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## PATENTS AND THE PANDEMIC: INTELLECTUAL PROPERTY, SOCIAL CONTRACTS, AND ACCESS TO VACCINES

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## PATENTS AND THE PANDEMIC: INTELLECTUAL PROPERTY, SOCIAL CONTRACTS, AND ACCESS TO VACCINES

### Cover Page Footnote

\* Martin Luther King Jr. Professor of Law, UC Davis School of Law. This Article is based on the 2021 Distinguished Roger L. Shidler Lecture, which was delivered at the University of Washington School of Law on November 4, 2021. Although originally drafted in November 2021, this Article has been updated to address certain recent developments. I would like to thank Professor Robert Gomulkiewicz for inviting me to deliver the Shidler Lecture. I would like to extend special gratitude to the legacy of Roger L. Shidler and to all who have supported this endowed lecture. Thanks as well to the panelists who provided valuable feedback and to the editors of the Washington Journal of Law, Technology & Arts.

PATENTS AND THE PANDEMIC:  
INTELLECTUAL PROPERTY, SOCIAL CONTRACTS, AND ACCESS TO VACCINES

2021 Shidler Lecture

Peter Lee\*  
UC Davis School of Law

*Through enormous public support and private initiative, biopharmaceutical firms developed safe and effective COVID-19 vaccines in record time. These remarkable vaccines represent humanity’s best chance to end the devastating pandemic. However, difficult questions about ownership and access have arisen alongside the development and deployment of these vaccines. Biopharmaceutical companies have patented many of the technologies underlying these vaccines, thus seeming to pit intellectual property rights against the objective of wide and rapid dissemination of these critical resources. While prevailing debates have been framed in the language of intellectual property, this Article suggests that contract principles can help break the impasse and expand access to COVID-19 vaccines. This Article explores the significant leverage that governments have in conditioning public research support on increased access to patented vaccines and related technical knowledge. It also questions whether biopharmaceutical firms have upheld their end of the patent quid pro quo by adequately disclosing their technologies in exchange for exclusive rights. Finally, it considers how changed circumstances justify modifying the bargain that developed and developing countries struck in strengthening global intellectual property standards. In a variety of ways, governments can leverage public funding, quid pro quos, and changed circumstances to increase access to patented vaccines, thus helping to improve health and welfare on a massive scale.*

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## INTRODUCTION

For the past several years, the COVID-19 pandemic has completely transformed our world. However, amid a devastating pandemic and incalculable loss, medical research has offered some rays of hope. Through enormous private initiative and public support, biopharmaceutical firms developed safe and effective COVID-19 vaccines in record time.<sup>1</sup> Since their introduction in late 2020, billions of people have received vaccinations against the novel coronavirus.<sup>2</sup> These vaccines have saved countless lives, but due to their extraordinary ability to protect public health, they have also engendered significant controversy over issues of ownership, access, and distribution. While numerous factors have constrained access to these vaccines, intellectual property rights have attracted significant attention. This Article will examine the role of patents in inhibiting access to COVID-19 vaccines and what we can do about it.

Before proceeding, it is useful to take stock of where we have been. Developments have unfolded with breathtaking speed. In December 2019, the World Health Organization (WHO) China Country Office received reports of a mysterious pneumonia originating around Wuhan.<sup>3</sup> The disease quickly spread, and on January 5, 2020, Chinese officials released the genetic sequence of what would ultimately become known as the SARS-CoV-2 virus.<sup>4</sup> On January 20, 2020, the Centers for Disease Control and Prevention (CDC) confirmed the first case of COVID-19 in the United States.<sup>5</sup> On March 13, 2020, then-President Trump

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<sup>1</sup> See *infra* Part I.

<sup>2</sup> Our World in Data, Coronavirus (COVID-19) Vaccinations, <https://ourworldindata.org/covid-vaccinations> (reporting that as of November 4, 2021, over 3 billion people had completed an initial protocol for COVID-19 vaccination).

<sup>3</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, CDC MUSEUM COVID-19 TIMELINE, <https://www.cdc.gov/museum/timeline/covid19.html> (last visited Jan. 21, 2022) [hereinafter CTRS. FOR DISEASE CONTROL & PREVENTION, TIMELINE].

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

declared the COVID-19 outbreak a national emergency.<sup>6</sup> In late April 2020, the White House launched Operation Warp Speed, an ambitious initiative aimed at rapidly developing COVID-19 vaccines.<sup>7</sup>

Toward the end of 2020, we received some very encouraging news. On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization for the COVID-19 vaccine made by Pfizer and its German partner, BioNTech.<sup>8</sup> A week later, the FDA granted Emergency Use Authorization for Moderna's COVID-19 vaccine.<sup>9</sup> Massive vaccination drives began, and the FDA granted Emergency Use Authorization for a third vaccine—from Johnson & Johnson—on February 27, 2021.<sup>10</sup> Due to vaccinations, some areas of life in the United States began to return to normal. Of course, enormous challenges continued, most notably in the form of new coronavirus variants. As of November 2021, there were 46 million COVID-19 cases in the United States.<sup>11</sup> 193 million people in the United States, which corresponds to 58.1% of the country's population, had been fully vaccinated.<sup>12</sup>

While the rapid development of COVID-19 vaccines was an enormous public health victory, challenges quickly emerged over issues of ownership, access, and distribution. The domestic rollout of vaccinations has faced numerous obstacles, particularly from difficulties of racial equity and vaccine hesitancy.<sup>13</sup> This Article, however, will focus on enormous disparities in access to COVID-19 vaccines on the global stage. Residents of wealthy and middle-income countries received about ninety percent of the first 400 million doses of vaccines.<sup>14</sup> As of late September 2021, close to sixty percent (more than 700 million) of the 1.2 billion

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<sup>6</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, Proclamation No. 9994, 85 Fed. Reg. 15337 (March 13, 2020), <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

<sup>7</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, TIMELINE, *supra* note 3.

<sup>8</sup> Press Release, U.S. Food & Drug Admin., FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine (Dec. 11, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19> [hereinafter U.S. Food & Drug Admin., First Covid-19 Vaccine].

<sup>9</sup> Press Release, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid> [hereinafter U.S. Food & Drug Admin., Second Covid-19 Vaccine].

<sup>10</sup> Press Release, U.S. Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2020), <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

<sup>11</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, COVID DATA TRACKER, <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

<sup>12</sup> *Id.*

<sup>13</sup> See, e.g., Angela K. Shen, Richard Hughes IV, Erica DeWald, Sara Rosenbaum, Amy Pisani & Walt Orenstein, *Ensuring Equitable Access to COVID-19 Vaccines in the United States: Current System Challenges and Opportunities*, 40 HEALTH AFF. 62 (2021).

<sup>14</sup> Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, N.Y. TIMES (Mar. 21, 2021), <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html> (last updated Nov. 10, 2021).

people living in the sixty-three high-income countries that have reported vaccinations were fully vaccinated.<sup>15</sup> By contrast, about one percent (9 million) of the more than 650 million people living in the twenty-six lowest-income countries with any reported vaccinations were fully vaccinated.<sup>16</sup> Clearly, access to lifesaving vaccines is grossly unequal around the world.

While numerous factors have contributed to stark disparities in vaccine access, intellectual property rights have attracted significant attention.<sup>17</sup> The branch of intellectual property most implicated is patents, which confer twenty years of exclusive rights on novel, useful, and nonobvious technologies.<sup>18</sup> Biopharmaceutical companies have been patenting the technologies underlying COVID-19 vaccines for years—in most cases, based on work that long predated the pandemic. This is the case, for instance, for novel mRNA vaccines, which represent the most promising class of COVID-19 vaccines. A study of English-language U.S., European, and international patents and applications published from January 2010 to April 2020 revealed that private companies own 80 of 113 mRNA vaccine patent families.<sup>19</sup> Among them, a handful of companies—Moderna, BioNTech, CureVac, and GSK—collectively own nearly half.<sup>20</sup>

Patents on COVID-19 vaccines have engendered significant controversy. On one side of the debate are those who argue that patents inhibit access to essential vaccines and should be subject to significant limitations.<sup>21</sup> According to this view, wide access to vaccines is particularly justified given that the COVID-19 pandemic represents an enormous public health crisis with literally billions of lives at stake. On the other side of the debate are innovative biopharmaceutical companies that developed COVID-19 vaccines. They assert that the rapidity with which private patentees developed vaccines reflects the success of a property rights-based model of technological development.<sup>22</sup> According to this view, weakening patent

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<sup>15</sup> Joe Murphy, *Biden Wants to Address the Covid-19 Vaccination Disparity Between Rich and Low-Income Countries. Here's How Wide It Actually Is*, NBC NEWS (Sept. 24, 2021), <https://www.nbcnews.com/news/world/biden-wants-address-covid-19-vaccination-disparity-between-rich-low-n1280050>.

<sup>16</sup> *Id.*

<sup>17</sup> See, e.g., Achal Prabhala, Arjun Jayadev & Dean Baker, *Want Vaccines Fast? Suspend Intellectual Property Rights*, N.Y. TIMES (Dec. 7, 2020), <https://www.nytimes.com/2020/12/07/opinion/covid-vaccines-patents.html>; Walden Bello, *The West Has Been Hoarding More Than Vaccines*, N.Y. TIMES (May 3, 2021), <https://www.nytimes.com/2021/05/03/opinion/covid-biden-wto-vaccine.html>; Matthew Kavanagh & Madhavi Sunder, *Opinion: Poor Countries May Not Be Vaccinated Until 2024. Here's How to Prevent That*, WASH. POST (Mar. 10, 2021, 5:01 PM), <https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/>.

<sup>18</sup> 35 U.S.C. §§ 101, 102, 103 & 154.

<sup>19</sup> Cecilia Martin & Drew Lowery, *mRNA Vaccines: Intellectual Property Landscape*, 19 NATURE REV. DRUG DISCOVERY 578, 578 (2020).

<sup>20</sup> *Id.*

<sup>21</sup> See, e.g., Prabhala et al., *supra* note 17.

<sup>22</sup> Christopher Rowland, Emily Rauhala & Miriam Berger, *Drug Companies Defend Vaccine Monopolies in Face of Global Outcry*, WASH. POST. (Mar. 21, 2021), <https://www.washingtonpost.com/business/2021/03/20/covid-vaccine-global-shortages/>.

protection would undermine incentives to invent, thus imperiling innovation both in the present and for future pandemics.<sup>23</sup>

Amidst this difficult debate, this Article offers a path forward. Many commentators have framed the controversy over access to patented vaccines in the language of property, particularly intellectual property.<sup>24</sup> However, this Article argues for a conceptual shift. It suggests that contract principles can help break the impasse and increase access to patented COVID-19 vaccines in a manner that respects both public values and private ordering. In particular, this Article will apply three concepts from contract law to reframe the debate over access to patented COVID-19 vaccines. In doing so, it aims not for precise fidelity to contract doctrine but to invoke contract principles to balance competing interests and craft solutions to the challenge of vaccine access.

This Article examines the intersection of contract principles and access to COVID-19 vaccines in three parts. Part I explores the concept of consideration, which refers to the value provided by a party that can undergird a contractual obligation.<sup>25</sup> It contends that public entities have provided enormous consideration, particularly in the form of research and development funding, to support the creation of privately patented vaccines. This arrangement enables what I call a “consideration-based” model of patent regulation. In this model, public institutions can leverage massive contributions to privately patented vaccines to demand greater access to those vaccines, particularly for low-income populations.

Part II examines the concept of a quid pro quo—a fundamental bargain or exchange at the heart of a contract.<sup>26</sup> Patent law is often characterized as a grand societal quid pro quo in which inventors receive exclusive rights in exchange for disclosing their inventions. This Part argues that holders of vaccine patents have not disclosed tacit knowledge critical for manufacturing their vaccines, and it questions the adequacy of the prevailing quid pro quo. Accordingly, it suggests enhancing the disclosure obligations of patentability. Augmenting this approach, this Part also explores how government agencies can leverage the quid pro quo of public funding to increase technical disclosure by innovators—including patentees—receiving public support. Doing so would remove an important obstacle to widespread, parallel manufacturing of COVID-19 vaccines around the world.

Part III turns to the doctrine of changed circumstances, which can excuse nonperformance of a contract when conditions surrounding that contract change

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<sup>23</sup> See Mario Biagioli, *Of Viruses and Licenses: Lessons from COVID-19 Vaccine Patent Debates*, L.A. REV. BOOKS (July 9, 2021), <https://www.lareviewofbooks.org/article/the-tangled-web-of-viruses-and-licenses-lessons-from-covid-19-vaccine-patent-debates/> (“This narrative is characterized by a discursive drift from results to potentials: from a traditional focus on patents as direct incentives for achieving *specific innovations* in the present to seeing them, instead, as providing the *conditions of possibility* for a vast pharmaceutical innovation ecology. . .”).

<sup>24</sup> See, e.g., Prabhala et al., *supra* note 17; Rowland et al., *supra* note 22.

<sup>25</sup> See Melvin Aron Eisenberg, *Principles of Consideration*, 67 CORNELL L. REV. 640, 641-43 (1982) (articulating an expansive conception of consideration in modern contract law that extends beyond explicit bargains between two parties).

<sup>26</sup> See generally Jed Lewinsohn, *Paid on Both Sides: Quid Pro Quo Exchange and the Doctrine of Consideration*, 129 YALE L.J. 690 (2020) (examining and suggesting modifications to the role of quid pro quos in contract doctrine).



dramatically.<sup>27</sup> It considers contracts writ large by examining the key international agreement that governs global intellectual property obligations. In particular, it focuses on the bargain that developed and developing countries struck when concluding the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). It also considers the recently adopted proposal to temporarily waive certain provisions of the TRIPS Agreement, and it argues that changed circumstances in the form of the devastating COVID-19 pandemic provide a justification for doing so. Drawing from historical examples, it argues that altering global intellectual property rules can facilitate greater access to lifesaving vaccines.

## I. PUBLIC CONTRIBUTIONS TO PRIVATELY PATENTED INNOVATION

Viewed from certain angles, the development of COVID-19 vaccines represented a triumph of speed and private enterprise. Indeed, the rapidity of vaccine development was truly unprecedented. In January 2020, researchers found the viral sequence of SARS-CoV-2 roughly ten days after the first reported pneumonia cases in Wuhan.<sup>28</sup> Less than ten weeks later, Moderna's mRNA vaccine candidate entered Phase 1 clinical trials.<sup>29</sup> This is a remarkable pace given that moving from sequencing a virus to Phase 1 clinical trials usually takes three to nine years.<sup>30</sup> Watching the news, the rapid drumbeat of progress was astonishing. In early November 2020, Pfizer announced initial, promising data on its COVID-19 vaccine,<sup>31</sup> and the FDA granted Emergency Use Authorization a month later.<sup>32</sup> Emergency Use Authorization for Moderna's vaccine followed the next week.<sup>33</sup> Innovative biopharmaceutical firms such as Pfizer, BioNTech, Moderna, and Johnson & Johnson committed significant resources, navigated deep uncertainty, and utilized cutting-edge science to develop vaccines in record time.<sup>34</sup>

While the rapidity of vaccine development was truly impressive, this achievement represented the culmination of research programs going back many years. Moderna and BioNTech had been working on the mRNA platform undergirding their COVID-19 vaccines long before the pandemic broke out. Along

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<sup>27</sup> See generally John Eloffson, *The Dilemma of Changed Circumstances in Contract Law: An Economic Analysis of the Foreseeability and Superior Risk Bearer Tests*, 30 COLUM. J.L. & SOC. PROBS. 1 (1996) (examining the doctrine of changed circumstances in contract law).

<sup>28</sup> Jocelyn Solis-Moreira, *How Did We Develop a COVID-19 Vaccine So Quickly?*, MEDICAL NEWS TODAY (Dec. 15, 2020), <https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly>.

<sup>29</sup> Nicole Lurie, Melanie Saville, Richard Hatchett & Jane Halton, *Developing Covid-19 Vaccines at Pandemic Speed*, 382 N. ENG. J. MED. 1969, 1971 (2020).

<sup>30</sup> Penny M. Heaton, *The Covid-19 Vaccine-Development Multiverse*, 383 N. ENG. J. MED. 1986, 1987 (2020).

<sup>31</sup> Katie Thomas, David Gelles & Carl Zimmer, *Pfizer's Early Data Shows Vaccine Is More Than 90% Effective*, N.Y. TIMES (May 26, 2021), <https://www.nytimes.com/2020/11/09/health/covid-vaccine-pfizer.html>.

<sup>32</sup> U.S. Food & Drug Admin., *First Covid-19 Vaccine*, *supra* note 8.

<sup>33</sup> U.S. Food & Drug Admin., *Second Covid-19 Vaccine*, *supra* note 9.

<sup>34</sup> See generally Sharon LaFraniere, Katie Thomas, Noah Weiland, David Gelles, Sheryl Gay Stolberg & Denise Grady, *Politics, Science and the Remarkable Race for a Coronavirus Vaccine*, N.Y. TIMES (Nov. 30, 2020), <https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html> (detailing efforts to rapidly develop vaccines by Moderna and Pfizer).

the way, they were patenting their technological advances. These firms were following the common “race-to-patent R&D format” in the biopharmaceutical industry, wherein firms aggressively seek intellectual property protection for their discoveries to recoup high development costs and generate profits.<sup>35</sup> Indeed, the fact that biopharmaceutical firms possess so many patents on COVID-19 vaccines attests to the long-term nature of this research. Patent prosecution can easily take over three years, and the vast majority of COVID-19 vaccine patents held by these companies arose from research that long predated the pandemic.

Extending this theme, if we disaggregate the notion of invention itself, we see that public support over several decades played a critical role in developing today’s privately patented COVID-19 vaccines. As I will argue further below, these massive public contributions to vaccine development provide governmental entities with significant claims on these vaccines. In particular, these contributions enable a “consideration-based” model of governance in which public entities can demand greater access to patented vaccines, which arose in substantial part from public funds, intellectual property, and other resources. In elucidating the significant public contributions to COVID-19 vaccine development, I will focus on the newest and most prominent class of vaccines: so-called mRNA vaccines, which were developed by Moderna and Pfizer-BioNTech. Furthermore, I will focus on the “pre-history” of federal support for such vaccines before considering the more recent history of federal support, primarily from Operation Warp Speed.

#### A. The “Pre-History” of Federal Support for Vaccine Development

Scientists have been studying coronaviruses for over half a century, and much of that research has been publicly funded.<sup>36</sup> Scientists have also been studying vaccines for decades, and the recent success in developing COVID-19 vaccines benefitted substantially from billions of dollars spent on HIV vaccine research since 2000.<sup>37</sup> Focusing on the newest and most promising mRNA COVID-19 vaccines, one commentator observes, “the path to mRNA vaccines drew on the work of hundreds of researchers over more than 30 years.”<sup>38</sup> For example, since 2006, Congress has appropriated hundreds of millions of dollars to the Biomedical Advanced Research and Development Authority (BARDA) to support the scientific infrastructure underlying mRNA vaccines.<sup>39</sup> In 2012, the Defense Advanced

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<sup>35</sup> Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J.L. & POL’Y 167, 173 (2021).

<sup>36</sup> Solis-Moreira, *supra* note 28; see also Richard G. Frank, Leslie Dach & Nicole Lurie, *It Was the Government That Produced COVID-19 Vaccine Success*, HEALTH AFF. BLOG (May 14, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210512.191448/#:~:text=It%20Was%20The%20Government%20That%20Produced%20COVID%2D19%20Vaccine%20Success,-Richard%20G.&text=The%20success%20of%20the%20US,the%20COVID%2D19%20vaccines%20themseIves.>

<sup>37</sup> Jeffrey E. Harris, *The Repeated Setbacks of HIV Vaccine Development Laid the Groundwork for SARS-CoV-2 Vaccines* (Nat’l Bureau of Econ. Rsch., Working Paper 28587, March 2021), <https://pubmed.ncbi.nlm.nih.gov/35340773/>.

<sup>38</sup> Elie Dolgin, *The Tangled History of mRNA Vaccines*, 597 NATURE 318, 319 (2021).

<sup>39</sup> Frank et al., *supra* note 36.

Research Projects Agency (DARPA) started funding industry researchers investigating RNA and drugs. One of the early grant recipients was Moderna.<sup>40</sup>

Federally funded research was critical to developing the core technologies that enable mRNA vaccines. Here, I will focus on just two. First, public funding was crucial to developing genetically engineered spike proteins. The novel coronavirus, SARS-CoV-2, possesses a distinctive “spike” protein that plays a key role in mRNA vaccine design. mRNA vaccines use the body’s machinery to create similar spike proteins, which elicit an immune response and thus prime the immune system to attack the coronavirus if and when it enters the body.<sup>41</sup> Decades before the current pandemic, Dr. Barney Graham, who was then at Vanderbilt University, conducted federally funded research on viral proteins.<sup>42</sup> Graham later moved to the National Institutes of Health (NIH), where he further refined his work on bioengineered viral proteins, particularly the coronavirus spike protein.<sup>43</sup> Starting in 2017, Graham’s NIH lab worked directly with Moderna on another coronavirus, and the partnership intensified when the COVID-19 pandemic emerged.<sup>44</sup> Moderna’s COVID-19 vaccine grew directly from its partnership with NIH.<sup>45</sup> In January 2020, within two days of China’s release of the genetic sequence for the novel coronavirus, NIH and Moderna scientists had designed a vaccine.<sup>46</sup> Moderna partnered with NIH to conduct mouse studies and began human trials within less than ten weeks.<sup>47</sup>

Federally funded research was also critical to a second innovation underlying mRNA vaccines: RNA modification, which allows bioengineered RNA to slip past the body’s immune system.<sup>48</sup> Bioengineered RNA can perform highly beneficial functions, but in its unmodified state, it represents an antigen that the body’s immune system may try to destroy.<sup>49</sup> In the 1990s and early 2000s, researchers Katalin Karikó and Drew Weissman from the University of Pennsylvania received millions of dollars in NIH grants to explore RNA preparations and uses.<sup>50</sup> They discovered a process for modifying RNA that would

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<sup>40</sup> Dolgin, *supra* note 38, at 323.

<sup>41</sup> Arthur Allen, *For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork*, SCI. AM. (Nov. 18, 2020), <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>; Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed’s \$18 Billion Sprint for a Vaccine*, BLOOMBERG BUSINESSWEEK (Oct. 29, 2020), <https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine>.

<sup>42</sup> Allen, *supra* note 41.

<sup>43</sup> Gebrekidan & Apuzzo, *supra* note 14.

<sup>44</sup> Allen, *supra* note 41; Rutschman, *supra* note 35, at 179; LaFraniere et al., *supra* note 34; Denise Grady, Abby Goodnough & Noah Weiland, *F.D.A. Approves Moderna’s COVID Vaccine, Adding Millions of Doses to U.S. Supply*, N.Y. TIMES (March 16, 2021), <https://www.nytimes.com/2020/12/19/world/the-fda-approves-modernas-covid-vaccine-adding-millions-more-doses-to-the-us-supply.html>.

<sup>45</sup> Allen, *supra* note 41; LaFraniere et al., *supra* note 34; Grady et al., *supra* note 44.

<sup>46</sup> Grady et al., *supra* note 44.

<sup>47</sup> Dolgin, *supra* note 38, at 323.

<sup>48</sup> Allen, *supra* note 41; Dolgin, *supra* note 38, at 321-22.

<sup>49</sup> Allen, *supra* note 41.

<sup>50</sup> LUIS GIL ABINADER, KNOWLEDGE ECOLOGY INT’L, FOUNDATIONAL MRNA PATENTS ARE SUBJECT TO THE BAYH–DOLE ACT PROVISION (Nov. 20, 2020), <https://www.keionline.org/34733>.

allow bioengineered DNA to evade immune system defenses. They filed several patents covering RNA modification, and an analysis by Knowledge Ecology International revealed that six of their patents acknowledge federal funding.<sup>51</sup> The University of Pennsylvania exclusively licensed various patents and applications to CellScript and its affiliate, mRNA RiboTherapeutics, in 2016.<sup>52</sup> CellScript entered into non-exclusive, worldwide sublicenses with Moderna and BioNTech in 2017.<sup>53</sup> Here again, crucial technology that undergirds mRNA COVID-19 vaccines arose from federal funding.<sup>54</sup>

#### B. The Recent History of Federal Support for Vaccine Development: Operation Warp Speed

While the federal government made enormous contributions over several decades to the so-called “pre-history” of vaccine development, the government’s most visible contributions came shortly after the outbreak of the pandemic. In April 2020, when the pandemic was only a few months old, the U.S. government launched Operation Warp Speed. This initiative represented a partnership between the Department of Health and Human Services (HHS) and the Department of Defense (DOD), and it had the ambitious goal of producing 300 million doses of safe and effective COVID-19 vaccine.<sup>55</sup> Operation Warp Speed pursued a portfolio strategy in which it funded six companies utilizing three different vaccine “platform technologies” to see which ones would be successful first.<sup>56</sup> Massive public funding played a crucial role in rapidly developing safe and effective COVID-19 vaccines, including the novel mRNA vaccines produced by Moderna and Pfizer.

In a short period of time, Operation Warp Speed provided about \$18 billion in federal funding. Moderna received approximately \$2.5 billion to develop, manufacture, and sell its vaccine,<sup>57</sup> a sum that covered all R&D expenses.<sup>58</sup> This funding included \$53 million to expand its manufacturing capacity.<sup>59</sup> Pfizer has been quick to point out that it did not take any Operation Warp Speed money for research and development.<sup>60</sup> However, Pfizer received an advance purchase commitment of \$1.95 billion for the sale of 100 million doses to the U.S.

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 45; Allen *supra* note 41.

<sup>53</sup> ABINADER, *supra* note 50; Dolgin, *supra* note 38, at 322.

<sup>54</sup> Public support (not limited to contributions by the U.S. government) also undergirded the development of other technologies at the heart of mRNA vaccines. One of these technologies is lipid nanoparticles, which envelop modified mRNA and allow it to enter cells. Foundational research by Pieter Cullis, a biochemist at the University of British Columbia, yielded important early insights about lipid nanoparticles. Dolgin, *supra* note 38, at 322-23.

<sup>55</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-21-319, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES (Feb. 11, 2021).

<sup>56</sup> *Id.* at 1; LaFraniere et al., *supra* note 34.

<sup>57</sup> LaFraniere et al., *supra* note 34.

<sup>58</sup> Prabhala et al., *supra* note 17.

<sup>59</sup> Frank et al., *supra* note 36.

<sup>60</sup> LaFraniere et al., *supra* note 34; *see* Prabhala et al., *supra* note 17 (estimating a total of nearly \$6 billion in advance purchase commitments from the United States and the European Union).

government,<sup>61</sup> and this commitment greatly mitigated the risk of vaccine development.<sup>62</sup> Additionally, while Pfizer did not take R&D money from Operation Warp Speed, Pfizer's German partner, BioNTech (which actually developed the mRNA vaccine) received \$455 million from the German government.<sup>63</sup> It is thus accurate to say that, directly and indirectly, Pfizer benefitted substantially from public support for vaccine development. Johnson & Johnson received \$1.5 billion from Operation Warp Speed. Additionally, Sanofi and GSK, working jointly, received \$2 billion; Novavax received \$1.6 billion; and AstraZeneca received \$1.2 billion.<sup>64</sup>

Operation Warp Speed provided not just funding but critical logistical support as well. For instance, as part of Operation Warp Speed, DOD and HHS provided logistical help to increase Moderna's manufacturing capacity.<sup>65</sup> The two agencies utilized the Defense Production Act to prioritize eighteen supply contracts for materials necessary to manufacture vaccines.<sup>66</sup> Operation Warp Speed officials even worked with the State Department to expedite visa approvals for key technical personnel to work on vaccine development.<sup>67</sup> Overall, Operation Warp Speed played a critical role in the rapid creation of COVID-19 vaccines: "The government essentially removed the bulk of traditional industry risks related to vaccine development: a) scientific failures, b) failures to demonstrate safety and efficacy, c) manufacturing risks; and d) market risks related to low demand."<sup>68</sup> While private enterprise and ingenuity were essential to vaccine development, such efforts may not have achieved fruition, and certainly would not have done so in such a rapid fashion, without massive public support.

### C. A Consideration-Based Model for Enhancing Access to Patented COVID-19 Vaccines

The federal government made enormous contributions to both the pre-history and recent development of privately patented COVID-19 vaccines. These enormous contributions, moreover, provide the government with several levers to enhance access to these essential technologies. In particular, they enable what I have previously characterized as a "consideration-based" model of patent regulation.<sup>69</sup> Within this model, public institutions providing valuable consideration (such as funding, labor, intellectual property, and other support) contributing to the development of privately patented inventions obtain certain

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<sup>61</sup> LaFraniere et al., *supra* note 34.

<sup>62</sup> As of May 2021, Pfizer had received advance purchase commitments of \$5.97 billion for 300 million doses. Frank et al., *supra* note 36.

<sup>63</sup> Prabhala et al., *supra* note 17.

<sup>64</sup> Baker & Koons, *supra* note 41.

<sup>65</sup> LaFraniere et al., *supra* note 34; U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 55, at 2.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> Frank et al., *supra* note 36.

<sup>69</sup> Peter Lee, *Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 889 (2009) [hereinafter Lee, *Contracting*]; Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917 [hereinafter Lee, *Distributive Commons*].

claims on those inventions. Within certain parameters, public institutions can leverage such consideration to advance public policy objectives, such as enhancing access to privately patented technologies. In the present context, massive public support for privately patented COVID-19 vaccines provides several mechanisms to demand greater access to these resources.

Notably, this is an essentially contractual model for enhancing access to patented vaccines. Within this model, the federal government does not seek to increase access to COVID-19 vaccines by changing the rules of patent law or unilaterally expropriating such technologies.<sup>70</sup> Rather, it operates as a market actor, leveraging the enormous consideration it provides to downstream private entities to require greater access to resulting technologies. In this sense, consideration-based approaches are less intrinsically coercive than unilateral state regulation. In fact, the logic of consideration-based regulation reflects private ordering and should appeal to some of the most vociferous proponents of strong property rights and market-based technological development.

Enormous federal contributions to COVID-19 vaccines provide several avenues to assert claims on these patented technologies. First, at the most basic level, the federal government may actually own or co-own key intellectual property undergirding COVID-19 vaccines.<sup>71</sup> This is evident, for example, in federally funded research on spike proteins.<sup>72</sup> In 2017, Dr. Graham, who at the time worked for NIH, and several colleagues utilized protein engineering to stabilize the spike protein on a coronavirus before it fused with other cells.<sup>73</sup> NIH and its academic partners patented this technology, which plays a core role in mRNA vaccines.<sup>74</sup> Notably, BioNTech and other companies have licensed this technology from NIH.<sup>75</sup> However, much to the chagrin of NIH, Moderna has not paid for a license.<sup>76</sup> The need for vaccine developers to use this technology provides NIH with an opportunity to license it with certain conditions attached, such as requiring licensees to make COVID-19 vaccines widely available to certain low-income populations. More specifically, the threat of a patent infringement suit against Moderna would provide NIH with substantial leverage to demand significant concessions from that firm, including commitments to make its vaccine more widely available in the developing world.

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<sup>70</sup> It bears noting that the U.S. government has these powers as well. Under prevailing law, the federal government can use any patented invention at the cost of “reasonable and entire compensation for such use and manufacture.” 28 U.S.C. § 1498. See 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 (2016); Christopher J. Morten & Charles Duan, *Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1 (2020).

<sup>71</sup> Rutschman, *supra* note 35, at 179.

<sup>72</sup> See *supra* Part I.A.

<sup>73</sup> Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 9, 2021), <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>.

<sup>74</sup> *Id.*; Gebrekidan & Apuzzo, *supra* note 14; U.S. Patent No. 10,960,070 (filed Oct. 25, 2017).

<sup>75</sup> Stolberg & Robbins, *supra* note 73.

<sup>76</sup> *Id.*

Apart from outright ownership of intellectual property, NIH recently engaged in a dispute with Moderna over co-ownership of a key patent application. The application covers the genetic sequence that prompts the mRNA vaccine to produce an immune response.<sup>77</sup> A July 2020 submission from Moderna lists its own employees as inventors of the subject technology.<sup>78</sup> Moderna acknowledges that NIH believes that three NIH scientists, including Dr. Graham, should be listed as co-inventors on the patent application. However, Moderna's submission states that it has "reached the good-faith determination that these individuals did not co-invent the mRNAs and mRNA compositions claimed in the present application."<sup>79</sup> Despite Moderna's statement, NIH has a strong claim of co-ownership over this patent application.<sup>80</sup> Research agreements between NIH and Moderna indicate a commitment to joint ownership of the results of that research.<sup>81</sup> In May 2020, NIH Director Francis Collins stated that "we do have some particular stake in the intellectual property" of Moderna's vaccine candidate.<sup>82</sup> When NIH first announced the interim results of the "NIH-Moderna COVID-19 Vaccine" in November 2020, it noted that the vaccine candidate "was co-developed by . . . Moderna, Inc., and the National Institute of Allergy and Infectious Diseases (NIAID) . . ."<sup>83</sup> An analysis by Public Citizen also strongly suggests that NIH has an ownership stake in patents and patent applications covering Moderna's vaccine.<sup>84</sup> The implications of this inventorship dispute are enormous. If the Patent and Trademark Office (PTO) recognizes NIH scientists as co-inventors, then NIH, as a co-owner of any resulting patent, would have unfettered ability to license the technology to other parties without Moderna's permission, thus greatly expanding access.<sup>85</sup> Moderna has recently decided to not make the payment that would allow the contested patent application to issue, thus temporarily pausing the inventorship

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<sup>77</sup> *Id.*

<sup>78</sup> HELEN C. LOCKHART, STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98 (July 28, 2021), *available at* <https://www.nytimes.com/interactive/2021/11/09/us/moderna-patent-filing.html>.

<sup>79</sup> *Id.* at 1.

<sup>80</sup> Co-ownership claims could be based on either co-inventorship of the underlying technology or agreements between Moderna and NIH to jointly own patent applications and patents.

<sup>81</sup> ZAIN RIZVI, PUB. CITIZEN, THE NIH VACCINE 7-8 (2020), <https://www.citizen.org/article/the-nih-vaccine/> [hereinafter RIZVI, NIH VACCINE].

<sup>82</sup> ECON. CLUB, VIRTUAL SIGNATURE EVENT WITH DR. FRANCIS COLLINS, CHRIS NASSETTA, AND MARY BRADY, YOUTUBE (May 29, 2020), <https://youtu.be/EHyB3zTZBvY?t=340> (transcript available at <https://www.economicclub.org/events/dr-francis-collins-chris-nassetta-and-mary-brady/>); *see id.* ("One of the vaccines, the one that's furthest along, was actually at the federal government in our own vaccine center at NIH, and then worked with a biotechnology company called Moderna to get to where we are now, with very impressive phase one results, and getting ready to go into a large-scale trial as early as July.") (quoting Francis Collins, Director of NIH).

<sup>83</sup> NIH, Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine (Nov. 16, 2020), <https://www.nih.gov/news-events/news-releases/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine>.

<sup>84</sup> RIZVI, NIH VACCINE, *supra* note 81, at 5-7.

<sup>85</sup> Stolberg & Robbins, *supra* note 73.

dispute with NIH.<sup>86</sup> However, Moderna may still seek to obtain patent protection on this subject matter at a later date.

Second, aside from any direct ownership stake in patents, the U.S. government can exercise certain claims on privately patented technologies arising from federal funds. These claims are statutorily enumerated in the Bayh–Dole Act, a federal law that Congress enacted in 1980 to promote the commercialization of patented technologies arising from federal funding.<sup>87</sup> The Act allows recipients of public funds, such as universities, to take title to patents arising from federally funded research. Under the Act, if an academic researcher obtains an NIH grant that supports developing a patented invention, the researcher or her university can take title to that patent, even though a federal agency paid for it. The law was enacted on the theory that allowing universities—rather than federal agencies—to own patents would lead to greater licensing and commercialization of federally funded technologies. In essence, the Act offers a valuable “double subsidy” to grant recipients, who receive both taxpayer funds and patents on their research outputs.

However, in consideration for providing public funds and patent rights, the federal government retains certain rights in inventions subject to the Act.<sup>88</sup> In this sense, the Bayh–Dole Act reflects a consideration-based model of patent regulation. For instance, while patentees have significant latitude in how they use and license their patents, the federal government retains a “paid-up license to practice, or have practiced” on its behalf, any invention falling under the Act.<sup>89</sup> Furthermore, federal agencies retain so-called “march-in rights” to issue compulsory licenses for subject inventions if certain statutorily defined criteria are met.<sup>90</sup> Among them, a federal agency can license a subject invention to a third party—without the permission of a patentee—“to alleviate health or safety needs which are not reasonably satisfied by the contractor.”<sup>91</sup> In principle, the Bayh–Dole Act provides NIH with the power to exercise march-in rights on any patented inventions arising from at least partial NIH funding. This would include federally funded, privately patented technologies underlying COVID-19 vaccines.<sup>92</sup> Although NIH has been highly reluctant to exercise march-in rights,<sup>93</sup> these rights represent another mechanism by which the federal government could leverage massive research funding to increase access to patented vaccines.

Third, simply as a matter of contract negotiations, enormous funding and procurement of COVID-19 vaccines provides the federal government with leverage to demand greater access to these essential technologies. Importantly, these demands do not rely on any ownership stake in the underlying intellectual property

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<sup>86</sup> Rebecca Robbins & Sheryl Gay Stolberg, *Moderna Backs Down in Its Vaccine Patent Fight with the N.I.H.*, N.Y. TIMES (Dec. 17, 2021), <https://www.nytimes.com/2021/12/17/us/moderna-patent-nih.html>.

<sup>87</sup> Bayh–Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019–27 (1980) (codified as amended at 35 U.S.C. §§ 200–212); *see generally* Lee, *Distributive Commons*, *supra* note 69, at 951–55.

<sup>88</sup> Rutschman, *supra* note 35, at 182.

<sup>89</sup> 35 U.S.C. § 202(c)(4).

<sup>90</sup> 35 U.S.C. § 203(a)(1).

<sup>91</sup> 35 U.S.C. § 203(a)(2).

<sup>92</sup> *See supra* Part I.A.

<sup>93</sup> *See* Lee, *Distributive Commons*, *supra* note 69, at 955–60.



or the technicalities of the Bayh–Dole Act. In Operation Warp Speed, the federal government provided billions of dollars to six vaccine developers. Just as the federal government negotiated over the price it would pay for vaccines, it could have negotiated for commitments that vaccine developers make their vaccines widely available at no or little profit in the developing world. This is a common practice among funding entities. For instance, the Bill & Melinda Gates Foundation, which provides substantial funding for vaccine research, “includes grant language requiring equitable access to vaccines. As leverage, the organization retains some right to the intellectual property.”<sup>94</sup> Similarly, addressing the present COVID-19 pandemic, the WHO has called on research funders to “[m]ake appropriate provisions in funding agreements regarding accessibility and affordability of resulting health products globally including through non-exclusive voluntary licensing and other means to expand access by sharing know-how and data.”<sup>95</sup> Governments and nonprofits are contributing huge amounts of money to accelerate vaccine development, and they can bargain for greater access to vaccines in the developing world.

However, rich countries ignored calls by the WHO to include contract language that would have guaranteed doses for poor countries or encouraged companies to share patents.<sup>96</sup> According to public records, the U.S. government “used unusual contracts that omitted its right to take over intellectual property or influence the price and availability of vaccines. They did not let the government compel companies to share their technology.”<sup>97</sup> Some Operation Warp Speed contracts narrowed the window for the government to exercise march-in rights.<sup>98</sup> Pfizer’s initial contract explicitly stated that the government had no march-in rights at all.<sup>99</sup> Other government bodies that funded COVID-19 vaccine development also refrained from leveraging massive public investment to secure greater vaccine access. “We funded the research, on both sides of the Atlantic,” said Udo Bullmann, a German member of the European Parliament. “You could have agreed on a paragraph that says ‘You are obliged to give it to poor countries in a way that they can afford it.’ Of course you could have.”<sup>100</sup> But they did not. However, the

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<sup>94</sup> Gebrekidan & Apuzzo, *supra* note 14.

<sup>95</sup> WORLD HEALTH ORG., OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP): A CONCEPT PAPER 2 (2020), [https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9\\_36&download=true](https://cdn.who.int/media/docs/default-source/essential-medicines/intellectual-property/who-covid-19-tech-access-tool-c-tap.pdf?sfvrsn=1695cf9_36&download=true).

<sup>96</sup> Gebrekidan & Apuzzo, *supra* note 14.

<sup>97</sup> *Id.*

<sup>98</sup> Sydney Lupkin, *HHS Released More Coronavirus Vaccine Contracts as Election Results Unfolded*, NPR (Nov. 8, 2020) (analyzing Johnson & Johnson’s contract), <https://www.npr.org/sections/health-shots/2020/11/08/932793698/hhs-released-more-coronavirus-vaccine-contracts-as-election-results-unfolded> [hereinafter Lupkin, *HHS Released*].

<sup>99</sup> Sydney Lupkin, *Pfizer’s Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NPR (Nov. 24, 2020), <https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections> [hereinafter Lupkin, *Pfizer’s*].

<sup>100</sup> Gebrekidan & Apuzzo, *supra* note 14; *see also* Maria Cheng & Lori Hinnant, *Countries Urge Drug Companies to Share Vaccine Know-how*, ASSOC. PRESS (March 1, 2021), <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f>

opportunity is not lost. Far beyond the frenzy of the opening months of the pandemic, the United States and other governments are still negotiating to procure hundreds of millions (and potentially billions) of vaccine doses. Each of these contracts provides an opportunity for governments to utilize a consideration-based model to enhance access to patented COVID-19 vaccines, particularly for those with the least resources to obtain them.

Of course, a consideration-based model of patent regulation faces certain risks and limitations. Aggressive assertion of ownership rights by federal agencies and onerous strings attached to public money may chill private entities from partnering with the government. This specter hangs over the recent dispute between NIH and Moderna; while their collaboration has received praise as a model for public-private partnerships, it may devolve into a bitter fight over patent ownership. Concerns over antagonizing private partners and “interfering” in the market have also prevented NIH from exercising march-in rights under the Bayh–Dole Act. Over the past several decades NIH has received only five petitions to exercise march-in rights, and it has denied all of them. These petitions have focused on patented therapies, and NIH has articulated a very wide conception of what it means for a patented therapy to be commercially available. Furthermore, NIH has expressed deep apprehension over utilizing march-in rights to control drug prices.<sup>101</sup> For a brief period in the 1980s, NIH experimented with a “reasonable pricing clause” in research collaborations with private drug companies. However, private firms significantly opposed such controls, and NIH quickly dropped the provision.<sup>102</sup> Additionally, speed was paramount in the race to develop vaccines, and negotiating greater access to vaccines could have consumed precious time.<sup>103</sup> Dr. Moncef Slaoui, the chief scientific advisor for Operation Warp Speed, has stated, “I can guarantee you that the agreements with the companies [to enhance vaccine access] would have been much more complex and taken a much longer time.”<sup>104</sup> For instance, the European Union negotiated with biopharmaceutical companies over price and liability provisions, which delayed vaccine deployment.<sup>105</sup>

While it is not without risks, leveraging enormous public investment to enhance access to privately patented vaccines holds tremendous promise. Moderna, Pfizer, Johnson & Johnson, and other biopharmaceutical companies deserve

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8887bcf6 (citing a biotech industry executive for the proposition that governments should have demanded more from the biopharmaceutical companies they were heavily funding).

<sup>101</sup> See Lee, *Distributive Commons*, *supra* note 69, at 955-57 (profiling three instances in which NIH declined to exercise march-in rights). If anything, proposed reforms to march-in rights seek to go in the opposite direction by clarifying that federal agencies cannot use march-in rights “exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.” National Institute of Standards and Technology, Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35, 37 (Jan. 4, 2021). It bears noting that this constraint would not apply to the proposal here, which is aimed at not simply reducing the prices of COVID-19 vaccines, but also expanding manufacturing and supply.

<sup>102</sup> Lee, *Distributive Commons*, *supra* note 69, at 974-75.

<sup>103</sup> See Lupkin, *Pfizer’s*, *supra* note 99 (citing an HHS spokesperson who noted the need to obtain doses “as quickly as possible” from Operation Warp Speed companies).

<sup>104</sup> Gebrekidan & Apuzzo, *supra* note 14 (quoting Moncef Slaoui).

<sup>105</sup> Gebrekidan & Apuzzo, *supra* note 14.

substantial credit for developing lifesaving vaccines in record time. However, if we disaggregate the act of invention, we see that over the past several decades, government agencies played a critical role in developing these vaccines. Contributions of upstream money, labor, and intellectual property represent valuable consideration that the federal government can use to assert claims on downstream patented technologies. In some cases, the government may even own or co-own key intellectual property. In other cases, when the U.S. government contributes public funds to privately patented technologies, the government retains certain statutorily enumerated rights over those inventions. Finally, simply as a matter of contract negotiations, the government can leverage its status as an enormous market participant to secure greater access to critical COVID-19 vaccines produced by its contractors. In this manner, public entities can utilize private ordering to help ensure the wide availability of lifesaving vaccines.

## II. THE PATENT QUID PRO QUO AND TACIT KNOWLEDGE

Consideration-based regulation is one way in which contract principles can enhance access to patented COVID-19 vaccines. However, while access to vaccines is vitally important, so is access to the underlying technical knowledge necessary to manufacture them. Such knowledge is critical to enabling mass, parallel vaccine production by multiple parties, which can greatly amplify vaccine availability. Vaccine developers, however, possess tacit technical knowledge critical to manufacturing their products that they do not disclose in patents. Contract principles can help unlock some of this patent-related tacit knowledge, as well as other valuable knowledge.<sup>106</sup>

Of particular note, the contract principle of the quid pro quo can justify greater technical disclosure from patentees of COVID-19 vaccines. Although patents are a species of intellectual property, they are often characterized in contract terms. Patents reflect a grand societal bargain between an inventor and the public at large. According to this quid pro quo, inventors receive twenty years of exclusive rights in exchange for disclosing a novel, useful, and nonobvious invention.<sup>107</sup> For centuries, patent lawyers and technologists have recognized that a critical benefit of the patent system is not just the introduction of new technologies, but the disclosure of new technical information by patentees.<sup>108</sup> The collective disclosures of patents represent an “invisible college of technology” that propels further

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<sup>106</sup> This Part draws upon Peter Lee, *COVID-19 Vaccines, Technical Disclosure, and Public-Private Quid Pro Quos*, in *INTELLECTUAL PROPERTY, COVID-19, AND THE NEXT PANDEMIC: DIAGNOSING PROBLEMS, DEVELOPING CURES* (Cambridge University Press forthcoming 2022).

<sup>107</sup> *Universal Oil Prods. Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944) (“[T]he quid pro quo [for the patent grant] is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted.”).

<sup>108</sup> See John N. Adams & Gwen Averly, *The Patent Specification: The Role of *Liardet v. Johnson**, 7 J. LEG. HIST. 156 (1986) (describing the 1778 opinion in *Liardet v. Johnson*, which emphasized the value of the patent disclosure).

advances.<sup>109</sup> Extending the contract metaphor, this technical disclosure is the consideration that inventors provide in exchange for exclusive rights.

The disclosure function of patents is well established in patent law. The U.S. patent statute states that

the [patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.<sup>110</sup>

In pertinent part, the so-called enablement requirement mandates that a patent must enable a person of ordinary skill in a technical art to make and use a patented invention without undue experimentation.<sup>111</sup> The patent system is designed so that a technical artisan in a field should be able to read a patent, such as for a technology related to COVID-19 vaccines, and understand how to make and use that invention. In essence, the patent “codifies” an invention, translating knowledge from the inventor’s mind into a text that other technical artisans can readily absorb.<sup>112</sup>

#### A. Tacit Knowledge

While critically important, patent disclosure is limited in many ways.<sup>113</sup> This Part focuses on one of these limitations, namely the inability of patents to disclose tacit knowledge. As scientist and philosopher Michael Polanyi famously observed, “*We can know more than we can tell.*”<sup>114</sup> Polanyi was describing tacit knowledge—personal, experiential knowledge that is not amenable to codification. For example, a world-class chef may be able to write a detailed recipe for beef Wellington, but I can assure you that even if I follow that recipe very closely, the chef’s dish will taste much better than mine.<sup>115</sup> Much of cooking, as with other fields requiring technical information and skill, involves tacit, personal knowledge residing in the minds of practitioners. Such knowledge is borne of unique personal

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<sup>109</sup> Carolyn C. Cooper, *Nineteenth-Century American Patent Management as an Invisible College of Technology*, in *LEARNING AND TECHNOLOGICAL CHANGE* 40, 40 (Ross Thompson ed., 1993).

<sup>110</sup> 35 U.S.C. § 112.

<sup>111</sup> *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1360 (Fed. Cir. 2007) (citing 35 U.S.C. § 112).

<sup>112</sup> See generally Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 *BERKELEY TECH. L.J.* 1009 (2009).

<sup>113</sup> For representative critiques of the disclosure requirement, see Sean B. Seymore, *The Teaching Function of Patents*, 85 *NOTRE DAME L. REV.* 621 (2010); Jeanne C. Fromer, *Patent Disclosure*, 94 *IOWA L. REV.* 539 (2009); Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 *VAND. L. REV.* 1715, 1718 (2016) [hereinafter Fromer, *Dynamic*].

<sup>114</sup> MICHAEL POLANYI, *THE TACIT DIMENSION* 4 (1967).

<sup>115</sup> See Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 *CALIF. L. REV.* 1503, 1524 (2012) [hereinafter Lee, *Tacit Dimension*].

experience, observation, and even muscle memory. In the context of patented technologies, tacit knowledge encompasses invention-related knowledge that resides in the minds of inventors. It represents “intangible knowledge, such as rules of thumb, heuristics, and other ‘tricks of the trade.’”<sup>116</sup> Such knowledge is not amenable to codification, and it is not disclosed in a patent or any other type of document.

In introducing tacit knowledge, it is important to draw several distinctions. First, tacitness is a question of degree. At one end of the spectrum is knowledge that is technically codifiable though presently uncoded, which is referred to as latent knowledge.<sup>117</sup> At the other end of the spectrum is purely tacit knowledge that is not capable of codification.<sup>118</sup> Second, it is useful to distinguish between tacit knowledge that is helpful for practicing some basic version of an invention and tacit knowledge that is helpful for commercializing an invention in an industrial context. For example, an inventor’s tacit knowledge may be useful for creating one dose of a patented vaccine in a controlled laboratory environment. However, the inventor’s tacit knowledge may be particularly useful for ramping up production of hundreds of millions of doses of a patented vaccine.<sup>119</sup>

The importance of tacit knowledge to practicing patented inventions casts new light on the adequacy of the patent quid pro quo. In theory, technical disclosure by patentees provides the consideration that justifies the grant of exclusive rights. Biopharmaceutical companies asserting patents on COVID-19 vaccines implicitly maintain that they have upheld their end of the bargain. They have adequately disclosed their inventions, and as such, they should receive twenty years of exclusive rights. Recently, there has been reason to question whether the prevailing quid pro quo strikes the right balance. And a significant reason for doubt, somewhat ironically, has come from biopharmaceutical patentees themselves.

In October 2020, India and South Africa proposed a temporary waiver of global intellectual property rules under the TRIPS Agreement for all technologies related to diagnosing, preventing, and treating COVID-19.<sup>120</sup> In June 2022, the World Trade Organization (WTO) adopted a limited waiver focused on patented COVID-19 vaccines.<sup>121</sup> I address the waiver at greater length below,<sup>122</sup> but for present purposes, it temporarily suspends the obligation of member states to

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<sup>116</sup> Ashish Arora, *Contracting for Tacit Knowledge: The Provision of Technical Services in Technology Licensing Contracts*, 50 J. DEV. ECON. 233, 234 (1996).

<sup>117</sup> Ajay Agrawal, *Engaging the Inventor: Exploring Licensing Strategies for University Inventions and the Role of Latent Knowledge*, 27 STRATEGIC MGMT. J. 63 (2006)

<sup>118</sup> Cf. RICHARD R. NELSON & SIDNEY G. WINTER, AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE 73 (1982) (noting that knowledge of “skills” is largely tacit).

<sup>119</sup> Cf. Lee, *Tacit Dimension*, *supra* note 115, at 1529.

<sup>120</sup> India & South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 (IP/C/W/669)*, Council for Trade-Related Aspects of Intellectual Property Rights (2020).

<sup>121</sup> WORLD TRADE ORG., DRAFT MINISTERIAL DECISION ON THE TRIPS AGREEMENT (June 17, 2022), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R1.pdf&Open=True> [hereinafter WORLD TRADE ORG., DRAFT MINISTERIAL DECISION]. The decision indicates that within six months, WTO members will decide on whether to extend the waiver to patented COVID-19 diagnostics and therapeutics. *Id.*

<sup>122</sup> See *infra* Part III.

observe certain minimum requirements for patent protection as enumerated in a binding international agreement.

When India and South Africa proposed the TRIPS waiver in 2020, biopharmaceutical companies immediately opposed it. Unsurprisingly, they argued that it would expropriate valuable intellectual property rights and undermine incentives to invent.<sup>123</sup> They further argued that such a waiver would be not only unfair but also ineffective. Specifically, biopharmaceutical patentees argued that waiving intellectual property rights would do little to ramp up manufacturing and distribution of COVID-19 vaccines because, among other constraints,<sup>124</sup> third parties lack critical tacit knowledge for manufacturing vaccines in industrial quantities. Put differently, even if governments did not enforce patents, the absence of tacit knowledge would prevent third-party manufacturers from effectively producing billions of doses of generic COVID-19 vaccines.<sup>125</sup>

Tacit knowledge is particularly critical to the industrial production of novel mRNA vaccines. It has been long recognized that ramping up production of biologic products in industrial quantities often requires significant tacit knowledge from the original inventor.<sup>126</sup> Commentators argue that for “complex COVID-19 vaccines and biological therapeutics, fast manufacturing, particularly of products originally developed by other firms, will require not only physical capacity but also access to knowledge not contained in patents or in other public disclosures.”<sup>127</sup> In similar fashion, Alain Alsalhani, a vaccine expert from Doctors Without Borders, observed, “You need someone to share the process, because it’s a new technology . . . . One of the problems we have is that the scientific literature about industrial-scale manufacturing of mRNA vaccines is so slim. This is why it’s not just about a recipe, it’s about an active and full tech transfer.”<sup>128</sup> Accordingly, third-party firms need to obtain tacit knowledge from originator firms in order to manufacture patented COVID-19 vaccines.<sup>129</sup>

Moderna seized on the importance of tacit knowledge in vaccine manufacturing to argue against the TRIPS waiver. The company has several patents covering components of COVID-19 vaccines. But Moderna has famously pledged to not assert these patents against any entities making COVID-19 vaccines during

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<sup>123</sup> Eric Martin & Susan Decker, *U.S. Weighs Global Vaccine-Expansion Move Opposed by Drugmakers*, BLOOMBERG LAW NEWS (Apr. 22, 2021); Rowland et al., *supra* note 22.

<sup>124</sup> Other factors include shortages of manufacturing capacity and raw materials at various sites around the world. Martin & Decker, *supra* note 123.

<sup>125</sup> Ian Lopez, *Vaccine IP Enforcement Takes Stage in Global Immunization Fight*, BLOOMBERG LAW NEWS (Apr. 27, 2021).

<sup>126</sup> Cf. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016) (discussing the difficulty of replicating large-molecule biologic drugs).

<sup>127</sup> W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-scale Vaccine Manufacturing*, 369 SCIENCE 912, 912 (2020).

<sup>128</sup> Stephanie Nolen & Sheryl Gay Stolberg, *Pressure Grows on U.S. Companies to Share Covid Vaccine Technology*, N.Y. TIMES (Sept. 22, 2021) (quoting Alain Alsalhani, Doctors without Borders).

<sup>129</sup> Price II et al, *supra* note 127, at 912.

the pandemic.<sup>130</sup> As such, Moderna can argue that its patents are not preventing generic production of its mRNA vaccine. However, it vociferously opposed the TRIPS waiver. In so doing, Moderna argued that other constraints would render such a waiver ineffectual. In particular, it contended that third-party manufacturers lack the technical capacity, including knowledge and specialized equipment, to produce their vaccine in industrial quantities.<sup>131</sup> Tellingly, Moderna has refused to widely share its tacit knowledge related to vaccine manufacture.<sup>132</sup>

Contrary to Moderna's claim, however, vaccine manufacturers around the world possess sophisticated equipment and are ready to manufacture vaccines—if they only had the blueprints and technical know-how from vaccine developers like Moderna.<sup>133</sup> According to Suhaib Siddiqi, former director of chemistry at Moderna, with the appropriate blueprint and technical advice, a modern vaccine manufacture should be able to begin producing vaccines in at most three to four months.<sup>134</sup> Beyond patent rights, a key missing ingredient is tacit knowledge from vaccine developers.

The inability of third parties to practice technologies that inventors have ostensibly disclosed in patents raises serious questions about the sufficiency of the patent quid pro quo. I am not necessarily suggesting that Moderna, BioNTech, and other vaccine patentees have not satisfied the existing disclosure requirements of patent law, although others have made that claim. I am suggesting, however, that the disclosure obligations placed on patentees—which form an essential part of the patent quid pro quo—are too low. Where patentees retain significant technical knowledge as tacit and undisclosed, and where persons of ordinary skill are at a significant informational disadvantage relative to patentees in practically making and using inventions, there is good reason to doubt the adequacy of the patent quid pro quo.

## B. Modifying the Patent Quid Pro Quo

So, what can be done? One set of interventions involves increasing the general disclosure requirements of patent law as a condition for obtaining exclusive rights. This approach would orient the disclosure requirement more toward the “downstream,” practical application of patented technologies. In general, these interventions would facilitate greater disclosure of relatively low-hanging fruit: latent knowledge that is presently uncodified but codifiable. This Article proposes several reforms in this regard.

First, this Article suggests rehabilitating the best mode requirement. U.S. patent law presently requires that inventors disclose any known “best mode” for practicing their invention.<sup>135</sup> The best mode requirement goes beyond mere

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<sup>130</sup> Moderna, Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (Oct. 8, 2020).

<sup>131</sup> Gebrekidan & Apuzzo, *supra* note 14 (quoting Moderna's chief executive, Stephane Bancel).

<sup>132</sup> See Nolen & Stolberg, *supra* note 128 (detailing the Biden administration's frustration with Moderna for not transferring its technology widely to other vaccine manufacturers).

<sup>133</sup> Cheng & Hinnant, *supra* note 100.

<sup>134</sup> *Id.*

<sup>135</sup> 35 U.S.C. § 112.

enablement: if a patent applicant “develops specific instrumentalities or techniques which are recognized by the applicant at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well.”<sup>136</sup> Thus, for example, if a vaccine inventor knew of the best way of manufacturing a vaccine when filing a patent application, the best mode requirement would require disclosing such information in the patent. While disclosing a best mode is still technically a requirement of patentability, recent patent reforms have rendered it toothless; unlike all other requirements of patentability, challengers cannot invalidate a patent based on failure to comply with the best mode requirement, and patent authorities rarely enforce it.<sup>137</sup> This Article suggests rehabilitating the best mode requirement to its prior status. Requiring patentees to disclose any known best mode for practicing their inventions would lead to greater codification of valuable tacit knowledge. It would further eliminate a troubling paradox—reflected by the controversy over access to patented vaccines—in which a patentee ostensibly “discloses” a technology in a patent, yet it retains crucial knowledge about that invention as a trade secret.<sup>138</sup>

Second, this Article joins others in arguing for a more dynamic patent disclosure requirement. Presently, the enablement requirement only applies to a basic version of a claimed invention. Courts have long held that patents need not provide production specifications for a commercial product.<sup>139</sup> Consistent with this orientation, disclosure is largely fixed at the time of filing a patent application. Indeed, a patent applicant has an incentive not to amend the disclosure during patent prosecution because doing so may lead to losing an earlier (and more desirable) priority date. However, as law professor Jeanne Fromer notes, much valuable information about an invention, particularly relating to commercialization, arises after patent filing.<sup>140</sup> Fromer has argued for a doctrine of “dynamic patent disclosure” that requires patentees to disclose information about a patented invention, particularly regarding commercialization, as a condition of maintaining

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<sup>136</sup> *Spectra-Physics, Inc. v. Coherent Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987).

<sup>137</sup> *See Leahy-Smith America Invents Act of 2011*, Pub. L. No. 112-29, 125 Stat. 284 (codified in scattered sections of 35 U.S.C.) (eliminating the failure to disclose a best mode as a ground for canceling, invalidating, or rendering unenforceable any patent claim). Prior to these reforms, several concerns emerged about the best mode requirement, including that it unduly increased the expense and complexity of litigation. *See* Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 *YALE J.L. & TECH.* 1, 8-9 (2012). Accordingly, in 2011 Congress eliminated the failure to comply with the best mode requirement as a ground upon which one could challenge a patent, effectively rendering this requirement unenforced. However, Congress’s justifications for weakening the best mode requirement “do not hold much water.” *See id.* at 16-20 (arguing, among other contentions, that rehabilitating the best mode requirement could actually decrease the expense and complexity of litigation).

<sup>138</sup> *See* W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 *NOTRE DAME L. REV.* 1611, 1617 (2017) (“In both scholarship and court opinions, the dominant view is that an invention cannot be protected by both a patent and trade secrecy.”).

<sup>139</sup> *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962); *CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003) (“Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment . . .”).

<sup>140</sup> *See* Fromer, *Dynamic*, *supra* note 113, at 1720-21.



patent rights.<sup>141</sup> She advances a modest proposal requiring patentees to identify known commercialized products produced by the patentees and their licensees that fall within their patent claims.<sup>142</sup> This Article extends this principle and argues for a more robust obligation of dynamic disclosure. It proposes that patentees must disclose relevant technical information related to practicing their patented inventions (including any known or updated best mode) in order to maintain patent rights. Such an ongoing obligation would persist for a reasonable time, say five years, from the date of filing. Failure to provide such dynamic disclosure would lead to patent invalidation. This requirement would provide a lever by which the patent system could, for example, compel vaccine patentees to disclose details about how to commercially manufacture their vaccines, even after the date of patent filing.

Third, this Article suggests a more concrete proposal for ongoing patent disclosure for a class of patented technologies that includes vaccines. The foregoing proposal for dynamic patent disclosure is subject to obvious monitoring and enforcement challenges. After all, five years after a patent issues, how would the PTO know that a patentee possessed tacit knowledge related to manufacturing that it should disclose? In some instances, however, we do know that such information exists because the patentee discloses it elsewhere. As a condition for obtaining regulatory approval for a diagnostic, therapeutic, or prophylactic—such as a vaccine—biopharmaceutical companies must submit significant information to regulatory agencies such as the FDA. Regulators want to know how health products are manufactured, and “regulatory approval typically requires the extensive codification of tacit manufacturing knowledge.”<sup>143</sup> For instance, the FDA examined Moderna’s production facilities and clinical trial sites before approving its COVID-19 vaccine.<sup>144</sup> Existing law prevents the FDA from easily disclosing this information.<sup>145</sup> However, this Article suggests requiring patentees to disclose such discrete, codified knowledge—which they already submit to a regulatory agency—as a condition of maintaining patent rights. A heightened, ongoing disclosure requirement would lead patentees to share valuable knowledge—in this case, codified trade secrets rather than uncoded tacit knowledge—for commercializing their inventions.

### C. Beyond the Patent Quid Pro Quo

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<sup>141</sup> *Id.* at 1722.

<sup>142</sup> *Id.*

<sup>143</sup> Price II et al., *supra* note 127, at 913.

<sup>144</sup> Grady et al., *supra* note 44.

<sup>145</sup> *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984) (holding that unauthorized disclosure of trade secrets by a federal regulator, which interfered with the claimant’s reasonable, investment-backed expectation of nondisclosure, is subject to the Takings Clause of the Fifth Amendment); 21 U.S.C. § 331(j) (prohibiting the FDA from disclosing manufacturing processes protected as trade secrets); see Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 CALIF. L. REV. 493, 532 (2021) (discussing this provision).

Augmenting this proposal, this Article suggests leveraging additional public-private quid pro quos to induce greater technical disclosure by innovators—including patentees—receiving public funds. Such measures may be necessary to unlock purely tacit knowledge. Several of the foregoing proposals would compel patentees to disclose latent knowledge—that which is uncodified but codifiable. However, purely tacit knowledge is not amenable to codification, and attempts to codify it may be highly costly and inefficient. Rather than codification, transferring purely tacit knowledge often requires direct interpersonal interaction between possessors and adopters of such knowledge.<sup>146</sup> For instance, I could spend days reading instructional manuals on how to serve a tennis ball, but I would progress much faster by working directly with a tennis coach who could impart tacit knowledge through interpersonal instruction. In the technological context, transferring purely tacit knowledge often requires direct personal and organizational linkages between inventors and technology adopters. This is evident, for instance, in university-industry technology transfer. As I have described in other work, companies licensing university patents routinely hire academic inventors as consultants to help transfer and commercialize patented inventions.<sup>147</sup> While in theory the licensee should be able to read the patent and understand how to make and use a technology, there is often no substitute for talking directly with an inventor herself to understand an invention.

The importance of personal communications to transferring invention-related tacit knowledge raises several possibilities to improve such transfer. One proposal would be to require patentees to commit to working with technology adopters to transfer tacit knowledge and assist with commercializing patented technologies. Such an obligation could range from providing additional codified disclosure to licensees to negotiating in good faith for consulting services with technology adopters. While Congress could engraft such an obligation onto the patent quid pro quo, this Article ultimately argues against such a proposal. An obligation for patentees to directly work with individual licensees would be much more burdensome than simply heightening general disclosure requirements. It would require patentees to redirect key personnel from important projects, and it would be particularly onerous in the context of compulsory licenses, where a patentee would have to share tacit knowledge with third parties against its will.<sup>148</sup> More generally, it would be very difficult for government authorities to monitor and enforce the sufficiency of compulsory tacit knowledge transfer. Ultimately, forcing patentees to engage in direct tacit knowledge transfer as a condition of maintaining a patent is a bridge too far.

The calculus may be different, however, for innovators—including patentees—receiving substantial public funding. Returning to a previous theme, this Article proposes a “consideration-based” form of regulation to help unlock tacit

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<sup>146</sup> See Lee, *Tacit Dimension*, *supra* note 115, at 1528-29.

<sup>147</sup> *Id.* at 1531-33 (presenting case studies where licensees of university patents engaged the consulting services of faculty inventors).

<sup>148</sup> Borrowing again from contract principles, the law is generally chary about forcing people to perform acts against their will, such as by enforcing personal services contracts through specific performance. See, e.g., *Ford v. Jermon*, 6 Phila. 6 (Dist. Ct. 1865).

knowledge where federal funds helped to develop a novel technology. For example, government agencies funding research leading to vaccines could require that funding recipients not only make products widely available but also transfer tacit knowledge to select manufacturers to facilitate mass production.<sup>149</sup> This could be accomplished, for instance, by contractually mandating that funding recipients participate in knowledge-sharing “hubs,” such as the WHO’s COVID-19 Technology Access Pool (C-TAP).<sup>150</sup> C-TAP represents a potentially powerful resource for sharing tacit knowledge for manufacturing COVID-19 vaccines. To date, however, vaccine developers (which have received significant public funds) have not agreed to share their patents or know-how with C-TAP or similar entities.<sup>151</sup> However, public entities could require recipients of public funds to commit to transferring tacit knowledge to knowledge hubs or designated licensees on reasonable terms.

An obligation for public funding recipients to directly provide tacit knowledge would run into familiar objections regarding manpower shortages. Indeed, Pfizer and Moderna have both argued that personnel knowledgeable about mRNA vaccine production are in such scarce supply that they cannot send them to other sites around the world.<sup>152</sup> It bears mentioning that under this proposal, publicly funded innovators sharing tacit knowledge would be able to charge a reasonable royalty,<sup>153</sup> which would mitigate to some extent their personnel and financial burdens. However, to heighten the incentive and address resource constraints, public entities may have to provide financial and other support to enable private entities to share tacit knowledge with others. This seems eminently feasible in the current pandemic; after all, Operation Warp Speed provided Moderna with not only funds but also help in obtaining personnel to ramp up vaccine development.<sup>154</sup>

As a general matter, the receipt of substantial public funds opens significant avenues to compel vaccine developers to disclose valuable technical knowledge. This applies to not only tacit knowledge but also codified knowledge currently

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<sup>149</sup> Price II et al., *supra* note 127, at 914 (“[A] government commitment could usefully require transfer of manufacturing know-how across firms with which it has contracted.”); *id.* (“[T]he EU might well be suited to using the lure of funding to nudge firms toward knowledge transfer.”); Matthew M. Kavanagh, Lawrence O. Gostin & Madhavi Sunder, *Sharing Technology and Vaccine Doses to Address Global Vaccine Inequity and End the COVID-19 Pandemic*, 326 JAMA 219, 220 (2021) (“The Biden administration has leverage to incentivize sharing, given extensive public funding.”).

<sup>150</sup> See WORLD HEALTH ORG., *supra* note 95.

<sup>151</sup> Ed Silverman, *Pharma Leaders Shoot Down WHO Voluntary Pool for Patent Rights on Covid-19 Products*, STAT: PHARMALOT (May 28, 2020), <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>.

<sup>152</sup> Nolen & Stolberg, *supra* note 128. Manufacturing techniques can be so complex and tacit that even vaccine developers do not understand them, relying instead on the expertise of contract vaccine manufacturers. See Cynthia Koons & Susan Decker, *Inovio Tells Court Supplier Is Holding Covid Vaccine ‘Hostage,’* BLOOMBERG LAW (June 3, 2020) (describing a dispute in which Inovio, a vaccine developer, accused VGXI, a vaccine manufacturer, of not providing information to allow other entities to manufacture Inovio’s vaccine).

<sup>153</sup> Silverman, *supra* note 151 (citing Ellen ‘t Hoen of the University of Groningen and former executive director of the Medicines Patent Pool).

<sup>154</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 55, at 28.

maintained as trade secrets. By default, the government retains broad rights to data arising from government contracts. The Federal Acquisition Regulations define data broadly to include “recorded information, regardless of the form or the media on which it may be recorded,” including “technical data.”<sup>155</sup> In the context of Operation Warp Speed contracts for COVID-19 vaccines, such data include cell lines, studies, and manufacturing know-how.<sup>156</sup> As a statutory default, the government would have broad rights to technical knowledge that is vital to COVID-19 vaccine manufacturing. However, companies participating in Operation Warp Speed successfully negotiated around this default, retaining proprietary rights to such data.<sup>157</sup> Relatedly, the White House has said that it does not believe the federal government has the authority to compel Moderna and other vaccine manufacturers to transfer tacit knowledge.<sup>158</sup> However, an analysis by Public Citizen concludes that the federal government retains unlimited rights in Moderna’s data arising from government contracts, including data related to commercial manufacturing.<sup>159</sup> Furthermore, the federal government “would seem free to share the commercial-scale up vaccine recipe” with other parties.<sup>160</sup> Continuing the theme of *quid pro quos*, significant government support leading to patented vaccines provides leverage for the government to demand greater accessibility to not only vaccine doses themselves, but also the technical knowledge necessary to manufacture them.

### III. CHANGED CIRCUMSTANCES AND INTERNATIONAL INTELLECTUAL PROPERTY LAW

While this Article has focused on domestic mechanisms to enhance global access to COVID-19 vaccines, this Part turns more centrally to the international legal landscape. It focuses on the TRIPS Agreement, an important multilateral intellectual property agreement established in connection with the formation of the WTO. In this context, this Article suggests that another contract principle, the doctrine of changed circumstances, can help justify modifying this international agreement in light of the drastic exigencies of the COVID-19 pandemic. In general, the doctrine of changed circumstances excuses nonperformance of a contract when

<sup>155</sup> Fed. Acquisition Reg., 48 C.F.R. § 52.227-14(a) (2014).

<sup>156</sup> Lupkin, *HHS Released*, *supra* note 98.

<sup>157</sup> See Lupkin, *Pfizer’s*, *supra* note 99 (analyzing provisions excluding taxpayer protections in Pfizer’s original Operation Warp Speed contract); KATHRYN ARDIZZONE, KNOWLEDGE ECOLOGY INT’L, BIDEN ADMINISTRATION’S \$3.5 BILLION PURCHASE AGREEMENT WITH PFIZER FOR INTERNATIONAL VACCINE DONATION (Sept. 22, 2021), <https://www.keionline.org/36568> (noting Pfizer’s use of a “loophole” to sidestep government data rights in standard contracts); Lupkin, *HHS Released*, *supra* note 98 (“The data rights in the contract, which typically govern disclosure and sharing of key studies, cell lines, and know-how for making a product, are especially weak.”).

<sup>158</sup> Jen Psaki, Press Sec’y, The White House, Press Briefing at The White House (October 18, 2021), <https://www.whitehouse.gov/briefing-room/press-briefings/2021/10/18/press-briefing-by-press-secretary-jen-psaki-october-18-2021/> (“[M]y understanding is also that the U.S. government does not have the ability to compel Moderna to take certain actions.”).

<sup>159</sup> ZAIN RIZVI, PUB. CITIZEN, SHARING THE NIH-MODERNA VACCINE RECIPE 25 (2021), <https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/> [hereinafter RIZVI, SHARING].

<sup>160</sup> *Id.*

the conditions surrounding the original bargain have changed in substantial and unforeseeable ways.<sup>161</sup> The principle of changed circumstances has a long history in domestic law, and it even finds recognition in international law and the Vienna Convention on the Law of Treaties.<sup>162</sup> To be sure, there are complications to applying this domestic-law concept to international treaties, and this Article does not suggest direct application of the doctrine.<sup>163</sup> Nonetheless, the principle of changed circumstances provides a conceptual basis for modifying international intellectual property agreements in light of an unprecedented pandemic.

#### A. Contract Metaphors in the Formation of International Intellectual Property Law

Though international patent law is well-developed today, substantive international harmonization of patent law is relatively recent. Historically, patent law was largely a domestic affair wherein states could craft their patent laws to suit their particular interests.<sup>164</sup> For example, up until several decades ago, over forty low- and middle-income countries, including Brazil and India, did not grant product patents on pharmaceuticals.<sup>165</sup> In many ways, this was sound policy. Most developing countries did not have innovative domestic biopharmaceutical industries that demanded patent protection for their products. Furthermore, the absence of patents on foreign medicines helped lower the cost and increase access to these resources for low-income populations. Finally, the absence of patent

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<sup>161</sup> See, e.g., U.C.C., Art. 2-615 (relieving a seller of liability “if performance has been made impracticable by the occurrence of a contingency the non-occurrence of which was a basic assumption on which the contract was made . . . .”); see generally John D. Wladis, *Impracticability as Risk Allocation: The Effect of Changed Circumstances upon Contract Obligations for the Sale of Goods*, 22 GA. L. REV. 503, 503-04 (1988). One variant of the changed circumstances principle is the rule of impossibility, which discharges the contractual obligations of a party if supervening events prevent it from fulfilling its part of the contract. See Uri Benoliel, *The Impossibility Doctrine in Commercial Contracts: An Empirical Analysis*, 85 BROOK. L. REV. 393 (2020).

<sup>162</sup> See Detlev F. Vagts, *Rebus Revisited: Changed Circumstances in Treaty Law*, 43 COLUM. J. TRANS. L. 459, 464, 470-71 (2005); Vienna Convention on the Law of Treaties, art. 62, May 23, 1969, 1155 U.N.T.S. 331.

<sup>163</sup> Vagts, *supra* note 162, at 460 (cautioning against applying principles of contract impossibility or frustration to international law). Among other considerations, domestic parties invoking the changed circumstances doctrine typically can resort to a neutral, third-party court, while such a forum may not be available in the international context. Additionally, treaties tend to be subject to more prolonged deliberation than ordinary contracts. Finally, potential application of the changed circumstances doctrine is complicated in the context of multilateral treaties involving multiple parties as opposed to the binary agreements typical of contracts. Vagts, *supra* note 162, at 465.

<sup>164</sup> Ellen ‘t Hoen, Jonathan Berger, Alexandra Calmy & Suerie Moon, *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14 J. INT’L AIDS SOC’Y 1, 2 (2011). Of course, international patent law has a long history, punctuated by the Paris Convention for the Protection of Industrial Property, which was originally signed in 1883. However, the Paris Convention focused primarily on streamlining the process by which an inventor can obtain patent protection on an invention in multiple countries rather than on harmonizing substantive patent law across countries. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305.

<sup>165</sup> Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT’L L. 123, 124 n.2 (2004).

protection prevented regressive wealth transfers from poor countries to wealthy multinational corporations in the form of patent royalties.

This landscape shifted dramatically toward the end of the last century. In the mid-1990s, after decades of negotiations, countries around the world established the WTO, an international organization devoted to promoting free trade and reducing tariffs and protectionist trade policies. As part of establishing the WTO, member states also concluded the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).<sup>166</sup> The TRIPS Agreement established minimum substantive standards for protecting patents, copyrights, trademarks, and other forms of intellectual property. Adopting the TRIPS Agreement was a requirement to join the WTO, though concessions were made to allow various categories of developing countries to delay fully implementing TRIPS.<sup>167</sup> While international patent law has existed for well over a century, the TRIPS Agreement represented an unprecedented step in displacing individual state sovereignty and substantively harmonizing (and strengthening) patent standards around the world.

Contract metaphors pervade the formation of the WTO and the TRIPS Agreement. In general, a multilateral treaty is a grand social contract among countries. States agree to give up some element of control to achieve gains from international cooperation. In a more direct sense, the WTO and the TRIPS Agreement represented a broad bargain between developed and developing countries. Developing countries received greater access to developed-country markets for agriculture, textiles, and other exports and a seat at the table when making global trade rules.<sup>168</sup> For their part, developed countries gained increased IP protection in developing countries, which had historically been hotbeds of piracy. Such “linkage bargaining,” which tied greater market access to stronger IP standards, helped convince developing countries to join the WTO, even though it meant strengthening substantive IP standards more than they would have preferred.<sup>169</sup>

Developed countries presented TRIPS to developing countries as a bargain worth taking.<sup>170</sup> On the one hand, developing countries would face some immediate welfare losses from strengthening intellectual property standards. For example, prices for pharmaceuticals, movies, and other IP-protected goods would increase, and individuals employed by piracy-based industries would face dislocation. On

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<sup>166</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), [https://docs.wto.org/gtd/WTOlegaltexts/Legal\\_texts\\_e.pdf](https://docs.wto.org/gtd/WTOlegaltexts/Legal_texts_e.pdf) [hereinafter TRIPS Agreement].

<sup>167</sup> See, e.g., WORLD TRADE ORG., DEVELOPING COUNTRIES’ TRANSITION PERIODS (Sept. 2006), [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm04\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm); WORLD TRADE ORG., WTO MEMBERS AGREE TO EXTEND TRIPS TRANSITION PERIOD FOR LDCS UNTIL 1 JULY 2034 (June 29, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/trip\\_30jun21\\_e.htm](https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm).

<sup>168</sup> See Bello, *supra* note 17.

<sup>169</sup> Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2840 (2006).

<sup>170</sup> See David M. Fox, *Technology Transfer and the TRIPS Agreement Are Developed Countries Meeting Their End of the Bargain?*, 10 HASTINGS SCI. & TECH. L.J. 1, 8 (2019) (“The TRIPS Agreement is microcosmic of the larger ‘bargained-for’ exchange reached during the Uruguay Round.”).

the other hand, developing countries hoped that strengthening intellectual property protection would lead to long-term gains from stimulating local innovation and increasing technology transfer from wealthier nations.<sup>171</sup> In theory, companies from developed countries would be more likely to invest directly in, and transfer technology to, developing countries with strong IP standards.<sup>172</sup> Furthermore, TRIPS requires developed countries to provide incentives for technology transfer to least-developed countries.<sup>173</sup> Whether or not this bargain has actually paid off for developing countries is a matter of intense debate.<sup>174</sup> Many observers view TRIPS as a one-sided bargain that heavily favored the interests of developed countries.<sup>175</sup>

As a result of this grand bargain, developing countries signed on to TRIPS and had to strengthen IP protections in several ways. Among other reforms, member states extended patentable subject matter to a wide range of inventions, including pharmaceuticals.<sup>176</sup> Additionally, TRIPS imposed regulations on countries' ability to issue compulsory licenses. TRIPS still permits countries to issue compulsory licenses, but it imposes procedural and substantive regulations that, in effect, make it harder for them to do so.<sup>177</sup> Unlike other international agreements, TRIPS obligations have real bite in that they are enforceable through the WTO dispute settlement procedures.<sup>178</sup>

#### B. Changed Circumstances and the TRIPS Waiver

This context leads to the current debate over patents and global access to COVID-19 vaccines. As noted, many observers view patents as constraining access to vaccines and other technologies valuable for fighting the pandemic. Accordingly, in October 2020, India and South Africa proposed a waiver of certain provisions of the TRIPS Agreement to accelerate the prevention, containment, and treatment of COVID-19.<sup>179</sup> Among other effects, the proposed waiver would temporarily suspend the requirement that member states maintain minimum standards of patent protection as provided by TRIPS. It should be noted that the proposed waiver would merely suspend international obligations under TRIPS; states may face other

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<sup>171</sup> See Carlos M. Correa, *The TRIPS Agreement and Developing Countries*, in THE WORLD TRADE ORGANIZATION: LEGAL, ECONOMIC AND POLITICAL ANALYSIS 419, 420 (2005); 't Hoen et al., *supra* note 164, at 2.

<sup>172</sup> *Id.*

<sup>173</sup> TRIPS Agreement, art. 66.2; see generally Fox, *supra* note 170.

<sup>174</sup> See, e.g., Keith E. Maskus, *Encouraging International Technology Transfer*, 7 INT'L CTR. FOR TRADE AND SUSTAINABLE DEV. 26 (2004).

<sup>175</sup> See, e.g., Keith E. Maskus, *Using the International Trading System to Foster Technology Transfer for Economic Development*, 2005 MICH. ST. L. REV. 219, 222 ("Critics see TRIPS as a mechanism for enhancing the global market power of information developers, permitting them to act in monopolistic and abusive ways that would slow down ITT, especially to the poorest countries."); 't Hoen et al., *supra* note 164, at 2 ("The negotiations leading to TRIPS had been primarily driven by the trade and commercial interests of the industrialized nations.").

<sup>176</sup> TRIPS art. 27.

<sup>177</sup> TRIPS art. 31.

<sup>178</sup> 't Hoen et al., *supra* note 164, at 2.

<sup>179</sup> India & South Africa, *supra* note 120 ¶ 12.

international or domestic constraints against changing IP laws, or they may simply choose to maintain existing TRIPS standards on their own accord.<sup>180</sup> Public health advocates argued that temporarily waiving IP protections under TRIPS would, among other benefits, help ramp up global production of generic versions of patented vaccines for billions of people.<sup>181</sup> As noted, biopharmaceutical companies and others roundly criticized the proposed TRIPS waiver as hurting incentives to invent and doing little to enhance vaccine availability.

To the surprise of many, in May 2021 the Biden administration announced its support for a narrow version of the TRIPS waiver focused on COVID-19 vaccines.<sup>182</sup> This was a remarkable sea change given that the United States had for decades been the most vocal advocate for strong intellectual property standards around the world. However, the exigencies of the COVID-19 pandemic caused a rethinking of IP policy. As President Biden has observed about the coronavirus pandemic in general, “We’re not going to be ultimately safe until the world is safe.”<sup>183</sup> Notably, in announcing this policy change, U.S. Trade Representative Katherine Tai explicitly invoked the language of changed circumstances. She stated, “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of these protections for COVID-19 vaccines.”<sup>184</sup>

After years of protracted negotiations, in June 2022 the WTO adopted a limited version of the TRIPS waiver focused principally on relaxing patents on COVID-19 vaccines.<sup>185</sup> In so doing, the WTO also explicitly referenced the “exceptional circumstances of the COVID-19 pandemic.”<sup>186</sup> Although the long time required to finally adopt the waiver and its narrow scope are far from ideal, it still represents a meaningful step toward increasing global production of vaccines.<sup>187</sup> The new TRIPS waiver remains deeply controversial, and in the

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<sup>180</sup> For instance, many countries are parties to regional trade agreements or bilateral investment treaties (BITS) that require heightened intellectual property protections, sometimes exceeding the minimums prescribed by TRIPS. ‘t Hoen et al., *supra* note 164, at 5, 8.

<sup>181</sup> See, e.g., Prabhala et al., *supra* note 17.

<sup>182</sup> Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (May 5, 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>; Thomas Kaplan, Sheryl Gay Stolberg & Rebecca Robbins, *Taking ‘Extraordinary Measures,’ Biden Backs Suspending Patents on Vaccines*, N.Y. TIMES (May 5, 2021), <https://www.nytimes.com/2021/05/05/us/politics/biden-covid-vaccine-patents.html>.

<sup>183</sup> Helene Gayle, Gordon LaForge & Anne-Marie Slaughter, *America Can—and Should—Vaccinate the World*, FOREIGN AFFAIRS (March 19, 2021), <https://www.foreignaffairs.com/articles/united-states/2021-03-19/america-can-and-should-vaccinate-world>.

<sup>184</sup> Tai, *supra* note 182.

<sup>185</sup> WORLD TRADE ORG., DRAFT MINISTERIAL DECISION, *supra* note 121. As noted, the draft decision establishes that in six months, WTO members will decide on whether to extend the TRIPS waiver to patented COVID-19 diagnostics and therapeutics as well. *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> See Rebecca Robbins, *W.T.O. Countries Agree to a Limited Relaxing of Patent Protections on Coronavirus Vaccines*, N.Y. TIMES (June 17, 2022), <https://www.nytimes.com/2022/06/17/business/wto-covid-vaccine-patent.html> (reporting various commentary criticizing the limitations of the waiver and praising its ability to increase vaccine access).



aftermath of its recent adoption, it is useful to address some of the principal objections levied against it.

First, as noted, TRIPS already provides for compulsory licenses, thus seemingly obviating the need for a broad-based waiver. However, the existing compulsory license framework under TRIPS is too cumbersome and unwieldy for the current pandemic. TRIPS creates a “product-by-product” and “country-by-country” regime that is ill suited to address the thicket of patents covering COVID-19 vaccines.<sup>188</sup> While the TRIPS framework generally requires negotiations between member states and individual patentees, this requirement can be waived in times of national emergency.<sup>189</sup> However, even aside from negotiating with patentees, merely identifying the patents that should be subject to individual compulsory licenses can be very difficult. For instance, at least thirteen patent claims cover the Pfizer-BioNTech vaccine, and at least twelve patent claims cover the Moderna vaccine.<sup>190</sup> This problem is compounded because many of the inputs to patented vaccines are patented themselves; issuing compulsory licenses for each of these upstream technologies would greatly increase transaction costs.<sup>191</sup> Additionally, member states issuing compulsory licenses under the existing TRIPS regime have received political blowback from wealthy countries, thus chilling their willingness to do so.<sup>192</sup>

The existing TRIPS framework for compulsory licenses also poses problems for countries that lack the domestic capacity to manufacture needed technologies. The original TRIPS Agreement limited compulsory licenses “for the supply of the domestic market of the Member authorizing such use.”<sup>193</sup> This rendered compulsory licenses unhelpful for many developing countries that lacked the domestic capacity to manufacture a licensed invention. As discussed further below, the WTO subsequently established a provision, TRIPS Article 31*bis*, that allows a country to issue a compulsory license to export a subject technology to another country, presumably one that does not have the capacity to manufacture it domestically.<sup>194</sup> Indeed, in the current pandemic, Bolivia has attempted to utilize TRIPS Article 31*bis* to import Johnson & Johnson’s COVID-19 vaccine from Biolyse Pharma, a Canadian company.<sup>195</sup> However, this provision is notoriously difficult to implement, and countries have only successfully used it once in the

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<sup>188</sup> PUB. CITIZEN, EXISTING TRIPS “FLEXIBILITIES” UNWORKABLE FOR NECESSARY SCALE UP OF COVID-19 MEDICINES PRODUCTION (Apr. 5, 2021), <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-existing-trips-flexibilities-unworkable-for-scale-up-of-covid-19-medicines-production/> [hereinafter PUB. CITIZEN].

<sup>189</sup> TRIPS art. 31(b).

<sup>190</sup> PUB. CITIZEN, *supra* note 188, at 3.

<sup>191</sup> According to another estimate, mRNA vaccines are covered by more than 100 patents held by many different parties. Kavanagh et al., *supra* note 149, at 219.

<sup>192</sup> PUB. CITIZEN, *supra* note 188, at 5.

<sup>193</sup> TRIPS art. 31(f).

<sup>194</sup> TRIPS art. 31*bis*; *see infra* note 235 and accompanying text.

<sup>195</sup> WORLD TRADE ORG., BOLIVIA OUTLINES VACCINE IMPORT NEEDS IN USE OF WTO FLEXIBILITIES TO TACKLE PANDEMIC, WTO NEWS (May 12, 2021), [https://www.wto.org/english/news\\_e/news21\\_e/dgno\\_10may21\\_e.htm](https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm) [hereinafter WORLD TRADE ORG., BOLIVIA].

decades prior to the pandemic.<sup>196</sup> All of these considerations suggest that a broad-based IP waiver offers substantially more functionality than the existing TRIPS framework for compulsory licenses.<sup>197</sup>

Second, waiver critics argue that even if countries temporarily suspended patents on COVID-19 vaccines, significant challenges of mass manufacturing vaccines would remain. As discussed, third-party manufacturers would still lack critical tacit knowledge.<sup>198</sup> Additionally, shortages of raw ingredients would also constrain production.<sup>199</sup> There are also concerns that the TRIPS waiver will exacerbate these shortages, as increased demand from unlicensed manufacturers will challenge already stretched supply chains.<sup>200</sup>

However, it is important to note that barriers to widespread vaccine production are cumulative. Although problems of tacit knowledge and raw ingredients will remain, temporarily suspending patent rights will remove one obstacle to widespread manufacturing. It is worth noting, moreover, that tacit knowledge challenges are surmountable. Sophisticated vaccine manufacturing facilities around the world possess the absorptive capacity to incorporate tacit knowledge and manufacture vaccines.<sup>201</sup> Additionally, although mRNA vaccines are novel, they require fewer steps and ingredients and less physical capacity than traditional vaccines.<sup>202</sup> In sum, “manufacturers from Canada to Bangladesh say they can make vaccines—they just lack patent licensing deals. When the price is right, companies have shared secrets with new manufacturers in just months, ramping up production and retrofitting factories.”<sup>203</sup> More generally, resolving the constraint of IP rights will create additional political pressure to address other constraints, such as those related to tacit knowledge, raw ingredients, and distribution infrastructure. Indeed, in the aftermath of the Biden administration’s

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<sup>196</sup> PUB. CITIZEN, *supra* note 188, at 4.

<sup>197</sup> See WORLD TRADE ORG., DRAFT MINISTERIAL DECISION, *supra* note 121 (“An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market . . .”).

<sup>198</sup> Ian Lopez & Matthew Bultman, *Pfizer, J&J Balk at Calls to Loosen Grip on Covid Vaccine Rights*, BLOOMBERG LAW NEWS (Apr. 22, 2021), <https://news.bloomberglaw.com/health-law-and-business/pfizer-j-j-balk-at-calls-to-loosen-grip-on-covid-vaccine-rights>.

<sup>199</sup> See *A Vaxxing Problem: American Export Controls Threaten to Hinder Global Vaccine Production*, THE ECONOMIST (Apr. 24, 2021), <https://www.economist.com/science-and-technology/2021/04/22/american-export-controls-threaten-to-hinder-global-vaccine-production> (noting that U.S. export controls on raw materials and equipment are stymying vaccine production abroad and that Ireland’s prime minister, Micheal Martin, stated that Pfizer’s vaccine requires 280 components from 86 suppliers in 19 countries).

<sup>200</sup> KING & SPAULDING, UPDATE ON THE PROPOSED TRIPS WAIVER AT THE WTO: WHERE IS IT HEADED, AND WHAT TO EXPECT? 3 (June 7, 2021), <https://www.kslaw.com/news-and-insights/update-on-the-proposed-trips-waiver-at-the-wto-where-is-it-headed-and-what-to-expect> [hereinafter KING & SPAULDING].

<sup>201</sup> Stephanie Nolen, *Here’s Why Developing Countries Can Make mRNA Covid Vaccines*, N.Y. TIMES (Oct. 22, 2021), <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>. Many vaccine manufacturers in developing countries are global or government-run entities that have strong records and oversight. Additionally, the WHO’s prequalification and emergency use process can help ensure strong safety and quality standards. Kavanagh et al., *supra* note 149, at 220.

<sup>202</sup> Nolen, *supra* note 201.

<sup>203</sup> Gebrekidan & Apuzzo, *supra* note 14.

support of a TRIPS waiver, advocates increased calls for vaccine developers to transfer tacit knowledge.<sup>204</sup>

Third, some might argue that direct donations by national governments and biopharmaceutical companies would more quickly disseminate vaccines to developing countries than the TRIPS waiver. Certainly, governments have enormous potential in this regard. The United States has stated its commitment to serve as “an arsenal of vaccines for the world.”<sup>205</sup> As of September 2021, it had pledged to donate 1.1 billion doses of vaccine to other countries.<sup>206</sup> Russia and China are aggressively pursuing “vaccine diplomacy,” providing vaccines to other countries—particularly developing countries—to curry favor.<sup>207</sup> Additionally, some biopharmaceutical firms have promoted wide access to their vaccines. AstraZeneca, which has commercialized the University of Oxford’s vaccine, has partnerships with the Coalition for Epidemic Preparedness Innovations, Gavi, and the Serum Institute of India to provide hundreds of millions of vaccine doses.<sup>208</sup> As noted, Moderna has already committed to not enforcing its vaccine-related patents during the pandemic.<sup>209</sup> In May 2021, Pfizer and BioNTech announced they would provide 2 billion doses of COVID-19 vaccine to developing countries over the following eighteen months.<sup>210</sup> Pfizer added that it was offering its vaccine at discounted prices or no profit to poorer countries.<sup>211</sup>

Addressing the coronavirus pandemic requires a multipronged approach. Direct donations by governments and biopharmaceutical firms are an essential part of the immediate and ongoing response, and they should continue at a robust pace. Longer term, however, the TRIPS waiver has the capacity to vastly scale up manufacturing of COVID-19 vaccines. Currently, manufacturing of patented vaccines, including mRNA vaccines, occurs in organizationally or contractually delimited siloes.<sup>212</sup> Opening access to vaccine patents—coupled with appropriate sharing of tacit knowledge and increased production of raw ingredients—would

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<sup>204</sup> Kiran Stacey, *Biden Urged to Oblige US Vaccine Makers to Share Technology*, FIN. TIMES (May 15, 2021), <https://www.ft.com/content/9408223f-0a6c-43b7-9f67-c7e4697005c2>.

<sup>205</sup> Press Release, White House, Fact Sheet: Biden-Harris Administration Unveils Strategy for Global Vaccine Sharing, Announcing Allocation Plan for the First 25 Million Doses to be Shared Globally (June 3, 2021).

<sup>206</sup> Jeff Mason & Carl O’donnell, *Under Pressure, U.S. Donates Half Billion More COVID-19 Vaccine Doses to World*, REUTERS (Sept. 22, 2021), <https://www.reuters.com/world/us/biden-pledges-new-vaccine-donations-bid-rally-global-pandemic-fight-2021-09-22/>; Zeke Miller, *Biden Doubles U.S. Global Donation of COVID-19 Vaccine Shots*, ASSOC. PRESS (Sept. 22, 2021), <https://apnews.com/article/united-nations-general-assembly-joe-biden-pandemics-business-united-nations-e7c09c1f896d83c0ed80513082787bd3>.

<sup>207</sup> Gebrekidan & Apuzzo, *supra* note 14; Gayle et al., *supra* note 183.

<sup>208</sup> AstraZeneca, *AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University’s COVID-19 Vaccine* (June 4, 2020).

<sup>209</sup> *See* Moderna, *supra* note 130.

<sup>210</sup> Jared S. Hopkins, *Pfizer, BioNTech to Deliver 2 Billion COVID-19 Vaccine Doses to Developing Countries*, WALL ST. J. (May 21, 2021), <https://www.wsj.com/livecoverage/covid-2021-05-21/card/GsPYoFscRppTzYYt014f>.

<sup>211</sup> *Id.*

<sup>212</sup> *See* Peter Lee, *Multinational Bounded Entities and International Technology Transfer* (unpublished manuscript on file with author) (discussing the manufacturing of COVID-19 vaccines within multinational “bounded entities”).

enable massive, parallel manufacturing of COVID-19 vaccines at dozens of sites around the world. Furthermore, local manufacture of COVID-19 vaccines could greatly assist with the logistics of distribution, particularly for mRNA vaccines, some of which require extremely low temperatures for storage and transportation.<sup>213</sup>

Fourth, at a more fundamental level, some criticize the TRIPS waiver on the view that weakening patents will chill long-term incentives to invent.<sup>214</sup> There are concerns that the IP waiver will imperil the continued development of COVID-19 vaccines by biopharmaceutical firms that depend on IP protection to recoup investments and turn a profit.<sup>215</sup> More generally, the TRIPS waiver allegedly sets a dangerous precedent, as it could chill incentives for biopharmaceutical companies to develop vaccines for the next pandemic.<sup>216</sup> While this is a plausible concern, it is overstated for several reasons. Intellectual property rights are frequently characterized as a trade-off between long-term dynamic efficiency, in the form of strong incentives to invent, and short-term static inefficiency, in the form of increased price and decreased access to technological goods.<sup>217</sup> Intellectual property law already recognizes that in some cases, the need to provide timely access to a technological good, such as a health-related invention, warrants relaxing strict exclusive rights. This is the basis, for instance, for expedited compulsory licenses during public health crises,<sup>218</sup> and a similar rationale applies to the current pandemic.

More importantly, however, the perceived trade-off between maintaining incentives to invent and providing wide access to essential vaccines is sometimes illusory. As discussed above, public entities provided massive funding for research and development leading to patented COVID-19 vaccines. They also made enormous advance purchase commitments that mitigated risk for vaccine developers.<sup>219</sup> Public funding satisfied much of the incentive to invent COVID-19 vaccines, thus calling into question the need for patents to spur such innovation. As Professor Ana Rutschman observes, “COVID-19 created a scenario in which intellectual property scarcely played a role at the incentives level.”<sup>220</sup> While it is difficult to predict the future, it is likely that governments will react in a similar fashion to future pandemics, thus ensuring a reliable incentive to invent even in the absence of strong patent protection.

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<sup>213</sup> Selena Simmons-Duffin, *Why Does Pfizer’s COVID-19 Vaccine Need To Be Kept Colder Than Antarctica?*, NPR (Nov. 17, 2020), <https://www.npr.org/sections/health-shots/2020/11/17/935563377/why-does-pfizers-covid-19-vaccine-need-to-be-kept-colder-than-antarctica>.

<sup>214</sup> See, e.g., Rowland et al., *supra* note 22; Robbins, *supra* note 187 (reporting pharmaceutical industry criticism of the recently adopted waiver).

<sup>215</sup> KING & SPAULDING, *supra* note 200.

<sup>216</sup> See, e.g., Rowland et al., *supra* note 22; Biagioli, *supra* note 23 (discussing but not endorsing this position).

<sup>217</sup> See Lee, *Contracting*, *supra* note 69, at 900.

<sup>218</sup> TRIPS art. 31(b) (waiving the requirement of reasonable efforts to negotiate with a patentee before issuing a compulsory license in “situations of national emergency or other circumstances of extreme urgency”).

<sup>219</sup> See *supra* Part I.A-B.

<sup>220</sup> Rutschman, *supra* note 35, at 176.

Furthermore, it is important to emphasize that the TRIPS waiver is not tantamount to a global suspension of patent rights. The waiver simply leaves individual states free to adjust (or not adjust) their patent laws without running afoul of their TRIPS obligations. Due to the political clout of biopharmaceutical companies and entrenched political values, it is likely that in most developed countries, national governments will choose to maintain current levels of patent and other forms of IP protection. Thus, a likely outcome of the TRIPS waiver is a bifurcated system in which developing countries weaken certain patents and developed countries maintain relatively strict patent protection. This could facilitate a useful regime of price discrimination in which COVID-19 vaccines sell for considerably more in developed countries (where governments have shown a high willingness and ability to pay) relative to developing countries. A similar situation pertains to HIV/AIDS medications, which are available at much higher prices in developed versus developing countries.<sup>221</sup> Such price discrimination helps maintain incentives to invent while also enhancing access to such essential resources.<sup>222</sup> For instance, Pfizer made \$36.7 billion and Moderna made \$17.7 billion from their COVID-19 vaccines in 2021,<sup>223</sup> overwhelmingly from sales in developed countries. It is possible for vaccine developers to make most of their profit from developed countries while lowering prices and increasing distribution in developing countries, thus maintaining incentives to invent while widening access to critical resources.

### C. Lessons from History and a Path Forward

History provides another example where changed circumstances warranted modifying global IP rules. In the 1990s, developing countries, particularly in sub-Saharan Africa, were devastated by another pandemic: HIV/AIDS. Global biopharmaceutical companies had developed and patented effective antiretroviral (ARV) treatments for HIV/AIDS. These ARVs were a lifeline for many people living with HIV, but patents greatly increased their price. In their patented form, ARVs cost about \$10,000 per patient per year, but in their generic form, they cost as little as \$168 per patient per year.<sup>224</sup> Patent-inflated prices were out of reach for millions of people who needed them.<sup>225</sup> To increase access to these essential

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<sup>221</sup> See Médecins Sans Frontières, *Untangling the Web of Antiretroviral Price Reductions 2* (2014) (noting that pharmaceutical companies are adopting “tiered pricing” in which they charge different prices for the same medicine in different jurisdictions, and suggesting that prices for antiretrovirals are much higher in middle-income than developing countries).

<sup>222</sup> See William W. Fisher III, *When Should We Permit Differential Pricing of Information?*, 55 *UCLA L. REV.* 1, 22 (2007); Jerry A. Hausman & Jeffrey K. MacKie-Mason, *Price Discrimination and Patent Policy*, 19 *RAND J. ECON.* 253 (1988). For price discrimination to be effective, arbitrage opportunities must be minimized, which seems eminently feasible for highly regulated items like vaccines. See Lee, *Distributive Commons*, *supra* note 69, at 1005-06.

<sup>223</sup> Spencer Kimball, *What’s Next for Pfizer, Moderna Beyond Their Projected \$51 Billion in Combined COVID Vaccine Sales This Year*, *CNBC* (March 3, 2022), <https://www.cnbc.com/2022/03/03/covid-pfizer-moderna-project-51-billion-in-combined-vaccine-sales-this-year.html>.

<sup>224</sup> Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 *BERKLEY TECH. L.J.* 1031, 1033 (2005).

<sup>225</sup> *Id.*

medicines, the government of South Africa enacted legislation allowing for parallel importation and generic manufacturing of patented ARVs.<sup>226</sup> Subsidiaries of large multinational pharmaceutical companies sued the South African government, alleging among other claims that South Africa—which was a member of the WTO—was violating its obligations under the TRIPS Agreement.<sup>227</sup> The litigation mobilized intense opposition to patents on AIDS drugs both domestically and globally.<sup>228</sup> AIDS advocates argued that pharmaceutical companies were placing profits over people’s lives and that the South African government had obligations under international human rights law to provide wide access to essential medicines.<sup>229</sup> Amid significant public backlash, the pharmaceutical companies dropped the lawsuit.<sup>230</sup> The cessation of litigation left South Africa free to implement its legislation to enhance access to patented medicines.<sup>231</sup>

The aftermath of the failed litigation resulted in reforms aimed at safeguarding access to patented essential medicines.<sup>232</sup> In 2001, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health. Among several statements, the Doha Declaration affirmed that “[w]e agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.”<sup>233</sup> The Doha Declaration also emphasized the availability of flexibilities in the TRIPS framework, and it recognized the need to supplement the compulsory license regime for countries that did not have the manufacturing capacity to produce patented articles for domestic consumption.<sup>234</sup> A few years later, the WTO adopted Article 31*bis*, which permits compulsory licenses for one country to manufacture patented articles for use in another country.<sup>235</sup> As noted, this is the provision that Bolivia has invoked to compulsorily license the COVID-19 vaccine manufactured by a Canadian firm.<sup>236</sup>

Perhaps more important than legal reforms, the controversy over access to patented HIV/AIDS medicines led to behavioral changes by certain biopharmaceutical firms. The controversy and associated public backlash helped

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<sup>226</sup> Medicines and Related Substances Control Amendment Act No. 90 of 1997 (S. Afr.).

<sup>227</sup> Erika George, *The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines*, 18 IND. J. GLOBAL LEG. STUD. 167, 183 (2011); ‘t Hoen et al., *supra* note 164, at 3.

<sup>228</sup> George, *supra* note 227, at 186.

<sup>229</sup> *Id.* at 184-86.

<sup>230</sup> *Id.* at 186; Donald G. McNeil Jr., *Drug Companies Are Focusing on the Poor After Decades of Ignoring Them*, N.Y. TIMES (June 24, 2019), <https://www.nytimes.com/2019/06/24/health/drugs-poor-countries-africa.html> [hereinafter McNeil Jr., *Drug Companies*].

<sup>231</sup> George, *supra* note 227, at 186.

<sup>232</sup> See ‘t Hoen et al., *supra* note 164, at 2.

<sup>233</sup> WORLD TRADE ORG., THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, para. 4, (Nov. 14, 2001).

<sup>234</sup> *Id.*

<sup>235</sup> ‘t Hoen et al., *supra* note 164, at 5; General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, (Sept. 1, 2003), [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm); see Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT’L ECON. L. 535, 540 (2020) (discussing the subsequent permanent ratification of this change).

<sup>236</sup> See WORLD TRADE ORG., BOLIVIA, *supra* note 195.

motivate a cultural shift at some firms, which traditionally have been among the most vocal advocates of strong intellectual property rights.<sup>237</sup> In 2000, five major drug companies announced their willingness to negotiate steep cuts in the price of AIDS drugs in low-income countries.<sup>238</sup> Since then, drug companies have expanded efforts to enhance access to medicines by voluntarily reducing prices, donating medicines, or sub-licensing patents to generic firms for distribution in developing countries.<sup>239</sup> Companies even compete on the Access to Medicine index, an independent measure of pharmaceutical companies' efforts to increase access to medicines in poor countries.<sup>240</sup> While formidable access gaps still remain, biopharmaceutical companies currently sell over 400 drugs at low prices in poor countries.<sup>241</sup>

The COVID-19 pandemic has provided another opportunity to revisit the social contract underlying international intellectual property law. TRIPS is an agreement that, at the broadest level, is supposed to enhance the welfare of its members. But strict protection of patent rights on COVID-19 vaccines does not achieve that goal, and significant changed circumstances should justify revising this agreement. In some ways, the prospect of adopting a TRIPS waiver has already paid dividends. For the past several years, the possibility that countries would renegotiate the fundamental TRIPS bargain hung like a Sword of Damocles over the heads of biopharmaceutical patentees. The desire to forestall a TRIPS waiver likely induced voluntary behavior to increase vaccine access, thus achieving some of the goals of the waiver before its adoption. For example, during negotiations over the proposed waiver, Pfizer committed to sell 500 million doses of its vaccine at a not-for-profit price to the federal government for donation overseas.<sup>242</sup> In similar fashion, in the early 2000s, some suspected drug companies of voluntarily lowering prices on AIDS treatments to prevent developing countries from taking more drastic measures to circumvent their patents.<sup>243</sup>

While it took too long to adopt and is overly narrow, the TRIPS waiver represents an incremental step in the right direction. More broadly, it illustrates the principle that changed circumstances can justify modifying the social contract undergirding international intellectual property law. Hopefully, this waiver will galvanize additional political momentum to tackle remaining technical, material, and infrastructural barriers to vaccine access. Relatedly, WTO members should extend the waiver to other fields of intellectual property, such as trade secrets, and other critical technologies necessary to fight the pandemic, such as diagnostics and therapeutics. In this fashion, additional modifications to the social contract

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<sup>237</sup> McNeil Jr., *Drug Companies*, *supra* note 230.

<sup>238</sup> See Donald G. McNeil Jr., *Companies to Cut Cost of AIDS Drugs for Poor Nations*, N.Y. TIMES (May 12, 2000), <https://www.nytimes.com/2000/05/12/world/companies-to-cut-cost-of-aids-drugs-for-poor-nations.html> [hereinafter McNeil Jr., *AIDS Drugs*].

<sup>239</sup> McNeil Jr., *Drug Companies*, *supra* note 230; *but see* 't Hoen et al., *supra* note 164, at 4, 7 (arguing that generic competition results in far lower prices than voluntary price discounts by drug manufacturers).

<sup>240</sup> McNeil Jr., *Drug Companies*, *supra* note 230.

<sup>241</sup> *Id.*

<sup>242</sup> Nolen & Stolberg, *supra* note 128.

<sup>243</sup> McNeil Jr., *AIDS Drugs*, *supra* note 238.

governing international intellectual property law can further increase access to lifesaving technologies.

### CONCLUSION

The COVID-19 pandemic has been devastating in many ways, but amid great loss there have been rays of hope. Through massive public investment and private initiative, biopharmaceutical companies developed safe and effective COVID-19 vaccines in record time. These companies have also patented these vaccines, which has contributed to significant controversy over access to these essential technologies. This controversy has been particularly acute on the global stage given dramatically unequal access to COVID-19 vaccines in developed versus developing countries. While the debate over access to patented vaccines has been framed in the language of intellectual property, this Article has suggested several ways in which contract principles can help widen access to these critical resources.

First, this Article has explored a consideration-based model of patent governance. For several decades, and particularly since the outbreak of the pandemic, national governments have massively subsidized the development of privately patented vaccines. Such consideration provides governments with significant leverage to demand greater access to essential technologies that they helped fund.

Second, this Article has used the concept of the *quid pro quo* to question the amount of technical disclosure that patentees currently provide. The patent system is often conceptualized as a grand societal bargain in which inventors disclose their technologies in exchange for exclusive rights. However, there is reason to doubt the sufficiency of the current *quid pro quo* when biopharmaceutical firms receive exclusive rights yet do not disclose enough information to allow technical artisans to make and use their patented technologies in a practically relevant sense. Accordingly, this Article has argued for enhancing the disclosure obligations for obtaining and maintaining a patent. Augmenting this approach, it has also suggested leveraging the *quid pro quo* of public research funding to compel private innovators—including patentees—to share tacit knowledge regarding how to make publicly funded technologies.

Finally, turning to the grand bargain underlying international patent law, this Article has argued that the principle of changed circumstances helps justify temporarily waiving prevailing IP obligations under the TRIPS Agreement. History provides a guide for relaxing intellectual property protection based on changed circumstances. Such lessons apply with great force to the present pandemic, and further modifications to international intellectual property law are warranted. From federal funding to the patent system to international agreements governing intellectual property, innovation is bound up in broad social contracts aimed at enhancing public welfare. Through the push and pull of contract mechanisms, innovation systems can better serve the interests of billions of people, and collectively we can bring this pandemic to a swift end.