medical-scientific background, briefly explaining the stages of vaccine development

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33. See BURK & LEMLEY, *supra* note 10, at 44–45. See generally Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003) (suggesting that a system of rewards can complement existing IP protection); Mark D. Janis, *Patent Abolitionism*, 17 BERKELEY TECH. L.J. 899 (2002) (reviewing the history of patent law reform).

and the types of vaccines currently being developed, and describing the central players in this market. We then move on to describe the legal background against which these actors operate in their efforts to create the different vaccines and the incentive structure the current patent system offers. This Part highlights a central problem—the *patent paradox*—that causes the patent to delay the very technological developments it is intended to promote.

*A. Scientific Background: The Race for the Vaccine*

The COVID-19 virus was first identified in December 2019 in Wuhan, China,<sup>34</sup> with full genome sequencing already available by January 2020.<sup>35</sup> By March 2020, the virus had spread globally, infecting millions and paralyzing economies worldwide.<sup>36</sup> Since then, the race to find a COVID-19 vaccine has been in full swing. The scale of this race is unprecedented, with hundreds of players vying to produce a successful vaccine.<sup>37</sup> As of this writing, there are over 300 discrete development projects for COVID-19 treatments.<sup>38</sup>

Ordinarily, a vaccine is developed through a standard set of phases, spread across long periods of time.<sup>39</sup> In the preclinical testing phase, scientists examine the effectiveness of the vaccine on lab animals to identify an immune response.<sup>40</sup> Then, during Phase 1 safety trials, a small number of people receive the vaccine, mainly to

34. Na Zhu, Dingyu Zhang, Wenling Wang, Xingwang Li, Bo Yang, Jingdong Song, Xiang Zhao, Baoying Huang, Weifeng Shi, Roujian Lu, Peihua Niu, Faxian Zhan, Xuejun Ma, Dayan Wang, Wenbo Xu, Guizhen Wu, George F. Gao & Wenjie Tan, *A Novel Coronavirus from Patients with Pneumonia in China, 2019*, 382 NEW ENG. J. MED. 727, 727 (2020) (describing the first diagnosed cases of COVID-19 infection).

35. See generally Fan Wu, Su Zhao, Bin Yu, Yan-Mei Chen, Wen Wang, Zhi-Gang Song, Yi Hu, Zhao-Wu Tao, Jun-Hua Tian, Yuan-Yuan Pei, Ming-Li Yuan, Yu-Ling Zhang, Fa-Hui Dai, Yi Liu, Qi-Min Wang, Jiao-Jiao Zheng, Lin Xu, Edward C. Holmes & Yong-Zhen Zhang, *A New Coronavirus Associated with Human Respiratory Disease in China*, 579 NATURE 265 (2020) (describing early research identifying the new COVID-19 virus).

36. See generally Maria Nicola, Zaid Alsafi, Catrin Sohrabi, Ahmed Kerwan, Ahmed Al-Jabir, Christos Iosifidis, Maliha Agha & Riaz Agha, *The Socio-Economic Implications of the Coronavirus Pandemic (Covid-19): A Review*, 78 INT'L J. SURGERY 185 (2020) (describing the toll of the COVID-19 pandemic in terms of the number of confirmed cases, the number of deaths, the resulting economic recession, and the increase in demand for medical services).

37. See Ewen Callaway, *The Race for Coronavirus Vaccines: A Graphical Guide*, 580 NATURE 576, 576 (2020); Carolyn Y. Johnson, *Inside the Extraordinary Race to Invent a Coronavirus Vaccine*, WASH. POST (May 3, 2020), <https://www.washingtonpost.com/science/2020/05/02/coronavirus-vaccine/> [<https://perma.cc/MQ8Y-CXLL>].

38. *Covid-19 Treatment and Vaccine Tracker*, MILKEN INST., <https://covid-19tracker.milkeninstitute.org> [<https://perma.cc/S3S4-6WJH>] (Jan. 3, 2022, 9:02 AM) (listing 332 treatment projects as of Jan. 3, 2022).

39. See Ho Lee, *Genetically Engineered Mouse Models for Drug Development and Preclinical Trials*, 22 BIOMOLECULES & THERAPEUTICS 267, 267 (2014) (describing the hurdles of preclinical trials and drug development).

40. See, e.g., *id.*; Jerry M. Collins, Charles K. Grieshaber & Bruce A. Chabner, *Pharmacologically Guided Phase I Clinical Trials Based Upon Preclinical Drug Development*, 82 J. NAT'L CANCER INST. 1321, 1321 (1990).

test for possible side effects and for any adverse outcomes.<sup>41</sup> During Phase 2 trials, the vaccine is given to hundreds of people, usually split into different age groups, to examine effectiveness across demographics.<sup>42</sup> Phase 3 is the largest and most significant stage, during which thousands of people are given the vaccine, and its efficacy is examined against a control group of people who received a placebo.<sup>43</sup> If Phase 3 proves successful, the vaccine is then approved for limited use in Phase 4,<sup>44</sup> and then for full use in the final phase, Phase 5.<sup>45</sup>

Of course, under the circumstances of the COVID-19 pandemic, every effort is being made to accelerate these processes.<sup>46</sup> For instance, some developers have gotten approval to combine Phase 1 and Phase 2 and have tested the vaccine for the first time on hundreds of people.<sup>47</sup> Yet, the general structure of vaccine development remains largely unchanged; even now, under the pressure of the COVID-19 pandemic, all vaccines must still go through the regular stages of testing.<sup>48</sup> And in fact, the great majority of COVID-19 vaccines have not even entered Phase 1 testing and are still in the preclinical or exploratory stages of their development.<sup>49</sup>

Since multiple research projects are underway simultaneously and proceeding on such a short timeline, great coordination efforts are essential to prevent duplication and wasteful investment in parallel projects.<sup>50</sup> Under normal circumstances, vaccine development is a sequential, decade-long process, comprising multiple, clearly defined stages of clinical trials, planned production, and

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41. *Ensuring the Safety of Vaccines in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/hcp/conversations/ensuring-safe-vaccines.html#clinical-trials> [<https://perma.cc/RN7C-BRPJ>] (June 27, 2018).

42. *Vaccine Testing and the Approval Process*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vaccines/basics/test-approve.html> [<https://perma.cc/8DTN-87PA>] (May 1, 2014).

43. *Id.*

44. *Id.*

45. *Id.*

46. Nicole Lurie, Melanie Saville, Richard Hatchett & Jane Halton, *Developing Covid-19 Vaccines at Pandemic Speed*, 382 NEW ENG. J. MED. 1969, 1969 (2020) (describing the urgent need for a COVID-19 vaccine and pointing out the recent technological advancement that can support this effort).

47. *See id.* at 1970–71.

48. *Id.* at 1969–70.

49. *Coronavirus Disease (Covid-19) Weekly Epidemiological Update and Weekly Operational Update*, WORLD HEALTH ORG., <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports> [<https://perma.cc/8FWS-8357>] (last visited Jan. 10, 2022); *COVID-19 Vaccine Tracker and Landscape*, WORLD HEALTH ORG., <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines> [<https://perma.cc/5VQE-FBXX>] (last visited Jan. 10, 2022) (click “Download” for the tracker).

50. *See* Lurie et al., *supra* note 46, at 1972–73 (discussing the need to coordinate manufacturing, production, and distribution efforts under pandemic conditions); Tung Thanh Le, Zacharias Andreadakis, Arun Kumar, Raúl Gómez Román, Stig Tollefsen, Melanie Saville & Stephen Mayhew, *The COVID-19 Vaccine Development Landscape*, 19 NATURE REV. DRUG DISCOVERY 305 (2020) <https://media.nature.com/original/magazine-assets/d41573-020-00073-5/d41573-020-00073-5.pdf> [<https://perma.cc/YUP9-PAYU>].

distribution.<sup>51</sup> However, based on past experience, because COVID-19 vaccines are being developed in the midst of a global pandemic, adhering to the typical timeline would result in considerable loss of life<sup>52</sup> and have dire economic and social consequences.<sup>53</sup> Accordingly, the scientific challenges of efficacy, safety, distribution, and storage all must be resolved simultaneously and quickly.<sup>54</sup> And while pandemic conditions produced increased funding and shorter timelines for vaccine R&D, this concentration of efforts inevitably led to wasteful duplication, coordination problems, and inefficient dispersion of resources in an overpopulated drug race.<sup>55</sup>

In the COVID-19 vaccine race, different types of vaccines are being investigated. Some vaccines being tested are traditional, whole-pathogen vaccines.<sup>56</sup> Such vaccines can be live-attenuated vaccines (i.e., live pathogens with reduced virulence)<sup>57</sup> or inactivated vaccines (i.e., whole pathogens that have been deactivated through thermal or chemical interventions).<sup>58</sup> These are more traditional vaccines, of the kind that have already proved effective in battling diseases such as measles, mumps, rubella, and polio. Live-attenuated vaccines introduce a weakened version of the virus into the body, prompting a strong immune response.<sup>59</sup> Such vaccines are often highly effective and produce long-lasting immunity; the main drawbacks typically relate to safety concerns.<sup>60</sup> Inactivated vaccines are often safer but also less effective in prompting an immune response, sometimes requiring multiple introductions into the body to establish immune memory.<sup>61</sup> Inactivated COVID-19 vaccines are being developed by the Wuhan Institute of Biological Products, by Sinovac Biotech, and by the Beijing Institute of Biological Products.<sup>62</sup> Another approach is to use repurposed vaccines, which is to say, vaccines that are already in use for other diseases and may prove effective against COVID-19 as well.

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51. Lurie et al., *supra* note 46, at 1970.

52. *See id.*; WHO Ebola Response Team, *After Ebola in West Africa—Unpredictable Risks, Preventable Epidemics*, 375 *NEW ENG. J. MED.* 587, 587 (2016); Thambisetty et al., *supra* note 1, at 3, 6.

53. *See* Lurie et al., *supra* note 46; Caroline Huber, Lyn Finelli & Warren Stevens, *The Economic and Social Burden of the 2014 Ebola Outbreak in West Africa*, 218 *J. INFECTIOUS DISEASES* S698 (2018); Thambisetty et al., *supra* note 1, at 3, 6.

54. *See* Lurie et al., *supra* note 46, at 1972–73.

55. Ana Santos Rutschman, *The Intellectual Property of Covid-19*, in *OUTSMARTING THE NEXT PANDEMIC* 173 (Elizabeth Kirley & Deborah Porter eds., 2021).

56. Jieliang Wang, Ying Peng, Haiyue Xu, Zhengrong Cui & Robert O. Williams III, *The Covid-19 Vaccine Race: Challenges and Opportunities in Vaccine Formulation*, 21 *AAPS PHARMSCITECH* 225, 226 (2020).

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 227.

62. *Id.* at 225.

Yet the front-runners in the COVID-19 vaccination race belong to newer generations of vaccines and are based on entirely new technologies.<sup>63</sup> For instance, recombinant protein vaccines,<sup>64</sup> unlike whole-pathogen vaccines, do not contain the whole virus but use only a fragment of the COVID-19 protein, together with a carrier protein as an antigen.<sup>65</sup> Such a vaccine is currently being developed by Novavax.<sup>66</sup> These vaccines are considered very safe, with their main drawback being that they sometimes trigger only a partial immune response<sup>67</sup> and may require an adjuvant to provide effective protection.<sup>68</sup> Manufacturers are also developing viral vector vaccines, in which a clone of the virus is created as an antigen.<sup>69</sup> Because the viral vector mimics the actual live viral infection, it can prompt a strong immune response, and because it cannot reproduce, it is considered very safe for use.<sup>70</sup> The ChAdOx1 nCov-19 vaccine,<sup>71</sup> developed by the University of Oxford's Jenner Institute together with AstraZeneca,<sup>72</sup> belongs to this category.<sup>73</sup> Other vaccine categories also exist (e.g., trained immunity-based vaccines<sup>74</sup> and plasmid DNA vaccines<sup>75</sup>), but the most talked-about vaccines currently in use are messenger-RNA

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63. *Id.* at 230. *See generally* Ning Wang, Jian Shang, Shibo Jiang & Lanying Du, *Subunit Vaccines Against Emerging Pathogenic Human Coronaviruses*, FRONTIERS MICROBIOLOGY, Feb. 2020, at 1 (describing recent advances in medical research that can be used to develop vaccines against the new virus).

64. Wang et al., *supra* note 56, at 226–27.

65. *Id.*

66. *Id.* at 226 tbl.1.

67. Min Fang, Hong Cheng, Zhongping Dai, Zimei Bu & Luis J. Sigal, *Immunization with a Single Extracellular Enveloped Virus Protein Produced in Bacteria Provides Partial Protection from a Lethal Orthopoxvirus Infection in a Natural Host*, 345 VIROLOGY 231, 236 (2006) (describing the disadvantages of recombinant protein vaccines).

68. Wang et al., *supra* note 56, at 229, 230.

69. *Id.* at 229; Lanying Du, Guangyu Zhao, Yongping Lin, Hongyan Sui, Chris Chan, Selene Ma, Yuxian He, Shibo Jiang, Changyou Wu, Kwok-Yung Yuen, Dong-Yan Jin, Yusen Zhou & Bo-Jian Zheng, *Intranasal Vaccination of Recombinant Adeno-Associated Virus Encoding Receptor-Binding Domain of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) Spike Protein Induces Strong Mucosal Immune Responses and Provides Long-Term Protection Against SARS-CoV Infection*, 180 J. IMMUNOLOGY 948, 948–49 (2008).

70. Wang et al., *supra* note 56, at 230; Du et al., *supra* note 69, at 949.

71. Wang et al., *supra* note 56, at 226 tbl.1.

72. *Id.*; Jonathan Corum & Carl Zimmer, *How the Oxford-AstraZeneca Vaccine Works*, N.Y. TIMES (May 7, 2021), <https://www.nytimes.com/interactive/2020/health/oxford-astrazeneca-covid-19-vaccine.html> [<https://perma.cc/6JWS-J5WF>].

73. Corum & Zimmer, *supra* note 72.

74. Wang et al., *supra* note 56, at 230; *BCG Vaccine for Health Care Workers as Defense Against COVID 19 (BADAS)*, CLINICALTRIALS.GOV (Oct. 6, 2021), <https://clinicaltrials.gov/ct2/show/NCT04348370> [<https://perma.cc/C8RN-XTPB>] (describing Bacille Calmette-Guerin (BCG), a vaccine for tuberculosis disease, currently under clinical evaluation for its ability to induce trained immunity against COVID-19).

75. Wang et al., *supra* note 56, at 229; Press Release, INOVIO, INOVIO Expands Manufacturing of Covid-19 DNA Vaccine INO-4800 with New Funding from CEPI (Apr. 30, 2020), <https://ir.inovio.com/news-releases/news-releases-details/2020/INOVIO-Expands-Manufacturing-of-COVID-19-DNA-Vaccine-INO-4800-With-New-Funding-from-CEPI/default.aspx> [<https://perma.cc/R75-8SQJ>] (describing efforts to develop a COVID-19 plasmid DNA vaccine).

vaccines (mRNA), such as those by Moderna<sup>76</sup> and Pfizer.<sup>77</sup> mRNA vaccines are the latest generation of vaccines used in medical research, and all components are chemically synthesized.<sup>78</sup> As no live materials are used at any stage, such vaccines are exceptionally safe<sup>79</sup> and offer great advantages in terms of quality-control and production capabilities.<sup>80</sup> The fact that the vaccine is completely synthetic also carries significant advantages in terms of production safety, as it eliminates the risk of infection among manufacturing teams.<sup>81</sup> This consideration is especially important in the context of highly contagious infections such as COVID-19.<sup>82</sup> Moderna's mRNA vaccine, mRNA-1273, was developed in collaboration with the National Institute of Allergy and Infectious Diseases,<sup>83</sup> and Pfizer's version, the BNT162 vaccine, was developed together with BioNTech.<sup>84</sup>

### *B. Legal Background: Patents Under Existing Law*

Patent law protects inventions through a procedure of application and examination at a government patent office.<sup>85</sup> Before issuing a patent, the patent office must verify that the application meets the necessary standards for patentability: subject matter eligibility,<sup>86</sup> novelty,<sup>87</sup> nonobviousness,<sup>88</sup> and utility.<sup>89</sup> Patent law operates as a race to the finish, protecting only the first applicant to file for a patent covering a particular technology.<sup>90</sup> Patent protection is territorial, meaning that a separate patent is required for each country or jurisdiction.<sup>91</sup> Centralized filing is available under the Patent Cooperation Treaty<sup>92</sup> and the

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76. Wang et al., *supra* note 56, at 226 tbl.1.

77. *Id.*

78. *Id.* at 229–30.

79. *Id.*

80. *Id.*

81. *Id.* at 230.

82. *Id.* at 225.

83. Jonathan Corum & Carl Zimmer, *How Moderna's Vaccine Works*, N.Y. TIMES (May 7, 2021), <https://www.nytimes.com/interactive/2020/health/moderna-covid-19-vaccine.html> [<https://perma.cc/8BVM-ZZJ5>].

84. Wang et al., *supra* note 56, at 226 tbl.1.

85. 35 U.S.C. § 111 (stating patent requires written application); BURK & LEMLEY, *supra* note 10, at 9 (describing the formal requirements for patent application).

86. 35 U.S.C. § 101. The requirement for subject-matter eligibility means the invention must fall under one of the familiar categories of utility patent, design patent, or plant patent.

87. 35 U.S.C. § 102 (requiring that the invention was never before publicly available); *see* BURK & LEMLEY, *supra* note 10, at 9–10 (explaining and discussing the novelty requirement).

88. 35 U.S.C. § 103; BURK & LEMLEY, *supra* note 10, at 9–10.

89. 35 U.S.C. § 101; BURK & LEMLEY, *supra* note 10, at 9.

90. 35 U.S.C. § 102(a)(1); BURK & LEMLEY, *supra* note 10, at 10.

91. WORLD INTELL. PROP. ORG., PCT FAQs: PROTECTING YOUR INVENTIONS ABROAD: FREQUENTLY ASKED QUESTIONS ABOUT THE PATENT COOPERATION TREATY (PCT) 1–2 (2020), [https://www.wipo.int/export/sites/www/pct/en/basic\\_facts/faqs\\_about\\_the\\_pct.pdf](https://www.wipo.int/export/sites/www/pct/en/basic_facts/faqs_about_the_pct.pdf) [<https://perma.cc/57MF-HE4G>].

92. *Id.* Patent Cooperation Treaty art. 3, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 (entered into force Apr. 1, 2002).

regional European Patent Convention,<sup>93</sup> but patent rights themselves are currently recognized only on a local, rather than global, level.<sup>94</sup>

Patents are typically divided into several types, the most well-known of which is the utility patent.<sup>95</sup> Utility patents are given for new and useful processes, machines, articles of manufacture, and compositions of matter.<sup>96</sup> A second type of patents is a design patent given to new ornamental designs for article of manufactures.<sup>97</sup> Finally, plant patents are given to new varieties of asexually reproducing plants.<sup>98</sup> Utility patents and plant patents ordinarily offer protection for a fixed term of twenty years from the date of filing,<sup>99</sup> although they may expire earlier if the patentee fails to pay periodical maintenance fees;<sup>100</sup> they may also be extended in some cases.<sup>101</sup> Design patents have a slightly shorter term of fifteen years from the date of issuance.<sup>102</sup>

Once a patent is issued, it provides the patent holder with the right to exclude all others from making, using, selling, importing, or offering an invention for sale.<sup>103</sup> The patent protects against direct copying<sup>104</sup> and also against independent invention.<sup>105</sup> Patent protection stands independent of any awareness by the infringing party of the patentee's rights.<sup>106</sup> The patent holder who establishes infringement is entitled to powerful remedies, including injunctions against future infringement,<sup>107</sup> damages for lost profits,<sup>108</sup> and, in cases of willful infringement, treble damages.<sup>109</sup> Note that the patent offers the patentee legal protection against infringement by others but does not in itself constitute a license to practice the invention. That is because part of the patented technology may be protected by another patent.<sup>110</sup>

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93. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter European Patent Convention].

94. 35 U.S.C. § 102(a)(1); BURK & LEMLEY, *supra* note 10, at 10.

95. 35 U.S.C. § 101; BURK & LEMLEY, *supra* note 10, at 9.

96. 35 U.S.C. § 101; BURK & LEMLEY, *supra* note 10, at 9.

97. 35 U.S.C. § 171; BURK & LEMLEY, *supra* note 10, at 8.

98. 35 U.S.C. § 161; BURK & LEMLEY, *supra* note 10, at 8.

99. 35 U.S.C. § 154(a)(2).

100. 35 U.S.C. § 41(b).

101. *See, e.g.*, 35 U.S.C. § 154(b) (allowing patent term adjustments for PTO-caused delays in patent examination).

102. 35 U.S.C. § 173.

103. 35 U.S.C. § 154(d).

104. *Id.*

105. *Id.*

106. *Id.*

107. 35 U.S.C. § 283(a).

108. 35 U.S.C. § 284.

109. *Id.*

110. Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 618–21 (2005) (describing the problem of patent “thickets,” whereby separate patents can cover different aspects of the same product or technology).

The protection of inventions through the use of patents is considered necessary to encourage innovation and scientific and technological progress.<sup>111</sup> In particular, investment in R&D is considered to be greatly dependent on the incentives the patent system creates.<sup>112</sup> Strong patent rights give patent holders proprietary control of their inventions,<sup>113</sup> ensuring that inventors can enjoy the exclusive economic benefit from their creations.<sup>114</sup> If proprietary control were not available, inventors would not be able to make the high investments necessary for innovation.<sup>115</sup> This is not always the case, of course, but it is especially true in the pharmaceutical industry, where innovation requires massive financial investments.<sup>116</sup> Patent protection is therefore a prerequisite for the advancement of human knowledge, science, and technology.<sup>117</sup>

Yet this proprietary approach to innovation, although designed to encourage scientific progress, can actually delay it or even thwart it. To incentivize innovative efforts, the patent system grants inventors monopolistic control of their inventions, allowing them to set supracompetitive prices.<sup>118</sup> Excessive prices can hinder distribution of new technologies, however, resulting in lower production levels.<sup>119</sup> To mitigate these effects, patent law limits patent rights in a number of ways, primarily in terms of their duration.<sup>120</sup> The current system applies a one-size-fits-all approach on this front, granting the same twenty-year period of protection to all inventions, irrespective of the field or nature of the invention.<sup>121</sup>

In the current Article, we focus on the duration of patent protection as a key feature of the patent regime. As current patent law always grants the same twenty-year period of protection to utility patents,<sup>122</sup> it should not come as a surprise that patent protection is often too weak or too strong. Patent protection symbolizes a bargain between the patentee and society: the patentee supplies society with the

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111. See Arrow, *supra* note 5, at 609; BURK & LEMLEY, *supra* note 10, at 66.

112. See *id.* at 616–17; BURK & LEMLEY, *supra* note 10, at 68.

113. See, e.g., WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294–96 (2003).

114. 35 U.S.C. § 271(a) (stating once a patent is granted, the patent owner has the exclusive right to make, use, sell, offer for sale, or import the claimed invention).

115. Cotropia, *supra* note 6, at 168–71 (explaining that patent law provides patentees with the ability to invent by offering them exclusive control over their invention); Lemley, *supra* note 6, at 129–30 (explaining the rationale for patent protection).

116. BURK & LEMLEY, *supra* note 10, at 204 n.1 (describing the costs of clinical research required to develop new drugs and vaccines); See *Research & Development Framework*, *supra* note 11 (“On average, it takes 10–15 years and costs \$2.6 billion to develop one new medicine, including the cost of the many failures.”).

117. See BURK & LEMLEY, *supra* note 10, at 8.

118. *Id.*

119. *Id.* at 68, 71.

120. 35 U.S.C. § 154(a)(2).

121. See Abraham Bell & Gideon Parchomovsky, *Reinventing Copyright and Patent*, 113 MICH. L. REV. 231, 234 (2014) (explaining that intellectual property rights follow a one-size-fits-all principle, and highlighting the drawbacks of this current legal arrangement).

122. 35 U.S.C. § 154(a)(2); BURK & LEMLEY, *supra* note 10, at 9.

use of a new invention and in return is assured some monetary gain.<sup>123</sup> Yet the extent of this monetary gain is crudely estimated through the one-size-fits-all twenty-year period of patent protection. There is no reason to expect this bargain to offer a fair exchange of value or a well-tailored set of incentives for inventors.<sup>124</sup>

In the pharmaceutical industry, patent protection can easily turn out to be too weak, since the costs of developing new drugs and vaccines—which, as noted, require multiple stages of clinical trials—can be astronomical.<sup>125</sup> When innovation is very costly and profits are uncertain, the standard twenty-year patent term is frequently insufficient to allow inventors to recoup their investment.<sup>126</sup> When this is the case, pharmaceutical companies simply cannot afford to invest, and the public is left without new and improved pharmaceutical products. This concern is particularly acute in the context of vaccines which are generally viewed as less profitable than therapeutic drugs.<sup>127</sup> For these reasons, there is relatively little research into new vaccines, and development typically commences only after particular disease strains are identified as a significant threat.<sup>128</sup>

On the other hand, patent protection is often too strong, hindering distribution and use of new inventions and technologies.<sup>129</sup> In the context of COVID-19 vaccines, patent protection can lead to shortages of patented products.<sup>130</sup> Since emerging vaccines are patent protected,<sup>131</sup> owners of these new vaccines have the opportunity to demand high prices. Governments around the world, anxious to ensure an adequate supply for their citizens, scrambled to purchase vaccines from multiple suppliers, even as the vaccines were still in development and their safety and efficacy were uncertain.<sup>132</sup> Considering the depth of the COVID-19 crisis, nations are willing to pay extremely high prices for a successful vaccine.<sup>133</sup> Importantly, patent protection for the emerging vaccines is of near global reach under TRIPS Agreement mandates,<sup>134</sup> as any exceptions to

123. BURK & LEMLEY, *supra* note 10, at 66.

124. Marcowitz-Bitton et al., *supra* note 7 (describing the inability of the current one-size-fits-all model to provide equitable solutions and efficient incentives).

125. BURK & LEMLEY, *supra* note 10, at 204 n.1; *Research & Development Framework*, *supra* note 11 (“On average, it takes 10-15 years and costs \$2.6 billion to develop one new medicine, including the cost of the many failures.”).

126. BURK & LEMLEY, *supra* note 10, at 3–4, 136–37.

127. Lisa Larrimore Ouellette & Q. Claire Xue, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCES 1, 20–21, 26 (2020).

128. *Id.*; Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200, 1207 (2018).

129. Marcowitz-Bitton et al., *supra* note 7.

130. Jorge L. Contreras, *Expanding Access to Patents for Covid-19*, in ASSESSING LEGAL RESPONSES TO COVID-19, 158, 160 (Scott Burris, Sarah de Guia, Lance Gable, Donna Levin, Wendy E. Parmet & Nicolas P. Terry eds., 2020).

131. Rutschman, *supra* note 26, at 177.

132. Rutschman, *supra* note 55, at 11.

133. Rutschman, *supra* note 26, at 183–84.

134. *See generally* Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement art. 27(1), Apr. 15, 1994, Marrakesh

patentability in the Agreement<sup>135</sup> fall largely outside the field of vaccine-related technology.<sup>136</sup> Accordingly, pharmaceutical companies can easily exploit patent protection to price their vaccines so profitably that developing countries are priced out of buying sufficient quantities of an emerging vaccine.<sup>137</sup> More broadly, high prices mean that large populations will lack access to new vaccines and remedies.<sup>138</sup> For instance, U.S health officials will not guarantee an affordable vaccine because they “need the private sector to invest.”<sup>139</sup> As an example, the first drug indicated for the treatment of COVID-19, Remdesivir, will reportedly cost American insurance companies \$3,120 per treatment.<sup>140</sup>

These difficulties are closely related to the phenomenon of “vaccine nationalism.” Early on in the vaccine race, developed countries rushed to secure doses of emerging COVID-19 vaccines for their populations by means of advance commitment agreements,<sup>141</sup> driving up prices and effectively reducing access to others.<sup>142</sup> Vaccine nationalism<sup>143</sup> has also been demonstrated by certain countries’ unwillingness to participate in global discussions regarding vaccine distribution.<sup>144</sup> Vaccine nationalism inevitably results in inequitable allocation of vaccines,<sup>145</sup> greatly disfavoring developing nations. By late summer 2020, developed countries had already placed pre-purchase orders for over two billion doses of COVID-19 vaccines, including 340 million doses by the U.K. and 800 million by the United

Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

135. *See id.* art. 27(3)(a).

136. Rutschman, *supra* note 26, at 177–78.

137. *See* Jean Akl, *Patent Exceptions in the Time of a Pandemic*, 55 LES NOUVELLES: J. LICENSING EXECUTIVES SOC’Y 204, 204 (2020).

138. Rutschman, *supra* note 55, at 7.

139. Nicole Wetsman, *Health Secretary Alex Azar Won’t Promise that a Coronavirus Vaccine Would Be Affordable*, VERGE (Feb. 27, 2020, 11:53 AM) <https://www.theverge.com/2020/2/27/21155879/alex-azar-coronavirus-vaccine-affordable-insurance> [<https://perma.cc/CAA9-2Y3J>].

140. Matthew Herper, *Gilead Announces Long-Awaited Price for Covid-19 Drug Remdesivir*, STAT (Jun. 29, 2020) <https://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19/> [<https://perma.cc/NY94-3G4C>].

141. Rutschman, *supra* note 26.

142. Ana Santos Rutschman, *The Reemergence of Vaccine Nationalism*, GEO. J. INT’L AFFS. (July 3, 2020), <https://gia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/> [<https://perma.cc/W8AK-2PQV>].

143. Greg Myre, *In the Battle Against Covid-19, a Risk of ‘Vaccine Nationalism’*, NPR (May 27, 2020) <https://www.npr.org/2020/05/27/861886520/in-the-battle-against-covid-19-a-risk-of-vaccine-nationalism> [<https://perma.cc/W3KP-DKN5>]; Peter Loftus & Gregory Zuckerman, *Inside Moderna: The Covid Vaccine Front-Runner with No Track Record and an Unsparing CEO*, WALL ST. J. (Jul. 1, 2020, 10:53 AM) <https://www.wsj.com/articles/inside-moderna-the-covid-vaccine-front-runner-with-no-track-record-and-an-unsparing-ceo-11593615205> [<https://perma.cc/NP26-MTWK>].

144. Richard Milne & David Crow, *Why Vaccine ‘Nationalism’ Could Slow Coronavirus Fight*, FIN. TIMES (May 13, 2020) <https://www.ft.com/content/6d542894-6483-446c-87b0-96c65e89bb2c> [<https://perma.cc/DB2N-8SNL>].

145. Rutschman, *supra* note 55, at 11.

States.<sup>146</sup> This contract bilateralism led to over-distribution of the first batches of emerging vaccines to pre-purchasing countries and vaccine shortages in developing countries.<sup>147</sup> Over distribution to developed countries creates a funding incentive but impedes equality of access to an emerging vaccine.<sup>148</sup>

Vaccine nationalism, driven by the patent-protected, private ownership of vaccines, will lead to price spikes, unnecessary hoarding in certain countries, and life-threatening shortages in others. Moreover, in today's interconnected world, vaccine nationalism is counterproductive, as *all* countries need adequate access to a vaccine in order to overcome the pandemic.<sup>149</sup> The current blend of excessive intellectual property protections and ill-conceived vaccine nationalism raises serious concerns of both affordability and equity<sup>150</sup> that, if left unaddressed, will likely re-emerge in future public health crises.<sup>151</sup> Of course, even if one country is able to secure the vaccine for its citizens, unless it is reasonably priced, economically-challenged populations will suffer domestically as a result of contractual bilateralism.<sup>152</sup> For instance, the pricing of Gilead's Remdesivir, which was partly developed through funding from the public sector,<sup>153</sup> has been sharply criticized,<sup>154</sup> yet no change in pricing has been announced.<sup>155</sup>

Another related effect of patent overprotection is that of rights-fragmentation, by which use of a single invention is unnecessarily limited because it is protected by several patents. The issue of over-fragmentation of property rights is often described under the category of the "anticommons" problem.<sup>156</sup> Anticommons refers to assets with multiple owners,<sup>157</sup> all of whom have the power to exclude all

146. Ewen Callaway, *The Unequal Scramble for Coronavirus Vaccines*, 584 NATURE 506, 506 (2020).

147. Yanqiu Rachel Zhou, *Vaccine Nationalism: Contested Relationships Between COVID-19 and Globalization*, GLOBALIZATIONS (2021); Rutschman, *supra* note 55, at 11.

148. Rutschman, *supra* note 55, at 11.

149. Tedros Adhanom, *Tedros Adhanom on Why Vaccine Nationalism Harms Efforts to Halt the Pandemic*, ECONOMIST (Sept. 8, 2020), <https://www.economist.com/by-invitation/2020/09/08/tedros-adhanom-on-why-vaccine-nationalism-harms-efforts-to-halt-the-pandemic> [<https://perma.cc/9Q9X-35RZ>].

150. Rutschman, *supra* note 26.

151. *Id.*

152. *Id.*

153. See Yaniv Heled, Ana Santos Rutschman & Liza Vertinsky, *The Problem with Relying on Profit Driven Models to Produce Pandemic Drugs*, 7 J.L. BIOSCIENCES 1, 11–17 (2020) (presenting a case study on the development of Remdesivir).

154. Rohan Chalasani & Wallid Gellad, *The US Is Paying Way Too Much for Remdesivir*, WIRED (July 17, 2020, 7:00 AM) <https://www.wired.com/story/the-us-is-paying-way-too-much-for-remdesivir/> [<https://perma.cc/7TG8-AFY6>].

155. Rutschman, *supra* note 26, at 187.

156. See BURK & LEMLEY, *supra* note 10 at 75–77 (describing the problem of anticommons in the context of patent law); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Harv. L. Rev. 621, 624 (1998) (“In an anticommons . . . multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use.”).

157. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998) (showcasing the detrimental

others.<sup>158</sup> In patent law, anticommons means that the same invention or product is protected by multiple patents,<sup>159</sup> meaning that no one entity is able to commercialize the product.<sup>160</sup> In extreme cases, such anticommons can become so complex and entangled as to create an impenetrable “patent thicket,”<sup>161</sup> when a single invention or process can be the subject of dozens, hundreds, or thousands of different patents.<sup>162</sup> Patent law protects any scientific contribution, regardless of the investment required to create it, meaning that it can be near impossible for a single entity to collect the multitude of overlapping patents necessary to commercialize an invention.<sup>163</sup> As a result, patent protection can easily—and ironically—prevent commercialization and research, instead of promoting them.<sup>164</sup> In the medical context, these problems are particularly acute with respect to DNA sequencing,<sup>165</sup> where different patents protect specific genes or fragments of genes.<sup>166</sup> The result is that use of the underlying knowledge may be inaccessible to everyone, as it would require the accumulation of too many separate patents or licenses.<sup>167</sup>

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effects of anticommons on biomedical research); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192–94 (showing that patents often bar the development of new treatments and drugs).

158. BURK & LEMLEY, *supra* note 10, at 76 (“The anticommons is characterized by fragmented property rights that must be aggregated to make effective use of the property.”).

159. *Id.*

160. *Id.* (“Aggregating such fragmented property rights entails high search and negotiation costs to locate and bargain with the many rights owners whose permissions are necessary to complete broader development. This type of licensing environment may quickly become dominated by ‘holdouts’ that refuse to license their component unless paid to do so. Because a given project will fail without their cooperation, ‘holdouts’ may demand a bribe close to the value of the entire project.”). See Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein’s Steady Course*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 195, 197–98 (F. Scott Kieff ed., 2003) (describing research “blockades”); Lloyd Cohen, *Holdouts and Free Riders*, 20 J. LEGAL STUD. 351, 356 (1991). See generally MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (1961) (explaining the problem of collective action). Scholars suggest different solutions to the anticommons problem, either in consolidating ownership or in preclude patent protection in some circumstances.; BURK & LEMLEY, *supra* note 10, at 77; Philippe Jacobs & Geertrui Van Overwalle, Opinion, *Gene Patents: A Different Approach*, 23 EUR. INTELL. PROP. REV. 505, 505; Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 838 (2001); cf. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CALIF. L. REV. 1293, 1295 (1996) (showing that collective rights organizations can lower transaction costs generated through the patent system).

161. BURK & LEMLEY, *supra* note 10, at 78.

162. *Id.*

163. *Id.*

164. See Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in INNOVATION POL’Y & ECON. 119, 121–22 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2000).

165. See BURK & LEMLEY, *supra* note 10, at 86.

166. See, e.g., S.M. Thomas, A.R.W. Davies, N.J. Birtwistle, S.M. Crowther & J.F. Burke, Commentary, *Ownership of the Human Genome*, 380 NATURE 387, 387–88 (1996).

167. See Rebecca S. Eisenberg, *Reaching through the Genome*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 160, at 209, 209–10).

Such dynamics are already manifest in the context of the COVID-19 crisis, as diverse patent holders are often unable to cooperate to combine their technologies productively to develop solutions for controlling disease outbreaks.<sup>168</sup> Rights-fragmentation and lack of coordination<sup>169</sup> can give rise to litigation, such as the current dispute between Moderna and Arbutus.<sup>170</sup> This dispute surrounds an Arbutus patent covering lipid nanoparticle technology that allows the body to generate therapeutic proteins.<sup>171</sup> This technology is crucial to the delivery system in Moderna's vaccine, which delivers mRNA drugs into cells.<sup>172</sup> Moderna claimed that the Arbutus patent should be revoked on the obviousness grounds.<sup>173</sup> The U.S. Patent and Trademark Office's Patent Trial and Appeal Board rejected this claim and ruled in favor of Arbutus.<sup>174</sup> As a result, Arbutus may be able to claim a royalty in the vaccine, which would likely contribute to price increases and also hinder the ability of Moderna to commercialize its vaccine. As a response to this development, Moderna's stock dropped by nine percent.<sup>175</sup>

All these related problems create significant delays in the timely distribution of new technologies. Proprietary rights and noncooperative behaviors prevent the replication of essential patented products by third parties in emergency situations,<sup>176</sup> as evidenced by the ventilator shortage in Italy.<sup>177</sup> There is currently no emergency legal mechanism for sharing intellectual property rights in a timely manner.<sup>178</sup> In the context of the COVID-19 crisis, the delays in distribution that these obstacles cause are immensely costly.

The high prices of emerging COVID-19 vaccines are especially infuriating given that much of the investment required to create them came from public funding, not from the private sector. For instance, the Oxford-AstraZeneca vaccine, ChAdOx1 nCov-19, is supported by the U.S.<sup>179</sup> government's Operation Warp Speed, under which the Biomedical Advanced Research and Development

168. Rutschman, *supra* note 128, at 1260; Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729, 761 (2019).

169. Heller, *supra* note 156.

170. Nick Paul Taylor, *Moderna Stock Sinks as Patent Case Spurs Concern for Covid-19 Vaccine*, FIERCE BIOTECH (July 24, 2020, 8:50 AM), <https://www.fiercebiotech.com/biotech/moderna-stock-sinks-as-patent-case-spurs-concern-for-covid-19-vaccine> [<https://perma.cc/2NJP-A628>].

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.*

176. *See* Rutschman, *supra* note 55, at 9.

177. Dinusha Mendis, Ana Santos Rutschman & Rosa Ballardini, *3D Printing: How an Emerging Technology May Help Fight a Pandemic*, IPR INFO (May 25, 2020), <https://iprinfo.fi/artikkeli/3d-printing-how-an-emerging-technology-may-help-fight-a-pandemic/> [<https://perma.cc/A2JW-8DLV>]; Anas Essop, *Hospital in Italy Turns to 3D Printing to Save Lives of Coronavirus Patients*, 3D PRINTING INDUSTRY (Mar. 18, 2020, 11:27 AM), <https://3dprintingindustry.com/news/hospital-in-italy-turns-to-3d-printing-to-save-lives-of-coronavirus-patients-169136/> [<https://perma.cc/N9TB-SXXG>].

178. *See* Rutschman, *supra* note 128, at 1205.

179. *Id.*

Authority (part of the U.S. Department of Health and Human Services) provided up to \$1.2 billion in funding.<sup>180</sup> In return, 300 million doses of the potential vaccine were promised to be shipped to the United States<sup>181</sup> This is, of course, merely vaccine nationalism with extra steps: public funds are given to private inventors, developed countries are investing to ensure early access to the eventual vaccine, and pharmaceutical giants are left with a monopoly that will bar access to the vaccine in developing countries. The same dynamic applies with respect to the mRNA-1273 vaccine developed by Moderna in collaboration with the National Institute of Allergy and Infectious Diseases,<sup>182</sup> similarly supported by the U.S. government under Operation Warp Speed.<sup>183</sup>

In addition, the Coalition for Epidemic Preparedness Innovations (CEPI), funded by several countries and philanthropists, invested \$1.4 billion to support COVID-19 vaccine R&D.<sup>184</sup> Similarly, the public-private partnership Gavi formed the COVID-19 Vaccine Global Access (COVAX) Facility, which offers participants the possibility of placing advance commitment orders for doses of the COVID-19 vaccine in exchange for a financial contribution.<sup>185</sup> 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.<sup>186</sup> Naturally, mass orders make the vaccine more affordable for countries in COVAX as compared to countries that negotiate directly with manufacturers.<sup>187</sup> This is yet another form of vaccine nationalism. Under each of these different schemes, developed nations offer public funding to private companies in return for a preferential supply of vaccine doses. These companies end up with proprietary patent rights, and developing nations are left at a disadvantage in the race to vaccinate their populations. These dynamics, generated under the auspices of the patent regime, can only delay universal vaccine distribution and thus impede a swift victory over the pandemic.

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180. Akash B, Guy Faulconbridge & Kate Holton, *U.S. Secures 300 Million Doses of Potential AstraZeneca COVID-19 Vaccine*, REUTERS (May 21, 2020, 11:13 PM), <https://www.reuters.com/article/us-health-coronavirus-astrazeneca/u-s-secures-300-million-doses-of-potential-astrazeneca-covid-19-vaccine-idUSKBN22X0J9> [<https://perma.cc/RGG5-CYUB>].

181. *Id.*

182. See Corum & Zimmer, *supra* note 82.

183. Noah Weiland & David E. Sanger, *Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists*, N.Y. TIMES (July 27, 2020), <https://www.nytimes.com/2020/06/03/us/politics/coronavirus-vaccine-trump-moderna.html> [<https://perma.cc/FXU6-RVYN>].

184. *Boost for Global Response to Covid-19 as Economies Worldwide Formally Sign Up to COVAX Facility*, CEPI (Sep. 21, 2020), [https://cepi.net/news\\_cepi/boost-for-global-response-to-covid-19-as-economies-worldwide-formally-sign-up-to-covax-facility/](https://cepi.net/news_cepi/boost-for-global-response-to-covid-19-as-economies-worldwide-formally-sign-up-to-covax-facility/) [<https://perma.cc/M653-M3ZN>].

185. GAVI, WHO MEMBER STATES BRIEFING ON THE COVAX FACILITY 3–4 (2020), [https://apps.who.int/gb/COVID-19/pdf\\_files/11\\_06/GAVI.pdf](https://apps.who.int/gb/COVID-19/pdf_files/11_06/GAVI.pdf) [<https://perma.cc/QBE3-D6HD>].

186. Rutschman, *supra* note 26, at 191.

187. See GAVI, *supra* note 185, at 3.

## II. THE PROPOSED MODEL: RECOUPMENT PATENT

Based on our previous work on the topic,<sup>188</sup> we propose a novel patent regime that keys the duration of patent protection to the level of investment required to create the invention. Thus, companies such as Moderna and Pfizer will continue to hold patent rights in their vaccines, but those patents will not necessarily last the current twenty-year term of patent protection. Instead, companies will hold rights to their patented inventions only for as long as it takes them to recoup their investment and earn a measure of profit.

This measure of patent protection addresses both the problem of underprotection and the problem of overprotection described above. Under current law, some vaccines may be too expensive to develop, meaning that a twenty-year patent will not suffice for the inventor to recoup its investment. Under our proposed regime, patent protection in such cases will extend beyond the standard twenty years, giving companies an incentive to invest in developing such vaccines.

Symmetrically, our proposed model can also solve the problem of overprotection under current patent law. Under our proposed regime, once the pharmaceutical company recoups its investment and a measure of profit, patent protection expires, and any firm is free to move into the market and sell the vaccine at competitive prices. This means that firms have full incentive to invest in R&D of new vaccines, but the vaccine becomes commercially available at competitive prices as soon as possible.

This proposal is well-tailored to offset the dynamic of vaccine nationalism. Under the current regime, developed nations drive prices up with early vaccine purchases, and no limiting mechanism exists—for the duration of the standard twenty-year patent term—for bringing prices down to a level that is accessible to developing countries. Under our proposed regime, by contrast, once developed economies have paid handsome sums for early access to the vaccine and patent holders have recouped their initial investments and a generous profit, the patents will expire, and consumers in developing nations will be able to purchase subsequent products at fair market prices. Importantly, since a significant share of the investment required to develop the vaccines originally came from public funds and not from private investments, the term of COVID-19 vaccine patents will be relatively short, despite the massive investments required to develop them. That is, recoupment under our model is measured according to the private investment by the patent holder, and once that investment (plus a percentage of profit) has been recouped, patent protection expires, regardless of any additional public investments.

Additionally, our approach mitigates the problems of patent thickets and patent anticommons, which, as explained above,<sup>189</sup> inevitably occur when multiple companies contribute to products or processes that later become necessary for the

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188. Marcowitz-Bitton et al., *supra* note 7.

189. See Shapiro, *supra* note 164, at 119.

creation of a single drug or vaccine.<sup>190</sup> Under the current regime, patents covering the separate components accumulate in confusion of overlapping twenty-year terms, potentially preventing anyone from creating a usable final product.<sup>191</sup> Our proposal can significantly limit the duration of some patents, especially low-investment patents, thereby reducing the likelihood that patent thickets will be created in the first place.

In sum, our proposal seeks to create a more equitable bargain between the pharmaceutical companies and the public.<sup>192</sup> In our model, the private inventor is fully compensated for investments and is allowed to profit, and the public receives equitable access to vaccines and a degree of control commensurate with the public investment in vaccine R&D. Our proposal eliminates the inherent problems in the one-size-fits-all approach of current patent law—which necessarily overprotects some inventions and underprotects others—and better balances inventor incentives with equitable access to important innovations and the imperatives of global public health challenges such as COVID-19.

#### *A. Administering the Recoupment Model*

The implementation of our proposal requires information about the level of investment required to develop individual vaccines. Therefore, under our proposed regime, applicants will be obligated to report their investment upon filing for patent protection and upon requesting periodic renewal of the patent. This will allow pharmaceutical companies to recoup their investment in developing new vaccines<sup>193</sup> and will replace the mechanisms currently used to extend pharmaceutical patents, which are costly and overly complex.<sup>194</sup>

Under the proposed regime, companies applying for patent protection will be required to document their actual and anticipated investment upon filing for the patent. Additionally, companies will be allowed to file periodic updates after filing and after patent issuance to reflect any changes to their investment. This will allow firms to apply early for their patents, as is common when multiple inventors race to be the first to file for patent protection and prevent copying by others,<sup>195</sup> even before they can fully evaluate all costs related to the development of their

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190. See BURK & LEMLEY, *supra* note 10, at 90.

191. *Id.* at 78 (“Like the anticommons problem, the patent thicket has the potential to prevent all parties from making a final product that incorporates multiple inventions.”).

192. *Id.* at 66 (explaining that patent law encourages the disclosure of information that might otherwise be kept secret).

193. Such investment can be astronomical. See BURK & LEMLEY, *supra* note 10, at 204 n.1; Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFFS. 420, 420–28 (2006); see also Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 267–68 (2012).

194. See BURK & LEMLEY, *supra* note 10, at 3–4, 136–37.

195. See Cotropia, *supra* note 6, at 168–70, 172–81.

inventions.<sup>196</sup> Similarly, our proposed regime does not require patentees to pay full filing fees at the time of application and may defer most of the payment to a later point in time. This measure will allow smaller firms, such as startup companies, to patent their early contributions, even before they have sufficient independent income to cover the costs of patent application fees.

Under the proposed model, it is crucial to define what counts as “investment” for the purposes of measuring patent protection. To incentivize companies appropriately to invest in vaccine R&D, any investment required to develop a vaccine must be accounted for in tailoring the length of patent protection. Such investments include labor, equipment, lab services, consulting services, administrative costs, regulatory costs, commercialization costs, and any other expenses incurred during basic research, clinical trials, regulatory approval, commercialization, and marketing of the vaccine. Importantly, the measure of investment must also account for the level of risk associated with vaccine development. Accurate calculation of recoupment values that takes into account the risk of investment can be done using standard economic measures such as the Black Scholes formula,<sup>197</sup> designed for evaluating options and other financial instruments.<sup>198</sup>

Once the patent is issued and the level of investment is evaluated, the patentee and the patent office can estimate the expected patent term necessary for the patentee to recoup the investment and obtain an appropriate measure of profit. In some cases, when significant government investment contributed to funding development of the vaccine, and when large amounts of the vaccine have been purchased in advance, the patentee and the general public will know that the patent will expire quite soon after it is granted, perhaps even immediately in exceptional cases.

Providing some estimate as to the duration of the patent is important to signal to other market players when the vaccine is likely to be commercially available on the free market so that competitors can prepare in advance for that scenario.<sup>199</sup> This information is also important for the patent holder, who will wish to manage its marketing efforts accordingly. We therefore propose nominating a designated body within the patent office that would be responsible for producing estimates regarding patent duration in accordance with evaluations of patent investment. This measure

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196. *Id.*

197. Fischer Black & Myron Scholes, *The Pricing of Options and Corporate Liabilities*, 81 J. POL. ECON. 637, 640–53 (1973) (introducing a formula for pricing an option).

198. See Ariel Pakes, *Patents as Options: Some Estimates of the Value of Holding European Patent Stocks*, 54 ECONOMETRICA 755, 755 (1986) (developing a model that allows recovering the distribution returns from holding patents at each age over the lifespan of patents from information on patent renewals to enable value calculations).

199. See James Boyle, *Foreword: The Opposite of Property*, 66 LAW & CONTEMP. PROBS. 1, 4, n.9 (2003); see also James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33 (2003) (explaining the role of the public domain in cultural and scientific development).

is intended to increase predictability and stability under the proposed regime<sup>200</sup> and will require full disclosure of investment information to protect against price manipulation by market players with strong bargaining power.

We suggest that the bulk of the work required to administer and operate the proposed regime will be undertaken by patent offices, which are naturally positioned to process patent applications and manage additional information relating to the process of patent filing.<sup>201</sup> Any additional work required to evaluate patent investment can be executed by independent valuation agencies under the supervision of the patent office. Several existing valuation agencies can perform these tasks,<sup>202</sup> and the patent office can choose a number of such agencies to conduct valuations under its auspices. Once the patent office chooses several agencies, individual patent applicants may select a specific agency to work with in evaluating their patent investment. Applicants will provide the agency with all information required to perform the valuation and will pay for its administrative costs. Applicants will also be able to provide their own valuation for the agency's consideration if they wish to do so. This valuation process resembles the existing process of patent application and examination, as applicants are required to submit all relevant materials and information required to assess their application.

To combat the adverse effects of vaccine nationalism effectively, our proposal must be implemented at the international level. This fits with current patent law trends favoring increased international coordination.<sup>203</sup> Under the international recoupment model, both investment and recoupment should be measured globally. Accordingly, once a company recoups the investment required to produce its vaccine, the patent for that vaccine will expire globally, in all jurisdictions, and new applications will not be accepted for the same vaccine. This global recoupment model is necessary to allow universal vaccine distribution. It means that in some cases, inventors may decline to apply for patent protection in certain jurisdictions, as they will expect to recoup their investments elsewhere. Indeed, companies will typically apply for patent protection only in developed economies, where they are likely to recoup their investment quickly, and will forego application in developing nations. This will not only save on application fees; it will also mean that vaccines

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200. See Michael S. Kramer, *Valuation and Assessment of Patents and Patent Portfolios Through Analytical Techniques*, 6 J. MARSHALL REV. INTELL. PROP. L. 463, 469–70 (2007) (highlighting the importance of stability through consistent regulatory schemes).

201. See Beth Simone Noveck, "Peer to Patent": *Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123, 134–35 (2006) (describing the resources available to the USPTO).

202. *Forbes: Top 25 Intellectual Property Valuation Firms*, CONSOR IP EXPERTS (Aug. 7, 2017), <http://consor.com/forbes-top-25-intellectual-property-valuation-service-firms/> [https://perma.cc/4RCP-8RJJG].

203. See, e.g., EUR. PAT. OFF., EUROPEAN PATENT CONVENTION (2020), [https://documents.epo.org/projects/babylon/eponet.nsf/0/53A0FE62C259803BC12586A90058BCAD/\\$File/EPC\\_17th\\_edition\\_2020\\_en.pdf](https://documents.epo.org/projects/babylon/eponet.nsf/0/53A0FE62C259803BC12586A90058BCAD/$File/EPC_17th_edition_2020_en.pdf) [https://perma.cc/C9L5-V3ME]; Amir H. Khoury, *The End of the National Patent Office*, 52 IDEA 197, 199–200 (2012) (suggesting the idea of a global patent regime).

will be quickly available in developing countries, resulting in distributional advantages and affordable prices.<sup>204</sup>

*B. Restrictions and Safeguards*

If patent protection is calibrated to the level of investment required to create the vaccine, this could create an incentive for companies to falsely report high investments in order to extend their patents (and increase their profits). To address this concern, we suggest that application and renewal fees be keyed to the declared level of investment. This fee structure will serve as a disincentive to false investment reporting: if patent applicants are required to pay application and renewal fees commensurate with their level of investment, they are less likely to exaggerate their investment in their reports to the patent office. Similarly, the burden of proof to establish the level of investment lies with the patent holder, which will also make false reporting more challenging. In case of infringement litigation, the patentee will have to prove the claimed level of investment, which will be the basis for calculating damages.<sup>205</sup>

More broadly, many existing mechanisms can guarantee honest reporting of investment and make it difficult for companies to overreport their investments. In particular, because large pharmaceutical companies are publicly traded, false reporting is not a real concern given the detailed oversight regimes pertaining to such firms.<sup>206</sup> False reporting can also be limited using similar mechanisms, such as those associated with state and federal income tax filings<sup>207</sup> and SEC filings.<sup>208</sup>

An additional, possible concern is that the recoupment model will lead to inefficient investment policy in vaccine R&D. After all, if companies know patent duration is extended when investment is higher, they may have an incentive to make unnecessary or wasteful investments. But pharmaceutical companies operate in a highly competitive environment as is evident from the COVID-19 vaccine race. Competitive pressures discourage such inefficiencies as companies have a strong incentive to speed up development and minimize expenses in order to be the first to bring their vaccines to the market.

Alternatively, one might argue that the proposed recoupment model will incentivize patent holders to slow vaccine sales to extend the life of the patent. This,

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204. See INT'L CTR. FOR TRADE & SUSTAINABLE DEV., *THE GLOBAL DEBATE ON THE ENFORCEMENT OF INTELLECTUAL PROPERTY AND DEVELOPING COUNTRIES* (2009).

205. See Lisa Larrimore Ouellette, *Adjusting Patent Damages for Nonpatent Incentives*, 26 TEX. INTEL. PROP. L.J. 187, 187–88 (2017).

206. See generally Ray Ball, *Infrastructure Requirements for an Economically Efficient System of Public Financial Reporting and Disclosure*, in BROOKINGS-WHARTON PAPERS ON FINANCIAL SERVICES: 2001, at 127, 127 (Robert E. Litan & Richard J. Herring eds., 2001).

207. Tax filings require detailed reports pertaining to all aspects of a company's business operations. See generally Jeffrey A. Dubin & Louis L. Wilde, *An Empirical Analysis of Federal Income Tax Auditing and Compliance*, 41 NAT'L TAX J. 61 (1988).

208. See generally Earl K. Stice, *The Market Reaction to 10-K and 10-Q Filings and to Subsequent Wall Street Journal Earnings Announcements*, 66 ACCT. REV. 42 (1991).

too, is an unwarranted concern, as patent holders will presumably want to recoup their investment as quickly as possible, before market conditions change, and it becomes more difficult for them to realize a profit. Indeed, the development and commercialization of the COVID-19 vaccine illustrates this principle.

Finally, the proposed recoupment model would introduce new costs, mainly in the process of evaluating the level of investment required to develop each vaccine. These costs would join the already high costs of operating the patent system.<sup>209</sup> Our proposal offers a more tailored and accurate level of patent protection, keyed to specific inventions; naturally, this precision comes with a price, as some cost must be incurred in further examination of individual patents.<sup>210</sup> Any procedure for differentiating patent protection by offering some inventions more protection than others would entail additional administrative costs.<sup>211</sup> Accordingly, some scholars favor the current one-size-fits-all system on the ground that uniform patent protection reduces the costs of negotiating, drafting, and policing licensing agreements.<sup>212</sup> Scholars have similarly argued that a unified form of patent protection lowers the cost of patent litigation, as it saves the need to adjudicate another aspect of the scope of legal protection.<sup>213</sup> According to this argument, any variation in patent protection would mean that “[c]ourts will have to expend efforts after the fact to determine the boundaries of the different rights, and legislators will have to do the same *ex ante*. Together, these efforts can impose substantial costs on society.”<sup>214</sup>

In this connection, we note first that the additional administrative costs are offset by the great economic advantages of our proposal, not to mention the number of lives our proposal would save by expediting vaccine distribution. Moreover, additional administrative costs could be financed either by payments by patent applicants directly or indirectly through taxation.<sup>215</sup> Second, we maintain that at least some of these increased costs will eventually disappear as the number of patent applications decreases.<sup>216</sup> Under our proposed model, inventions that require

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209. See U.S. PAT. & TRADEMARK OFF., PATENT PUBLIC ADVISORY COMMITTEE ANNUAL REPORT 16 (2007) (describing the administrative costs involved in the operation of a patent office).

210. See John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 507–09 (2003) (arguing against arrangements that may allow patentees to renegotiate patent rights).

211. See Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1828 (1984) (arguing that if more valuable inventions are offered stronger protection, the overall costs of managing the patent system will increase).

212. See Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361, 1399 (2009).

213. *Id.* at 1425.

214. Bell & Parchomovsky, *supra* note 121, at 248.

215. The USPTO is currently funded entirely through fees, following P.L. 101-508, the Omnibus Budget Reconciliation Act (OBRA) of 1990, as amended. GLENN J. MCLOUGHLIN, CONG. RSCH. SERV., RS20906, U.S. PATENT AND TRADEMARK OFFICE APPROPRIATIONS PROCESS: A BRIEF EXPLANATION 1 (2014), <https://fas.org/sgp/crs/misc/RS20906.pdf> [<https://perma.cc/Y89L-RV5W>].

216. U.S. PAT. & TRADEMARK OFF., REGULATORY IMPACT ANALYSIS: SETTING AND ADJUSTING PATENT FEES IN ACCORDANCE WITH SECTION 10 OF THE LEAHY-SMITH AMERICA

little to no investment will not enjoy patent protection. This means that the many low-quality patents filed under the current regime will not be filed, leading to significant savings overall in the administrative costs of operating the patent system.<sup>217</sup> Most importantly, we argue that any increase in the cost of administering the patent system is more than offset by the incalculable advantages of our proposal in terms of lives saved as a result of speedier and more equitable vaccine distribution.

### III. COMPARATIVE ANALYSIS

In the following sections, we provide an overview of alternative proposals for addressing access to COVID-19 vaccines and reasonable and fair pricing of vaccines. The discussion highlights that while other proposals can address current access and pricing challenges, the recouptment patent model is superior to them in many ways.

#### *A. Compulsory License*

As discussed above, pharmaceutical companies are likely to exploit patents for COVID-19 vaccines to price their products profitably and control the terms of licensing agreements, pricing developing countries out of access to these vaccines for many of their citizens.<sup>218</sup> Compulsory licensing schemes, including those contemplated by the TRIPS Agreement, are a major tool cited for addressing emergency health crises, such as the current COVID-19 pandemic.

Article 30 of the TRIPS 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.<sup>219</sup> In non-emergency situations, licensees must first negotiate directly with patent holders before a compulsory license can be considered, and government intervention is to be reserved for public health crises.<sup>220</sup> As discussed in negotiations leading up to the Doha Public Health Declaration,<sup>221</sup> compulsory licenses may be used in accordance with Article 30 to effectuate specific exceptions to intellectual property

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INVENTS ACT 4–5 (2013) (arguing that if patent application fees are increased, this can result in a decrease in the number of patent applications).

217. *See id.* at 15.

218. Akl, *supra* note 137.

219. 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: PRACTICAL EXPERIENCES AND WAYS FORWARD 235, 238 n.6 (Reto M. Hilty & Kung-Chung Liu eds., 2015).

220. *Id.* at 239.

221. 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'L ECON. L. 921, 935 (2007).

rights for the purpose of increasing access to medicines in times of public health crises.<sup>222</sup>

Many scholars worldwide have proposed the introduction of domestic legislation as a solution to the current crisis. Article 31(b) of the TRIPS Agreement contemplates compulsory licenses “in the case of a national emergency or other circumstances of extreme urgency,” such as a public health crisis.<sup>223</sup> Pursuant to domestic legislation in accordance with this provision, governments can allow third parties to replicate a patented vaccine;<sup>224</sup> suspend the patent rights of a given manufacturer; and/or allow the import, manufacture, and sale of a generic copy of the patented invention for the national demand to be met. Through measures such as these, domestic compulsory licensing increases public access to existing technologies and medicines. Nevertheless, Article 31(f) limits the use of compulsory licenses under these circumstances to domestic product distribution.<sup>225</sup>

Additionally, Article 31(k) of the TRIPS Agreement explicitly authorizes compulsory licenses<sup>226</sup> for use under domestic competition laws as a remedy for patent holders’ “anti-competitive” conduct,<sup>227</sup> although the Agreement does not specifically define “anti-competitive” behavior. Commentators have expressed differing views on the feasibility of increasing access to pharmaceuticals by granting compulsory licenses under Article 31(k).<sup>228</sup> Compulsory licenses under this section are not subject to the Article 31(f) no-export limitation.<sup>229</sup> Moreover, 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—remuneration.<sup>230</sup> These provisions highlight the need to balance patent protection with competition policies.<sup>231</sup>

222. Ong, *supra* note 219, at 246; Reichman & Abbott, *supra* note 221, at 957–58; *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’L ECON. L. 73, 89 (2004).

223. TRIPS Agreement, *supra* note 134, at art. 31(b).

224. Benjamin Tham & Mark Finlay, *COVID-19 Vaccine Research, Development, Regulation and Access* 20 (SMU Ctr. for AI & Data Governance Rsch. Paper, Paper No. 03, 2020), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3640153](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3640153) [<https://perma.cc/9KY7-JWSN>].

225. Ong, *supra* note 219, at 239.

226. *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, 186–87 (Inge Govaere & Hanns Ullrich eds., 2007).

227. Ong, *supra* note 219, at 237.

228. *See* Cottier, *supra* note 226; Wee Loon Ng-Loy, *Exploring the Flexibilities Within Global IP Standards*, 2 IPQ 162, 180 (2009).

229. *See* Ong, *supra* note 219, at 239–40.

230. *Id.* at 246.

231. *See* TRIPS Agreement, *supra* note 134, at art. 8(2).

In addition to the foregoing provisions, the 2001 Doha Declaration<sup>232</sup> and the General Council Decision<sup>233</sup> of 2003 gave rise to the inclusion of Article 31*bis* in the TRIPS Agreement,<sup>234</sup> which was intended to allow for greater flexibility in compulsory license regimes.<sup>235</sup> Article 31*bis* enumerates a list of circumstances in which the geographic limitation on compulsory licenses may be waived to allow drug exportation to developing countries facing public health challenges.<sup>236</sup>

Within the Article 31*bis* system, member states lacking sufficient domestic manufacturing abilities may import patented products for which a compulsory license has been issued.<sup>237</sup> While the *least* developed countries are assumed to lack this infrastructure, developing countries must be deemed incapable of domestic production by the TRIPS Council before receiving importing rights.<sup>238</sup> In their application to the TRIPS Council, importing countries must specify the name and expected quantity of the patented drug they wish to import.<sup>239</sup> Importing members are urged to prevent the re-exportation of products after their importation.<sup>240</sup>

Exporting countries are required to notify the TRIPS Council of the grant of a compulsory license and its conditions.<sup>241</sup> Exporters must specify the volume of the product being produced for export under a compulsory license and may not produce more than the quantity specified for this purpose.<sup>242</sup> The exported product must be demarcated by unique size or color, and information regarding both the quantity and the distinguishing features of the generic product must be publicized on the internet.<sup>243</sup>

The Article 31*bis* system has been criticized for the administrative burden it places on exporting countries.<sup>244</sup> 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.<sup>245</sup> Finally, the strict limitations placed on production and distribution of generic pharmaceuticals manufactured under a compulsory license

232. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

233. General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (2003) [hereinafter *Paragraph 6 of the Doha Declaration*].

234. Ong, *supra* note 219, at 242.

235. See General Council, *Annex to the Protocol Amending the TRIPS Agreement*, art. 31*bis*(5), WTO Doc. WT/L/641 (adopted Dec. 8, 2005); Ong, *supra* note 219, at 244.

236. See Ong, *supra* note 219, at 236.

237. See *id.* at 242–43 n.20.

238. See General Council, *Annex to the TRIPS Agreement*, WTO Doc. WT/L/641 (adopted Dec. 8, 2005); Ong, *supra* note 219, at 242–43 n.20.

239. *Annex to the TRIPS Agreement*, *supra* note 238, ¶ 2(a)(i).

240. See *id.* ¶ 3.

241. *Id.* ¶ 2(c).

242. See *id.* ¶ 2(b)(i), 2(c).

243. *Id.* ¶ 2(b)(ii)–(iii).

244. Ong, *supra* note 219, at 245.

245. *Id.*

disincentivize exportation by manufacturers.<sup>246</sup> Perhaps for these reasons, the Article 31*bis* mechanism has been used only once in practice.<sup>247</sup>

In the United States, the Bayh-Dole Act grants the government “march-in” rights for patents related to research that is at least partly government funded.<sup>248</sup> And in the EU, Regulation 816/2006,<sup>249</sup> adopted in May of 2006, allows the compulsory license of patents relating to the manufacture of pharmaceuticals for export to countries facing public health challenges.<sup>250</sup> This legislation reflects a 2003 decision by the World Trade Organization<sup>251</sup> and was intended to improve low-income countries’ access to medical relief.<sup>252</sup>

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 a Cabinet-level decision. The most salient concern about compulsory licenses is that these licenses 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.<sup>253</sup>

Numerous studies have explored the effects of compulsory licenses on innovation and investment in R&D.<sup>254</sup> Their findings vary by industry and are unclear with respect to the pharmaceutical industry.<sup>255</sup>

However, a number of scholars have questioned the wisdom of compulsory patent licensing and its effect on innovation and investment in R&D. In a recent empirical study, Jonathan Barnett explored shifting trends in patent protection and enforcement in the United States since the late nineteenth century and examines the prevalence of compulsory licensing in different periods.<sup>256</sup> He shows that during

246. See CAMPAIGN FOR ACCESS TO ESSENTIAL MEDS., NEITHER EXPEDITIOUS, NOR A SOLUTION: THE WTO AUGUST 30TH DECISION IS UNWORKABLE, 3 (2006), [https://doctorswithoutborders.org/sites/default/files/2018-08/WTO\\_chretien.pdf?\\_ga=2.114400449.713279006.1629663070-633622275.1629663070](https://doctorswithoutborders.org/sites/default/files/2018-08/WTO_chretien.pdf?_ga=2.114400449.713279006.1629663070-633622275.1629663070) [https://perma.cc/4CTR-BWEV].

247. See 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, WTO Doc. IP/N/9/RWA/1 (2007); see also Canada, Notification Under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. IP/N/10/CAN/1 (2007).

248. Akl, *supra* note 137, at 205.

249. 2006 O.J. (L 157) 1, 2.

250. Jakob Cornides, *European Union Adopts Regulation on Compulsory Licensing of Pharmaceutical Products for Export*, 10 J. WORLD INTELL. PROP. 70 (2007).

251. See *Paragraph 6 of the Doha Declaration*, *supra* note 233.

252. See Cornides, *supra* note 250, at 75.

253. See Akl, *supra* note 137, at 205.

254. Reto M. Hilty & Kung-Chung Liu, *Introduction*, in *COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD* 1, 1–2 (Reto M. Hilty & Kung-Chung Liu eds., 2015).

255. Ong, *supra* note 219, at 263.

256. Jonathan M. Barnett, *The Great Patent Grab*, in *THE BATTLE OVER PATENTS: HISTORY AND POLITICS OF INNOVATION* (Stephen H. Haber & Naomi R. Lamoreaux eds., 2021).

this period, the competing interests of patent enforcement, on the one hand, antitrust enforcement, on the other, and governmental support for R&D and innovation ebbed and flowed.<sup>257</sup> In general, periods characterized by comparatively weak patent protection, strong antitrust enforcement, and legal constraints on private firms' rights in inventions produced with government funding corresponded to an increase in efforts to pass compulsory licensing legislation,<sup>258</sup> while strong patent protection and weak antitrust enforcement yielded a surge in R&D investment.<sup>259</sup> During the former periods, federal antitrust bodies implemented compulsory licensing indirectly through litigation and consent decrees.<sup>260</sup> Between 1941 and 1959, for example, compulsory licensing orders in antitrust actions affected an estimated 40,000–50,000 patents (eight percent of all unexpired patents at the time).<sup>261</sup> Courts also employed compulsory licenses to dismantle monopolies<sup>262</sup> and reengineer<sup>263</sup> markets.<sup>264</sup> In addition to compulsory licensing, generous government funding also weakened intellectual property rights. In return for government support, firms forfeited certain patenting abilities.<sup>265</sup>

Relaxing intellectual property protections was predicted to promote innovation by lowering entry costs for small firms (through portfolio forfeiture) and stoke competition among large firms.<sup>266</sup> However, the rise of compulsory licensing culture led to a significant decline in patenting rates by U.S. inventors.<sup>267</sup> Post-war investment and innovation remained concentrated among several large, established firms that were less likely to produce breakthrough inventions challenging traditional technologies.<sup>268</sup> By the mid-1960s, even innovation by such firms began to decline as government funding fell.<sup>269</sup> Meanwhile, innovation by smaller firms ultimately increased only following the strengthening of patent protection in the 1980s.<sup>270</sup> 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.<sup>271</sup> This large study suggests that compulsory licensing schemes are generally unadvisable and eventually undermine investment in R&D and innovation.

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257. *See id.* at 3.

258. *Id.*

259. *See id.* at 3, 20.

260. *Id.* at 3.

261. *Id.* at 5.

262. *See* United States v. Aluminum Co. of Am., 148 F.2d 416, 446–47 (2d Cir. 1945).

263. *See* United States v. United Shoe Mach. Corp., 110 F. Supp. 295, 349–50 (D. Mass. 1953); *see also* In re Xerox Corp., 86 F.T.C. 364 (1975).

264. *See* Barnett, *supra* note 256, at 9.

265. *See id.* at 27.

266. *See id.* at 17.

267. *See id.* at 20.

268. *See id.* at 25–28.

269. *See id.* at 1–2.

270. *Id.* at 27.

271. *See id.* at 19.

Nevertheless, compulsory licensing schemes have occasionally been used internationally in the pharmaceutical sector, and a large body of scholarship addresses the market effects of such schemes. These studies have observed that while intellectual property rights incentivize innovation, they also result in market-freezing monopolies.<sup>272</sup> Because monopolies in the pharmaceutical field may restrict access to life-saving medicines,<sup>273</sup> compulsory licensing mechanisms have been incorporated into the TRIPS Agreement to allow for government intervention when necessary, as discussed above.<sup>274</sup>

Some scholars have argued that compulsory licensing disincentivizes innovation and reduces efficiency.<sup>275</sup> For example, in a 1994 study, Fisch argued that compulsory license in Canada would reduce R&D investment.<sup>276</sup> Lee and Mansfield and Bird and Cahoy predicted that compulsory license would reduce the flow of foreign direct investment (FDI) into Canada.<sup>277</sup> Although these predictions did not materialize,<sup>278</sup> the impact on global pharmaceutical distribution was minimal, as Canada's role in the global pharmaceutical market was insignificant to begin with.<sup>279</sup>

Other scholars have studied the impact of compulsory licensing on R&D and found a positive correlation between compulsory licensing and innovation. For instance, a one-year, 1977 study by Scherer examined 700 companies and found that the forty-two that were subject to compulsory licenses spent *more* on R&D than others.<sup>280</sup> Another study by Moser and Voena found that under the Trading with the Enemy Act passed during WWI, compulsory licensing led to a twenty percent increase in American innovation.<sup>281</sup> Stephanie Lee found a similar positive correlation post-WWII between compulsory licensing of German, Japanese, and Italian patents and U.S. domestic innovation.<sup>282</sup>

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272. See Yugank Goyal, *Economic and Procedural Constraints of Compulsory Licenses for Medicines*, in COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD, *supra* note 254, at 437, 438.

273. See, e.g., Kumariah Balasubramaniam, *Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 90, 100 (Peter Drahos & Ruth Mayne eds., 2002).

274. Goyal, *supra* note 272.

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

276. See Goyal, *supra* note 272, at 438–39.

277. *Id.* at 439.

278. See 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 65, 79, 108 (Robert D. Anderson & Nancy T. Gallini eds., 1998); see also Goyal, *supra* note 272, at 450.

279. See McFetridge, *supra* note 278, at 84.

280. Goyal, *supra* note 272, at 439.

281. Petra Moser & Alessandra Voena, *Compulsory Licensing: Evidence from the Trading with the Enemy Act*, 102 AM. ECON. REV. 396, 404 (2012).

282. Stephanie Lee, *Compulsory Licensing and Domestic Innovation: Evidence from the Trading with the Enemy Act After World War II (May 2011)* (B.A. thesis, Stanford University) (on file with SearchWorks, Stanford University).

Studies by Goyal and Chien suggest that the repercussions of compulsory licensing on innovation depend primarily on the size and importance of the licensed market.<sup>283</sup> 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.<sup>284</sup> These observations suggest that compulsory licensing is a sub-optimal way of dealing with COVID-19 vaccine access challenges, and that if governments do use this approach, they must sharpen and solidify the conditions and laws through which compulsory licensing is carried out to minimize these losses.<sup>285</sup>

In the wake of the Doha Declaration, new trends emerged regarding compulsory licensing. The waiver mechanism established in Article 31*bis* was designed to increase compulsory licensing in developing countries as a means of expanding access to affordable medicines.<sup>286</sup> A study by Beall and Kuhn reviewed twenty-four instances in which compulsory licensing was considered between 1995 and 2011 and found that in almost half of the cases, the mere specter of a compulsory license produced price reductions or a voluntary licensing agreement.<sup>287</sup> Notably, two-thirds of the compulsory licenses that were issued were for pharmaceuticals in response to an urgent need for HIV/AIDS treatments.<sup>288</sup> The study observed that while 2003–2005 saw a spike in compulsory licenses for antiretroviral drugs, compulsory licenses use dropped between 2006 and 2011.<sup>289</sup>

A major study by Goyal on the economic and medical effects of compulsory licenses collected data on compulsory license implementation, foreign direct investment (FDI) flow, and HIV prevalence between 2000 and 2012,<sup>290</sup> with a special focus on compulsory licenses use in a selected groups of countries in Africa, Asia, and South America. Findings from the fourteen countries studied<sup>291</sup> revealed that while the implementation of compulsory licensing schemes provoked a backlash in the form of trade sanctions in one instance (Egypt),<sup>292</sup> compulsory licensing generally improved access to pharmaceuticals in these countries, which saw corresponding declines in infection rates and did not have a lasting negative impact on FDI.<sup>293</sup> In fact, some compulsory license-issuing countries saw an

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283. See Goyal, *supra* note 272, at 451, 453–54; see also Colleen 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).

284. See Chien, *supra* note 283.

285. See Goyal, *supra* note 272, at 441.

286. See Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis*, PLOS MED., Jan. 2012, at 1, 3.

287. See *id.* at 3–4.

288. *Id.* at 4.

289. *Id.*

290. Goyal, *supra* note 272, at 443–48.

291. *Id.* (studying compulsory licensing in Egypt, Zimbabwe, Malaysia, Zambia, Mozambique, Ghana, Indonesia, Taiwan, Thailand, Brazil, Rwanda, Ecuador, India, and Indonesia).

292. *Id.* at 450–51.

293. *Id.* at 442, 451.

increase in FDI,<sup>294</sup> and most countries who lost FDI between 2008 and 2009 were suffering from the global recession.<sup>295</sup> Despite this positive outlook on compulsory licensing, as of 2020, compulsory licenses have rarely been employed in pharmaceutical contexts<sup>296</sup> due largely to the slow implementation of compulsory license legislation in both affluent, exporting countries and economically disadvantaged importing countries.<sup>297</sup> In addition, many patented manufacturers already designate a portion of their supply for subsidized distribution in developing countries, making drug prices lower in those countries than they would be if purchased from a generic provider.<sup>298</sup> Thus, compulsory licenses are not always the optimal medium for attaining affordability.<sup>299</sup> In addition, the mere adoption of compulsory licensing legislation can affect pharmaceutical patenting culture, regardless of whether compulsory licenses are frequently granted. Indeed, the threat of a compulsory license may force firms to lower their prices rather than risk having a generic manufacturer siphon off their success.<sup>300</sup>

Moreover, compulsory license applications are frequently subject to heavy resistance domestically and internationally. For example, in India, Natco's compulsory license applications<sup>301</sup> to enable the exportation of patented drugs to developing countries were denied.<sup>302</sup> All subsequent applications in India for compulsory licenses for drugs were either withdrawn or denied by the Patent Controller.<sup>303</sup> Similarly, Thailand's use of compulsory licenses in the pharmaceutical sector met with heavy opposition from different players,<sup>304</sup> even though Thailand appears to have acted within the parameters of the TRIPS Agreement.

294. *Id.* at 449.

295. *Id.* at 449–50.

296. Caranina (Nina) Colpaert, *Compulsory Licensing for Pharmaceuticals in the EU: A Reality Check*, HARV. L. PETRIE-FLOM CTR. BLOG (Oct. 21, 2020), <https://blog.petrieflom.law.harvard.edu/2020/10/21/compulsory-licensing-eu-pharma/#:~:text=In%20the%20EU%2C%20compulsory%20licensing,the%20context%20of%20public%20health> [<https://perma.cc/PXX3-SNFP>].

297. Cornides, *supra* note 250, at 75.

298. *Id.*

299. *Id.*

300. *Id.*

301. Divya Subramanian, *TRIPS and Compulsory Licensing: The NATCO Nuance*, in *COMPULSORY LICENSING: DEVELOPING ECONOMIES* 157, 162–63 (P. L. Jayanthi Reddy ed., 2008).

302. Sandeep K. Rathod, *Compulsory Licences on Pharmaceutical Patents in India: A Short Article*, 13 J. GENERIC MEDS. 108, 110 (2017).

303. *Id.* at 111.

304. 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* (Carlos M. Correa ed., 2009); see Editorial, *Bangkok's Drug War Goes Global*, WALL ST. J. (Mar. 7, 2007, 12:01 AM), <https://www.wsj.com/articles/SB117322181443628799> [<https://perma.cc/ZZ9V-J8GA>]; 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/78QV-4CDL>]; 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> [<http://web.archive.org/web/20190917185739/https://www.ft.com/content/6889bbbc-ac98-11db-9318-0000779e2340>]; Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition*, 48

In summary, the use of compulsory licenses can offer greater access and pricing of vaccines all over the world. 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 recoupment patent model, by contrast, preserves R&D incentives while carefully rewarding vaccine inventors. The recoupment model operates within the existing patent regime; it does not entail direct state intervention in the form of compulsory licensing, which is akin to a taking of the patent. Instead, our proposal simply calibrates the duration of patent protection to match the level of investment required to create the vaccine. Because our proposed regime does not involve an extreme departure from the existing legal arrangement, it benefits from a sense of legitimacy. In addition, the recoupment model offers internal consistency, which is lacking in compulsory licensing: our model defines in advance the criteria for the reward to which the inventor is entitled. The recoupment model is also advantageous in its global applicability, as compared to compulsory licensing, which operates on a state-by-state basis.

#### B. Government Incentives and Agreements

Another way to incentivize vaccine development while addressing pricing and access concerns is by using government non-patent incentives. Non-patent incentives are critical to vaccine development for several reasons.<sup>305</sup> First, vaccine R&D usually begins only after a particular disease strain is identified and recognized as a significant threat.<sup>306</sup> Second, patents are often held by diverse entities, making consolidation and effective R&D difficult.<sup>307</sup> Third, vaccines are generally viewed as less profitable than therapeutic drugs, resulting in their lack of development.<sup>308</sup>

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VA. J. INT'L L. 211, 241 (2007); Kevin E. Noonan, *Worldwide Drug Pricing Regime in Chaos*, PATENT DOCS (May 9, 2007), [https://www.patentdocs.org/2007/05/worldwide\\_drug.html](https://www.patentdocs.org/2007/05/worldwide_drug.html) [https://perma.cc/YB7U-U6UF]; Kevin E. Noonan, *The Law of Unintended Consequences Arises in Applying TRIPS to Patented Drug Protection in Developing Countries*, PATENT DOCS (May 1, 2007), [https://www.patentdocs.org/2007/05/the\\_law\\_of\\_unin.html](https://www.patentdocs.org/2007/05/the_law_of_unin.html) [https://perma.cc/68X7-2CX8]. See generally Kevin Outtersson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines in Developing Countries*, 27 HEALTH AFFS. 130, 133–34 (2008); Press Release, MSF Access Campaign, Abbott Should Reconsider its Unacceptable Decision to Not Sell New Medicines in Thailand (Mar. 22, 2007).

305. Rutschman, *supra* note 128; Rutschman, *supra* note 168, at 762–65; Qiwei Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. BIOSCIENCE 1, 7 (2020).

306. Rutschman, *supra* note 128, at 1207.

307. *Id.*; Rutschman, *supra* note 168, at 751–54.

308. Rutschman, *supra* note 168; Xue & Ouellette, *supra* note 305, at 3–4.

Government grants, subsidies, tax incentives, annuity exemptions, and prizes can all be used to offset these factors and incentivize innovation.<sup>309</sup>

Non-patent incentives could be awarded to manufacturers in return for their commitment to make their patented inventions openly available to the public for use in response to the COVID-19 crisis,<sup>310</sup> while allowing them to monetize the inventions in other fields.<sup>311</sup> While non-patent alternatives avoid the problems associated with the monopolistic pricing of patented products, they introduce their own problems. For instance, there is broad agreement that prize-and-reward systems would present thorny problems of administration.<sup>312</sup> Because a system that rewards inventors with prizes rather than patents 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, it may be difficult to assess the social value of an invention, particularly when it comes to unpredictable or new technologies. Moreover, the extent to which inventors should be able to appropriate the social value of their contributions is a subject of significant debate.

One type of non-patent incentive, which a number of developed countries have used in the context of emerging COVID-19 vaccines, is the advance commitment agreements we identified in a previous section.<sup>313</sup> Although such agreements help to support costly vaccine development, they tend to exacerbate problems of inequity in vaccine distribution characterized by over-allocating early batches of emerging vaccines to pre-purchasing countries, leaving shortages in developing nations.<sup>314</sup>

Another non-patent mechanism that governments may use to encourage innovation generally and to speed development of COVID-19 vaccines in particular is to fund R&D either in return for joint ownership in the intellectual property rights in the resulting vaccines or in exchange for preferential vaccine distribution for its population. Indeed, one of the 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).<sup>315</sup> Accordingly, the public sector may hold certain rights over emerging patentable research, including

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309. 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, 1275 (2018); Xue & Ouellette, *supra* note 305, at 39.

310. OPEN COVID PLEDGE, [opencovidpledge.org](https://opencovidpledge.org) (last visited Jan. 11, 2022).

311. Contreras, *supra* note 130, at 160.

312. Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1380–81, 1406–07 (2011).

313. *Supra* Section II.B; Rutschman, *supra* note 26.

314. Rutschman, *supra* note 55, at 11.

315. 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-ma/> [<https://perma.cc/8KYU-CW9K>].

an intellectual property stake in the vaccine.<sup>316</sup> Current evidence suggests that the federal government might indeed have retained some rights over the vaccine.<sup>317</sup> If joint ownership is confirmed, federal patent law will allow the NIH to produce and distribute vaccine doses with a focus on public health, not profits.<sup>318</sup> However, the major disadvantage of this solution is that donor states in the United States will receive millions of first-preference doses before vaccines are available in the free market. This can generate funding incentives but impedes equality of access to an emerging vaccine.<sup>319</sup>

Even if the NIH is not a joint owner of intellectual property rights in the Moderna vaccine, the federal government may still retain “march-in” rights which could be exercised to compel the issuance of nonexclusive licenses to other manufacturers<sup>320</sup> if Moderna were unable or unwilling to produce sufficient vaccine doses at affordable prices.<sup>321</sup> This solution resembles the compulsory license discussed above and presents similar challenges. In particular, it would require federal intervention of a kind the U.S. government has historically been reluctant to implement.<sup>322</sup>

The U.S. government could also invoke 28 U.S.C. § 1498,<sup>323</sup> which allows it to use patented inventions without permission upon payment of a “reasonable and entire compensation” to the patent holder, to secure an affordable vaccine.<sup>324</sup> However, this section applies only to products “used or manufactured by or for the United States.”<sup>325</sup> Another solution available to the U.S. government is the Defense

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

317. See Ed Silverman, *Pharmalittle: 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/PH6W-JMWL>]; Rutschman, *supra* note 26, at 180.

318. See 35 U.S.C. § 262; Rutschman, *supra* note 26, at 181.

319. *Id.* at 197.

320. 35 U.S.C. § 203.

321. Moderna has stated that it is on track to produce between 500 million and 1 billion doses annually. 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, 11:34 AM) <https://www.fiercepharma.com/pharma/moderna-has-started-producing-commercial-covid-19-vaccines-at-risk-ceo> [<https://perma.cc/6G3U-FTQD>].

322. See generally Ryan Whalen, Note, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching In?*, 109 NW. U.L. REV. 1083, 1108–11 (2015); Rutschman, *supra* note 26.

323. 28 U.S.C. § 1498; Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 301–02 (2016); see also Charles Duan & Christopher J. Morten, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 33 (2020) (on file with author).

324. Rutschman, *supra* note 55, at 8.

325. Brennan & Kapczynski, *supra* note 323.

Production Act, under which it may compel manufacturers to produce a vaccine on fair terms.<sup>326</sup>

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 emerging COVID-19 vaccines. 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 recoupment patent model, by contrast, encourages innovation while confronting both access and pricing challenges by setting reasonable caps on the profits a patentee can earn. Moreover, the recoupment model is not subject to political pressures, as the reward to inventors is not based on an ad hoc decision regarding a prize but is instead based on clear and objective criteria. In this sense, our proposal offers a more systematic solution that defines the criteria for determining the level of profit to which inventors are entitled.

### *C. Global Voluntary Initiatives to Reduce Drug Prices*

There are a number of voluntary initiatives and collaborative frameworks aimed at making pharmaceutical products accessible to those who need them while encouraging innovation and protecting intellectual property rights. Although the United States has generally opted not to join international collaborative frameworks,<sup>327</sup> the Patent and Trademark Office has created a voluntary program—Patents 4 Partnerships<sup>328</sup>—to facilitate the licensing of patented technologies relevant to treating COVID-19, as well as a searchable platform—the IP Marketplace Platform<sup>329</sup>—that provides access to a centralized list of patents and patent applications. These resources are intended to reduce transaction costs and expedite R&D. To date, there are over 300 patents listed as available for licensing.<sup>330</sup>

Inventors may also volunteer to join a fair, reasonable, and non-discriminatory group to be deemed an “essential” company by a standard-setting organization.<sup>331</sup> In return, these inventors commit to making their patents available on fair terms.<sup>332</sup> Currently, these licensing systems include only telecommunication companies.

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326. Rutschman, *supra* note 55, at 8. See Aishvarya Kavi, *Virus Surge Brings Calls for Trump to Invoke Defense Production Act*, N.Y. TIMES (July 22, 2020), <https://www.nytimes.com/2020/07/22/us/politics/coronavirus-defense-production-act.html> [<https://perma.cc/KC9N-B2H3>].

327. Rutschman, *supra* note 55, at 16.

328. *Patents 4 Partnerships*, U.S. PAT. & TRADEMARK OFF., <https://developer.uspto.gov/ipmarketplace/search/patents> [<https://perma.cc/VG4S-WXZJ>].

329. *Id.*

330. *About the Platform*, U.S. PAT. & TRADEMARK OFF., <https://developer.uspto.gov/ipmarketplace/search/platform> [<https://perma.cc/88C2-EC3U>].

331. Justine Pila, *Reflections on a Post-Pandemic European Patent System*, 42 EIPR 530, 530–31 (2020).

332. See Eur. Telecomm. Standards Inst., ETSI Intellectual Property Rights Policy, Annex 6, § 6.1 (Dec. 1, 2021), <https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf> [<https://perma.cc/KE2H-5XY7>]; Case C-170/13, *Huawei Techs. Co. v. ZTE Corp.* EU:C:2015:477 (July 16, 2015).

Extending this system to cover medical technologies, such as COVID-19 vaccines, 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 World Health Organization’s (WHO’s) List of Essential Medicines<sup>333</sup>—to determine which patents should be deemed “essential.”<sup>334</sup>

Licensing pools such as Unitaid’s “Medicines Patent Pool,” a “one-stop-shop” where licenses for multiple products are available for interested generic manufacturers,<sup>335</sup> represent another type of voluntary initiative that could be used to stabilize COVID-19 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 parties.”<sup>336</sup> Under negotiated terms and conditions, patent owners may permit certain generics manufacturers to produce and sell their vaccines in poorer countries that would otherwise face shortages due to the high prices of patent-protected vaccines.<sup>337</sup> The COVID-19 Technology Access Pool—formed in May 2020<sup>338</sup>—includes thirty countries and several international organizations to date<sup>339</sup> and promotes sharing gene sequencing research and clinical trial results;<sup>340</sup> inserting provisions into agreements which mandate equitable distribution of treatments, vaccines, and products, as well as the

333. *WHO Model List of Essential Medicines*, WORLD HEALTH ORG., [www.who.int/medicines/publications/essentialmedicines/en/](http://www.who.int/medicines/publications/essentialmedicines/en/) [<https://perma.cc/S4KU-8TYH>] (last visited Jan. 11, 2022).

334. Pila, *supra* note 331, at 18.

335. UNITAID, UNITAID’S APPROACH TO INTELLECTUAL PROPERTY 12 (2016), <http://unitaid.org/assets/Unitaids-approach-to-intellectual-property.pdf> [<https://perma.cc/XNX7-CQUX>].

336. WORLD INTELL. PROP. ORG., PATENT POOLS AND ANTITRUST – A COMPARATIVE ANALYSIS 3 (2014), [https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent\\_pools\\_report.pdf](https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf) [<https://perma.cc/NBY8-DV3B>]; see also Ryan Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry*, 70 J. ECON. HIST. 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 123, 129 (Rochelle Cooper Dreyfuss, Diane Leenheer Zimmerman & Harry First eds., 2010); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 119, 123 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001); Michael J. Madison, Brett M. Frischmann & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657, 660–61, 681–87, 700–06 (2010); Josh Lerner & Jean Tirole, *Efficient Patent Pools 2* (Nat’l Bureau of Econ. Rsch., 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, 216–220 (2004).

337. Tham & Finlay, *supra* note 224, at 20.

338. *WHO COVID-19 Technology Access Pool*, WORLD HEALTH ORG., <https://www.who.int/initiatives/covid-19-technology-access-pool> [<https://perma.cc/Z2KJ-SEQB>].

339. *COVID-19: Countries Support ‘One-Stop Shop’ to Share Science and Research*, UN NEWS (May 29, 2020), <https://news.un.org/en/story/2020/05/1065132> [<https://perma.cc/KVF5-VBGN>].

340. *WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19 – 29 May 2020*, WORLD HEALTH ORG. (May 29, 2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19--29-may-2020> [<https://perma.cc/JWW8-M8DR>].

disclosure of clinical trial data;<sup>341</sup> licensing vital products to a range of manufacturers and distributors;<sup>342</sup> “open innovation models and technology transfer that increase local manufacturing and supply capacity”;<sup>343</sup> reducing the risks involved in negotiations with patent holders;<sup>344</sup> and expediting R&D through their signaling function, meaning that scientists, representatives, and funders know early on that a patent committed to the pool indicates that the underlying technology or method can be licensed.<sup>345</sup>

Through these measures, patent-pooling arrangements undoubtedly facilitate access to emerging COVID-19 vaccines. Nevertheless, they are an incomplete solution to problems of supply and distribution inequalities. First, participation in patent pools is voluntary, which limits their magnitude and diversity.<sup>346</sup> Second, patent pools do not ensure equitable access, as patent licensors and licensees do not necessarily address vaccine pricing in their agreements.<sup>347</sup> Finally, key players in pharmaceutical R&D, such as the International Federation of Pharmaceutical Manufacturers & Association, have been reluctant to join a voluntary COVID-19 product pool.<sup>348</sup>

A similar initiative is the Open COVID-19 Pledge, launched in March 2020, which expresses<sup>349</sup> “commitments made voluntarily by patent holders to limit the enforcement or other exploitation of their patents.”<sup>350</sup> A number of influential companies, including Facebook, Amazon, Intel, IBM, Microsoft, Hewlett-Packard, and the Sandia National Laboratories, have joined the Pledge.<sup>351</sup> The initiative offers standard licenses that Pledgors can use that addresses the essential contractual areas

341. *Id.*

342. *Id.*

343. *Id.*

344. See 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. & BIOSCIENCES 1, 4 (2020); Daniel A. Crane, *Patent Pools, RAND Commitments, and the Problematics of Price Discrimination*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY, *supra* note 336, at 18.

345. *Id.* at 5.

346. Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543, 603–04 (2015).

347. See, e.g., Ana Santos Rutschman, *How ‘Vaccine Nationalism’ Could Block Vulnerable Populations’ Access to COVID-19 Vaccines*, CONVERSATION (June 17, 2020, 8:16 AM), <https://theconversation.com/how-vaccine-nationalismcould-block-vulnerable-populations-access-to-COVID-19-vaccines-140689> [<https://perma.cc/NKH3-R4YX>].

348. Chris Dall, *Pharma Execs Say Several COVID Vaccine Options Needed*, CIDRAP (May 29, 2020), <https://www.cidrap.umn.edu/news-perspective/2020/05/pharma-execs-say-several-COVID-vaccine-options-needed> [<https://perma.cc/WC9K-RWLW>]; see also Ed Silverman, *The WHO Launched a Voluntary COVID-19 Product Pool. What Happens Next?*, STAT (May 29, 2020), <https://www.statnews.com/pharmalot/2020/05/29/who-COVID19-coronavirus-patents/> [<https://perma.cc/2GPB-9RMZ>] (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”).

349. Rutschman, *supra* note 55, at 16–17.

350. Contreras, *supra* note 346, at 546.

351. *Make the Pledge to Share Your Intellectual Property in the Fight Against COVID-19.*, OPEN COVID PLEDGE, <https://opencovidpledge.org> [<https://perma.cc/2HDR-9EW4>] (last visited Jan. 11, 2022).

for technology licensing.<sup>352</sup> It also outlines requirements for other licenses to be deemed “compatible licenses” or “alternative licenses” vis-à-vis the terms of the Pledge.<sup>353</sup>

Compatible licenses “provide a set of minimum use permissions”<sup>354</sup> and include preexisting licensing frameworks that have been reviewed—or those reviewed on a case-to-case basis—which have been deemed consistent with the Pledge.<sup>355</sup> Alternative licenses are those licensing frameworks that do not fit the previous categories but which are nonetheless consistent with the Pledge.<sup>356</sup> Licenses cannot be granted exclusively for non-commercial uses nor bear any kind of fees to be considered in the “spirit” on the Pledge.<sup>357</sup> Patent holders can choose the specific terms of their license to best serve their interests.<sup>358</sup> While the term of some standard licenses is “until one year after WHO declares the COVID-19 pandemic to have ended,”<sup>359</sup> others will terminate on “January 1, 2023, unless otherwise extended by the Pledgor.”<sup>360</sup>

The Pledge is unique because it allows patent holders to maintain ownership of their interest while relinquishing some of their rights for a limited time, demonstrating that altering licensing protocols can promote technology transfer for the improvement of public health *within* the dynamics of intellectual property.<sup>361</sup> Nevertheless, the ability to contend with public health emergencies should not depend on the altruism of individual intellectual property owners<sup>362</sup> as access to safe and effective vaccines by all countries should not be subject to the vicissitudes of private philanthropy.

352. *OCL-PC v1.0*, OPEN COVID PLEDGE (Mar. 31, 2020), <https://opencovidpledge.org/v1-0/> [<https://perma.cc/2P28-4N7S>].

353. *About the Licenses*, OPEN COVID PLEDGE, <https://opencovidpledge.org/licenses/> [<https://perma.cc/W5CY-BSCX>] (last visited Jan. 11, 2022).

354. *Id.*

355. *Id.* See *The MIT License*, OPEN SOURCE INITIATIVE, <https://opensource.org/licenses/MIT> [<https://perma.cc/C9SQ-6GBJ>] (last visited Jan. 11, 2022); *Apache License, Version 2.0*, APACHE, <https://www.apache.org/licenses/LICENSE-2.0> [<https://perma.cc/D9RY-NPNL>] (last visited Jan. 11, 2022).

356. *About the Licenses*, *supra* note, 353; *Attribution-ShareAlike 4.0 International (CC BY-SA 4.0)*, CREATIVE COMMONS, <https://creativecommons.org/licenses/by-sa/4.0/> [<https://perma.cc/T7UV-7Z6E>] (last visited Jan. 11, 2022); *GNU General Public License*, GNU OPERATING SYS., <https://www.gnu.org/licenses/gpl-3.0.en.html> [<https://perma.cc/QP83-43D8>] (last visited Jan. 11, 2022).

357. *About the Licenses*, *supra* note, 353.

358. *Id.*

359. See, e.g., *supra* note 352.

360. See, e.g., *OCL-PC v1.1*, OPEN COVID PLEDGE, <https://opencovidpledge.org/v1-1-ocl-pc/> [<https://perma.cc/6YZR-N6AT>].

361. Rutschman, *supra* note 26, at 19.

362. JOSHUA D. SARNOFF, COVID-19 HIGHLIGHTS NEED FOR RIGHTS TO REPAIR AND PRODUCE IN EMERGENCIES (2020), [https://papers.ssm.com/sol3/papers.cfm?abstract\\_id=3636551](https://papers.ssm.com/sol3/papers.cfm?abstract_id=3636551) [<https://perma.cc/8S5B-PU7J>].

Public-private partnerships are another voluntary mechanism that may help to speed access to emerging COVID-19 vaccines.<sup>363</sup> Through such partnerships, nonprofit 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.<sup>364</sup> 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 and has raised \$1.4 billion in support of COVID-19 vaccine R&D.<sup>365</sup> CEPI supports international collaborations and governance in the development and production of new vaccines.<sup>366</sup> If a CEPI-developed vaccine receives FDA approval, CEPI and its partners can produce over two billion vaccine doses by the end of 2021, to be circulated through CEPI-affiliated regional distribution sites.<sup>367</sup>

Another public-private partnership, Gavi, formed COVAX, which allows members to place advance orders for COVID-19 vaccines.<sup>368</sup> 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.<sup>369</sup> Mass orders make the vaccine more affordable to countries in COVAX than to countries that choose to negotiate directly with manufacturers.<sup>370</sup> COVAX works with multiple vaccine manufacturers simultaneously,<sup>371</sup> which mitigates the “all eggs in one basket” problem which is particularly acute in poor countries.<sup>372</sup> Like nationalist approaches, the model relies on advance commitment agreements between governments and manufacturers, but in the case of COVAX, these negotiations are mediated by international third-parties.<sup>373</sup> 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

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363. See generally THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT (Margaret Chon, Pedro Roffe & Ahmed Abdel-Latif eds., 2018); JON F. MERZ, INTELLECTUAL PROPERTY AND PRODUCT DEVELOPMENT PUBLIC/PRIVATE PARTNERSHIPS (2005) (focusing on product development partnerships).

364. Rutschman, *supra* note 26, at 187.

365. CEPI, *supra* note 184.

366. Rutschman, *supra* note 26, at 190.

367. Julie Steenhuysen, *Exclusive: Vaccine Alliance Finds Manufacturing Capacity for 4 Billion Doses of Coronavirus Vaccines*, REUTERS (June 24, 2020, 4:10 PM), <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/DD2D-JQ6F>].

368. GAVI, *supra* note 185, at 3–4.

369. Rutschman, *supra* note 26, at 191.

370. GAVI, *supra* note 185.

371. *Id.* at 3.

372. Rutschman, *supra* note 26, at 193.

373. *Id.*

oversees “policy and allocation” issues, and COVAX (under Gavi) is responsible for “procurement and delivery at-scale.”<sup>374</sup>

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.<sup>375</sup> Indeed, information related to intellectual property developed by these ad hoc partnerships is often “vague.”<sup>376</sup> Moreover, despite the success of CEPI, many public-private partnerships—especially those relying on philanthropy—will likely suffer from donor fatigue.<sup>377</sup> There are also numerous asymmetries between the public and the private players.<sup>378</sup> A large number of participants in the partnership may also result in “coordination inefficiencies,”<sup>379</sup> as new partners to collaborative efforts may err in their cost estimations.<sup>380</sup>

It bears mention 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.<sup>381</sup> And despite COVAX’s professed aim of promoting “equal access” to vaccines for populations in both developing and developed countries,<sup>382</sup> its current allocation policy distinguishes between self-funding countries, which will receive a sufficient supply of an emerging vaccine for twenty percent of their populations, and funded countries, which will receive doses allocated by the WHO.<sup>383</sup> In this sense, solutions like COVAX in fact contribute to the problem of vaccine nationalism: nations compete over the supply of pricey vaccines, with developing countries gaining the upper hand. Indeed, self-funded countries are “encouraged to donate vaccines if they have

374. *Id.* at 194; see WORLD HEALTH ORG., ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR (2020), [https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator) [<https://perma.cc/HVQ6-VC24>] (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”).

375. Rutschman, *supra* note 26, at 195.

376. Hilde Stevens, Geertrui van Overwalle, Bart Van Looy & Isabelle Huys, *Intellectual Property Policies in Early-Phase Research in Public-Private Partnerships*, 34 NATURE BIOTECH. 504, 504 (2016).

377. MERZ, *supra* note 363, at 14.

378. See generally RACHEL M. TAYLOR & JENNIFER CHRISTIAN, THE ROLE OF PUBLIC-PRIVATE PARTNERSHIPS IN HEALTH SYSTEMS STRENGTHENING: WORKSHOP SUMMARY (2016). See also Liza Vertinsky, *Boundary-Spanning Collaboration and the Limits of Joint Inventorship Doctrine*, 55 HOUS. L. REV. 401, 426–27, 429 (2017) (describing over-rewarding private-sector players).

379. TAYLOR & CHRISTIAN, *supra* note 378, at 42.

380. Jens K. Roehrich, Michael A. Lewis & Gerard George, *Are Public-Private Partnerships a Healthy Option? A Systematic Literature Review*, 113 SOC. SCI. & MED. 110, 113 (2014).

381. See, e.g., Kenny Bruno & Joshua Karliner, *Tangled Up in Blue: Corporate Partnerships at the United Nations*, CORPWATCH, (Sep. 1, 2000), <https://corpwatch.org/article/tangled-blue> [<https://perma.cc/W52X-XPC3>].

382. GAVI, COVID-19 VACCINE GLOBAL ACCESS (COVAX) FACILITY 2 (2020).

383. Seth Berkley, *COVAX Explained*, GAVI (Sept. 3, 2020), <https://www.gavi.org/vaccineswork/covax-explained> [<https://perma.cc/U5Z8-NRAX>].

more than they need,<sup>384</sup> which runs counter to the goal of making vaccines affordable internationally. For all these reasons, these types of schemes fail to offer a comprehensive solution to the problem.

Finally, vaccine manufacturers could simply forego seeking patents for COVID-19 vaccines,<sup>385</sup> or they could elect not to enforce patents associated with their vaccines.<sup>386</sup> Some philanthropic groups have advocated this approach.<sup>387</sup> There is precedent for this approach.<sup>388</sup> China's president has pledged to make a potential Chinese COVID-19 vaccine a global public good.<sup>389</sup> Additionally, Moderna has declared that it will not enforce its patent rights, although it remains to be seen whether it will uphold this commitment.<sup>390</sup> Once the pandemic has been mitigated through mass inoculation, patent-holders could activate commercial rights.<sup>391</sup>

The major drawback of all these initiatives is that they are voluntary, and as such, they do not offer an organized, consistent, and reliable framework capable of addressing the persistent challenges of ensuring equitable and affordable access to vaccines. Our recoupment patent model offers a more promising, stable, and consistent way to address these concerns globally.

#### *D. Other Changes to Patent Law and Policy*

Some scholars have proposed amending the patent laws to accommodate them to the imperatives of a global pandemic.<sup>392</sup> The proposed changes range from incentivizing information sharing to narrowing the patent scope for vaccines to denying patent protection for vaccines altogether.<sup>393</sup> To incentivize information sharing, 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,<sup>394</sup> suggesting that the European Patent Convention 2000 (EPC), Art. 55 will be changed in a way that allows inventors to

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384. GAVI, *supra* note 382, at 4.

385. *Covid 19 Action for Access*, MSF ACCESS CAMPAIGN, <https://msfaccess.org/covid-19-action> [<https://perma.cc/8PHH-VMT5>] (last visited Jan. 11, 2022).

386. *Id.*

387. *Id.*

388. *See, e.g.*, Eric Wesoff, *Tesla's Elon Musk Declares 'All Our Patent Are Belong to You,'* GTM (June 13, 2014), <https://www.greentechmedia.com/articles/read/teslas-elon-musk-declares-all-our-patent-are-belong-to-you> [<https://perma.cc/9E7S-C6RW>].

389. *China's COVID-19 Vaccine to Become Global Public Good When Available: Xi*, XINHUANET (May 18, 2020, 7:54 AM), [http://www.xinhuanet.com/english/2020-05/18/c\\_139066851.htm](http://www.xinhuanet.com/english/2020-05/18/c_139066851.htm) [<https://perma.cc/KQE3-JRRM>].

390. Dan Shores, *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?*, IPWATCHDOG (Apr. 9, 2021), <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/> [<https://perma.cc/2DKJ-K5LU>].

391. Tham & Findlay, *supra* note 224, at 15.

392. Pila, *supra* note 331, at 1.

393. *Id.*

394. *Id.* at 4, n.11.

make their inventions available to the public for a limited period without sacrificing their novelty.<sup>395</sup>

Another proposal that has been made is to restrict the patentability of second medical indications (i.e., additional uses for patented products) and to anchor the assessment of inventive step more firmly to patent policy. In the 1970s, the EPC guaranteed protection for all product and process inventions, excluding methods of medical treatment.<sup>396</sup> Inventors circumvented this exception by describing medical inventions as the “use” of a compound in the manufacture of a medication in a new application.<sup>397</sup> In the 1980s, the European Patent Office confirmed the patentability of second medical uses of medicines previously patented under the EPC.<sup>398</sup> Therefore, restricting the patentability of second medical indications and anchoring assessments of inventive step more firmly to patent policy can address challenges arising from the patentability of vaccines developed using previously-patented technologies, such as mRNA vaccines.<sup>399</sup> The 2019 decision of the Supreme Court of the United Kingdom in *Actavis v. ICOS*<sup>400</sup> limited the ability of inventors to patent second medical methods by narrowing the definition of “inventiveness.” In *Actavis*, a new dosage regime for a previously patented medicine was deemed “obvious,” and therefore not inventive.<sup>401</sup> Adopting the Court’s reasoning in *Actavis* would improve assessments of second medical indication patent applications.<sup>402</sup>

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.<sup>403</sup> 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*,<sup>404</sup> the European Patent Office will deny a patent under that section only for inventions universally regarded as immoral.<sup>405</sup> One scholar has proposed expanding the *ordre public* ground for rejecting a patent application to reflect humanitarian considerations.<sup>406</sup> This could be achieved by lowering the burden for establishing an Article 53(a) objection,<sup>407</sup> considering the patent’s economic and distributive effects when assessing the

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395. *Id.*

396. European Patents Convention (1973) art. 52, § 4.

397. Pila, *supra* note 331, at 6.

398. Enlarged Bd. Of Appeal Dec. Gr 05/83, Eur. Pat. Off., at 13 (Dec. 5, 1984).

399. Pila, *supra* note 331, at 5.

400. *Actavis Group PTC EHF v. ICOS Corp.* [2019] UKSC 15 (U.K.).

401. *Id.*

402. Pila, *supra* note 331, at 10.

403. *Id.* at 13.

404. European Patents Convention (2000) art. 53, § (a).

405. Tech. Bd. Of Appeal Dec. 0272/95 - 3.3.4, Eur. Pat. Off., at 2 (Oct. 23, 2002); Bds. Of Appeal Dec. T0356/93 - 3.3.4, Eur. Pat. Off., at 2 (Feb. 21, 1995).

406. Pila, *supra* note 331, at 13.

407. *Id.* at 13–14.

implications of granting it,<sup>408</sup> and instituting a mechanism for assessing the likely social and humanitarian implications of commercializing an emerging technology.<sup>409</sup> 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.<sup>410</sup>

Patent offices could also deny a manufacturer's patent application by strictly interpreting the application requirements while implicitly preferring more open market access.<sup>411</sup>

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, since patent offices are unlikely to be in a position to evaluate these types of challenges. More importantly, these proposals could potentially have a devastating effect on innovation and R&D in the context of vaccines. For these reasons, carefully crafted and narrowly tailored changes to patent law to incorporate our recoupment model are a more promising route to ensuring adequate incentives to innovate life-saving pharmaceuticals while minimizing the obstacles patent protection creates to their widespread access.

#### CONCLUSION

This Article offers a new model for incentivizing vaccine development worldwide. Currently, patent law offers a crude and imprecise solution that poorly balances the need to incentivize innovation with the need to expedite vaccine distribution. If left untouched, this framework will sabotage our ability to overcome the COVID-19 crisis where vaccines are not available to poor countries and spell disaster when future pandemics inevitably arrive. If we aim to overcome global pandemics, we must offer incentives for R&D that do not prevent equitable access to reasonably priced vaccines throughout the world. To achieve this goal, we must reconsider the role of patent protection. While current alternatives take steps in the right direction, the solutions they offer are incomplete, inequitable, unreliable, and ultimately unsustainable. Our model offers a novel legal framework within the existing system of patent protection, while better tailoring it to the goals the system is intended to promote. A recoupment patent regime offers a more balanced solution, which ensures pharmaceutical companies have full incentive to invest in

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408. *Id.* at 14.

409. Justine Pila, *Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies*, 38 NATURE BIOTECHNOLOGY 555, 555 (2020).

410. Pila, *supra* note 331, at 15.

411. *Id.*

the development of new vaccines, while minimizing delays in vaccine distribution. The crisis presented by the COVID-19 pandemic demands no less.