

# Coronavirus, Compulsory Licensing, And Collaboration: Analyzing The 2020 Global Vaccine Response With 20/20 Hindsight

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### Abstract

In December 2019, COVID-19, a novel strain of the SARS-2 Virus, appeared in Wuhan, China. Within a year, over ninety million people had been infected, and two million had died. Amid all the death and desolation, humanity's ingenuity and will-power emerged in history's greatest vaccine race. The global community sought to find novel ways to protect innovation and intellectual property while still collaborating to roll out a vaccine in record time. Despite the presence of compulsory licensing provisions like 28 U.S.C. § 1498 and the Bayh-Dole Act in the U.S., and the TRIPS Agreement at the international level, the journey has been difficult. Thousands died while international players protected proprietary information and ensured that their countries' citizens are first in line for the vaccine. Although dubbed a "once in a lifetime pandemic," the COVID-19 outbreak provides a unique opportunity to contemplate ways to unify the world through intellectual property during a time of crisis, as well as a grim portent of what will become the new norm if we do not.

This Article examines the impact and effectiveness of intellectual property licensing provisions worldwide to suggest improvements that might result in a quicker and more efficient response to future global health crises. By examining and learning

from the plagues of the present, we might preserve the health of our future.

## I. Introduction

At a time when Europe dominated the world stage, Prussian diplomat Klemens Wenzel Furst von Metternich famously remarked, “When France sneezes, the whole of Europe catches a cold.”<sup>1</sup> While this phrase has been modified many times over the centuries, an increasingly interconnected global economy has forced us to realize that that phrase is now true for any nation or world power. 2020 proved that if one country “falls ill,” it is only a matter of time before the rest follow. This realization has prompted an increased look into how to unite the world in a common defense while still maintaining the individual rights of nations and their citizens. Unsurprisingly, with the COVID-19 pandemic ravaging the globe, intellectual property (“IP”) rights and their roles in helping and inhibiting the race for the cure have come under intense scrutiny.

Starting with the 1883 Paris Convention for the Protection of Industrial Property,<sup>2</sup> and continuing most recently with the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)<sup>3</sup> and its amendment, the Doha Declaration,<sup>4</sup> the international community has tried to balance the often-countervailing interests of IP holders and common citizens of the signatory nations. One of the most contested topics is the IP rights and protections afforded to pharmaceutical innovations. On one side are the pharmaceutical companies that research, develop, and manufacture treatments for a host of illnesses and diseases. The pharmaceutical industry often acts as a monolith and advocates for strict IP protections to safeguard patents and competitive secrets.<sup>5</sup> Pharmaceutical companies tend to maximize profit margins by prioritizing developing treatments for medical issues that affect large demographics of people with the financial means to pay for treatment.<sup>6</sup> Protecting IP is therefore

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<sup>1</sup> Alex Lubin, *Reading America from the Peripheries*, 67 AM. QUARTERLY 219, 219 (2015).

<sup>2</sup> WORLD INTEL. PROP. ORG., *Summary of the Paris Convention for the Protection of Industrial Property (1883)* (Oct. 18, 2020), [https://www.wipo.int/treaties/en/ip/paris/summary\\_paris.html](https://www.wipo.int/treaties/en/ip/paris/summary_paris.html) [<https://perma.cc/MN99-FVEY>].

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex I.C., LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (as amended on Jan. 23, 2017), [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_e.pdf](https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf) [<https://perma.cc/K2YE-DQC3>] [hereinafter TRIPS Agreement].

<sup>4</sup> WORLD TRADE ORG. MINISTERIAL CONF., *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001), <https://www.who.int/medicines/areas/policy/tripshhealth.pdf?ua=1> [<https://perma.cc/PK7Q-ALUD>] [hereinafter Doha Declaration].

<sup>5</sup> David W. Opperbeck, *Patents, Essential Medicines and the Innovation Game*, 48 VAND. L. REV. 501, 519 (2005).

<sup>6</sup> Richard G. Frank & Paul B. Ginsburg, *Pharmaceutical Industry Profits and Research and Development*, HEALTH AFFS. (Nov. 13, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171113.880918/full/> [<https://perma.cc/L8GW-JNEU>]; Melanie Newman, *Drug Companies are Incentivized to Profit Not to Improve Health, Says Report*, 363 BRIT.

paramount to the industry and is a “bedrock of their business.”<sup>7</sup> On the other side are developing countries, also known as lower-middle-income economies (“LMICs”),<sup>8</sup> with citizens who often cannot afford those pharmaceuticals. These nations see strong IP schemes as a significant barrier to access to pharmaceuticals that their citizens desperately need.<sup>9</sup> Most of the citizens in these LMICs cannot afford to pay hundreds of dollars for a patented drug, nor can these nations subsidize such treatments sufficiently to protect all, or even a majority, of their citizens. As a result, LMICs have been forced to look for ways to offset IP rights, such as through compulsory licenses that allow governments to license protected IP at will.<sup>10</sup> The pharmaceutical industry understandably opposes compulsory licenses and the purported disincentives to innovate that they bring.<sup>11</sup> The debate over compulsory licenses is not novel, nor will it be resolved easily.

The COVID-19 pandemic that started in 2020 brought global attention to this tumultuous debate. Many private and public research initiatives have tried to develop vaccines and other treatments to end the global disaster. Conspicuous in this effort was the minimal collaboration between different actors that all searched for the same cure. Three significant issues exist, which, thus far, have presented barriers that have significantly hindered a comprehensive global response to the COVID-19 outbreak and others in the past. First, on the national level, governments have struggled to enact and implement legislation that enforces march-in rights against pharmaceutical companies, which has hindered government access to vaccine technology and development. Second, vaccine nationalism and the current competitive international market have discouraged pharmaceutical companies and vaccine manufacturers from sharing information and collaborating in meaningful ways that might accelerate vaccine development and distribution. Finally, the lack of access to pharmaceutical-related infrastructure in LMICs has inhibited their response and put their citizens at a considerable disadvantage in terms of priority to receive the vaccine.

This Article will address these issues by first providing a basic understanding of vaccines, the challenges of creating them, and issues that hinder global vaccine distribution in Part II. Part III will cover existing initiatives in the U.S. and around the world, including compulsory licensing, vaccine pools, and the 2020 IP Waiver proposal. Finally, Part IV will look for ways to harmonize the disparate pieces of international legislation that deal with compulsory licensing to decrease vaccine

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MED. J. (Oct. 16, 2018), <http://dx.doi.org/10.1136/bmj.k4351> [<https://perma.cc/8T3W-AQ85>].

<sup>7</sup> Opderbeck, *supra* note 5.

<sup>8</sup> *World Bank Country and Lending Groups*, WORLD BANK (Mar. 13, 2021), <https://data-helpdesk.worldbank.org/knowledgebase/articles/906519> [<https://perma.cc/DQM2-QFG6>] (defining lower-middle income economies based on gross national income per capita. It also lists each country and its categorization).

<sup>9</sup> Sean Flynn et al., *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 188–90 (2009).

<sup>10</sup> *Id.*

<sup>11</sup> Mansi Sood, *Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India*, 6 NUJS L. Rev. 99, 101 (2013).

nationalism and increase international collaboration for future health crises. It will propose several novel licensing frameworks with an overall goal of increasing access to vaccine IP while still promoting rights holders' interests. These proposals are divided into two categories: non-voluntary licenses and voluntary licenses, based on the rights-holder's control over the terms of the license. While this Article emphasizes non-voluntary licensing, it aims to provide other equitable solutions that balance the health and safety of the world's citizens and the IP interests of the pharmaceutical industry.

## II. Background

In early 2020, COVID-19, a contagious respiratory and vascular disease resulting from an infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2),<sup>12</sup> took the world hostage. The virus originated in Wuhan province, China, and began appearing in reportable numbers in humans in December 2019.<sup>13</sup> Although initially slow to react, the Chinese government eventually locked the entire region down in a quarantine bubble to prevent the virus from spreading to other parts of China and the world at large.<sup>14</sup> Despite these preventive measures, countries across the world began reporting new cases as early as January 2020.<sup>15</sup> On March 11, 2020, the World Health Organization ("WHO") categorized the COVID-19 outbreak as a global pandemic,<sup>16</sup> and the world economy ground to a halt as nations scrambled to lock down and contain the spread.<sup>17</sup> A similar scramble occurred in the pharmaceutical industry as large and small drug developers raced to develop vaccines and protect their IP from infringement through patents.<sup>18</sup>

Chinese researchers published COVID-19's genetic sequence on January 11,

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<sup>12</sup> *Coronavirus Disease 2019 (COVID-19)*, MAYO CLINIC (Oct. 18, 2020), <https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963> [https://perma.cc/RU5H-ECGF].

<sup>13</sup> *Origins of AARS-CoV-2*, WORLD HEALTH ORG. (Mar. 26, 2020), [https://apps.who.int/iris/bitstream/handle/10665/332197/WHO-2019-nCoV-FAQ-Virus\\_origin-2020.1-eng.pdf](https://apps.who.int/iris/bitstream/handle/10665/332197/WHO-2019-nCoV-FAQ-Virus_origin-2020.1-eng.pdf) [https://perma.cc/LJE9-4RJQ].

<sup>14</sup> Andreas Illmer et al., *Wuhan Lockdown: A Year of China's Fight Against the Pandemic*, BBC NEWS (Jan. 22, 2021), <https://www.bbc.com/news/world-asia-china-55628488> [https://perma.cc/844S-QN5Y].

<sup>15</sup> *Timeline: How the New Coronavirus Spread*, AL JAZEERA (Dec. 31, 2020, 1:19 PM), <https://www.aljazeera.com/news/2020/12/31/timeline-how-the-new-coronavirus-spread> [https://perma.cc/E8D4-YBV6].

<sup>16</sup> *Timeline of WHO's Response to COVID-19*, WORLD HEALTH ORG. (Dec. 28, 2020), <https://www.who.int/news/item/29-06-2020-covid-timeline> [https://perma.cc/4Y8X-G2PE].

<sup>17</sup> Katie Zezima et al., *Coronavirus Now a Global Pandemic as U.S., World Scramble to Control Outbreak*, WASH. POST (Mar. 11, 2020, 10:09 PM CDT), [https://www.washingtonpost.com/national/coronavirus-global-pandemic-outbreak-spreading/2020/03/11/246998ec-63b6-11ea-b3fc-7841686c5c57\\_story.html](https://www.washingtonpost.com/national/coronavirus-global-pandemic-outbreak-spreading/2020/03/11/246998ec-63b6-11ea-b3fc-7841686c5c57_story.html) [https://perma.cc/RD2G-42TK].

<sup>18</sup> Ana S. Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, OUTSMARTING PANDEMICS (Elizabeth Kirley & Deborah Porter eds., 2021) (forthcoming 2021) (manuscript at 5–6), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3656929#](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3656929#) [https://perma.cc/RV3K-HBTW].

2020, and independent pharmaceutical companies and research labs kicked off vaccine research almost immediately.<sup>19</sup> By March 2020, the first vaccines entered human clinical trials in the U.S. and China.<sup>20</sup> By April 2020, there were over 115 vaccine candidates from “almost 80 companies and institutes in 19 countries” that were in some phase of development or testing.<sup>21</sup> As of that date, North America had around 46% of the world’s COVID-19 vaccine research, followed by 34% in Asia and Australia, and 19% in Europe.<sup>22</sup> Of those, 72% of the projects were developed by private developers and the rest were efforts led by academics, the public sector and other nonprofit organizations.<sup>23</sup> The largest national vaccine development initiative was a public-private partnership between U.S. and private developers codenamed “Operation Warp Speed” that allocated more than \$12 billion to vaccine makers.<sup>24</sup>

The most advanced of these research programs started bearing fruit in December 2020, when Pfizer-BioNtech’s Comirnaty vaccine was approved for emergency use after passing clinical trials.<sup>25</sup> Many countries, including the U.S., bypassed normal testing protocols and granted emergency approval to immediately administer doses.<sup>26</sup> Other vaccines followed, and by March 2021, exactly a year after the WHO declared the COVID-19 outbreak to be a global pandemic, eleven vaccines were in use worldwide, four of which were approved for widespread use by the U.S. or European Union.<sup>27</sup> With reliable vaccines finally making their way out to people across the world, the focus began shifting away from development and toward timely and equitable

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<sup>19</sup> Tung Thanh Le et al., *The COVID-19 Vaccine Development Landscape*, 19 NATURE REV. DRUG DISCOVERY 305, 305 (2020).

<sup>20</sup> *NIH Clinical Trial of Investigational Vaccine for Covid-19 Begins*, NAT’L INSTS. OF HEALTH (Mar. 16, 2020), <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins> [<https://perma.cc/J85G-AKUY>]. Javier Garcia, *CanSino Biologics: China Announces First Human Trials of Covid-19 Vaccine*, MARKET SCREENER (Mar. 18, 2020, 9:23 AM), <https://www.marketscreener.com/quote/stock/CANSINO-BIOLOGICS-INC-59318312/news/CanSino-Biologics-China-announces-first-human-trials-of-Covid-19-vaccine-30183232/> [<https://perma.cc/7YCF-APZZ>].

<sup>21</sup> Charles Schmidt, *The Vaccine Quest*, 322 SCI. AM. 6, 41 (2020). Thanh Le et al., *supra* note 19.

<sup>22</sup> Thanh Le et al., *supra* note 19, at 306.

<sup>23</sup> *Id.*

<sup>24</sup> Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136 (2020). *See also* Emily Barone, *The Trump Administration’s ‘Operation Warp Speed’ Has Spent \$12.4 Billion on Vaccines. How Much is That Really?*, TIME (Dec. 14, 2020, 3:52 PM), <https://time.com/5921360/operation-warp-speed-vaccine-spending/> [<https://perma.cc/GY56-YB8Y>] (stating that as of the writing of the article, the U.S. government had spent \$12.4 billion on Operation Warp Speed).

<sup>25</sup> *See* Christine Soares & Travis Hartman, *Tracking the Vaccine Race*, REUTERS (Mar. 5, 2021), <https://graphics.reuters.com/HEALTH-CORONAVIRUS/VACCINE-TRACKER/xegpbqnlovq/> [<https://perma.cc/ED7T-WSL2>] (providing information on the progress of COVID vaccines through clinical trials); Reuters Staff, *Fact check: It is standard practice for vaccine safety monitoring to continue after approval*, REUTERS (Feb. 12, 2021), <https://www.reuters.com/article/uk-factcheck-vaccine-monitoring-idUSKBN2AC2G3>.

<sup>26</sup> *See* Soares & Hartman, *supra* note 25 (providing that pandemic vaccines have been tested with overlapping phases to compress the timeline and providing that governments intended rapid distribution on regulatory approval).

<sup>27</sup> *Vaccines in Use*, COVID-19 VACCINE TRACKER (Mar. 8, 2021), <https://www.covid-19-vaccinetracker.org/authorized-vaccines> [<https://perma.cc/U3EC-AXZU>].

distribution.

#### A. Vaccine Primer

A vaccine is a preventive or prophylactic inoculant that aims to “confer immunity against a specific disease, usually employing an innocuous form of the disease agent . . . to stimulate antibody production.”<sup>28</sup> Once enough people in a community are inoculated, a “herd immunity” sets in that protects and benefits all individuals within the community, whether they have been vaccinated or not.<sup>29</sup>

Vaccine candidates go through various tests before being considered safe for human use.<sup>30</sup> First, the candidates are tested in animal studies, then in small control-group trials with healthy volunteers, and finally in large-scale trials with slices of the population representing diverse potential patients.<sup>31</sup>

#### B. Infrastructure and Technical Challenges of Creating a Vaccine

Vaccine manufacturing is a challenging and complex process that is both time and cost-intensive.<sup>32</sup> The research and development phase involves many steps, including sourcing and purifying raw ingredients from all across the world, developing and adding stabilizers and preservatives to maintain the stability of the drug, testing adjuvants to find one that maximizes the immune response, and packaging the individual doses into vials and syringes for distribution.<sup>33</sup> Because of stringent packaging regulations, the final step, the “fill and finish” of the individual doses, creates a logistical challenge that only a few dozen companies can surmount.<sup>34</sup> Of those companies, less than half a dozen that are primarily located in the U.S., United Kingdom, and European Union can manufacture active ingredients to the satisfaction of strict quality

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<sup>28</sup> *Vaccine*, DICTIONARY.COM (Jan. 10, 2021), <https://www.dictionary.com/browse/vaccine> [<https://perma.cc/PKW4-EZVN>].

<sup>29</sup> C. Jessica E. Metcalf et al., *Understanding Herd Immunity*, 36 *TRENDS IN IMMUNOLOGY* 753, 753 (2015).

<sup>30</sup> Barry C Buckland, *The Process Development Challenge for a New Vaccine*, 11 *NATURE MED. SUPPLEMENT* S16, S16-17 (2005).

<sup>31</sup> Amol B. Deore et al., *The Stages of Drug Discovery and Development Process*, 7 *ASIAN J. PHARM. RSCH. & DEV.* 62, 65 (2019); see generally Kavita Singh & Shantanu Mehta, *The Clinical Development Process for a Novel Preventative Vaccine: An Overview*, 62 *J. POSTGRADUATE MED.* 4, 4 (2016).

<sup>32</sup> See Stanley Plotkin, *Increasing Complexity of Vaccine Development*, 212 *J. INFECTIOUS DISEASES* S12, S12 (2015) (describing key problems in the development of future vaccines); Shyam Rele, *COVID-19 Vaccine Development During Pandemic: Gap Analysis, Opportunities, and Impact on Future Emerging Infectious Disease Development Strategies*, *HUM. VACCINES & IMMUNOTHERAPEUTICS* 1192, 1192 (2020), <https://www.tandfonline.com/doi/full/10.1080/21645515.2020.1822136> [<https://perma.cc/LE2L-MNCH>].

<sup>33</sup> Rele, *supra* note 32.

<sup>34</sup> Georgina Drury et al., *Process Mapping of Vaccines: Understanding the Limitations in Current Response to Emerging Epidemic Threats*, 37 *VACCINE* 2415, 2418 (2019).

control standards<sup>35</sup> at a scale that can meet the global demand for a particular vaccine.<sup>36</sup>

This complexity creates a specific problem where subtle changes can affect the safety and effectiveness of the vaccine.<sup>37</sup> Because of these high stakes, regulatory agencies worldwide pay special attention to each pharmaceutical company or manufacturer and the vaccines they create.<sup>38</sup> Every stage of development and production is carefully monitored and tested, and pharmaceutical companies often patent or license each stage of production to protect their investment.<sup>39</sup> These patents on the production stages, known as process patents, are often so numerous and broad that they present smaller vaccine developers with a greater barrier of entry into the manufacturing space than a patent just on the final vaccine composition would.<sup>40</sup> Furthermore, the massive costs of vaccine research and development, paired with the process and product patents, compel pharmaceutical companies to charge elevated prices for the final product; prices that do not always decline when the patents protecting those vaccines expire.<sup>41</sup>

Further complicating the COVID-19 vaccine race is the fact that the leading vaccine candidates are messenger ribonucleic acid (“mRNA”) vaccines.<sup>42</sup> mRNA vaccines, and other similar genetic vaccines, combine the immunological properties of a standard protein vaccine with increased the increased cost effectiveness and long-term stability.<sup>43</sup> While this decreases long-term recurring development costs and promises low-cost manufacture, which are essential traits for a developing vaccine that would need to be manufactured by the billions, the major drawback of this technology is that it is still rather novel.<sup>44</sup> Thus, the manufacturing costs of many components of the vaccine are either being produced in small quantities, or at a high cost.<sup>45</sup> These limitations understandably strain COVID-19 vaccine development and production and are felt by consumers who seek inoculation against the virus.

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<sup>35</sup> Thomas J. Bollyky & Chad P. Bown, *The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic*, 99 FOREIGN AFFS. 96, 99 (2020).

<sup>36</sup> Stanley Plotkin et al., *The Complexity and Cost of Vaccine Manufacturing – An Overview*, 35 VACCINE 4064, 4065 (2017).

<sup>37</sup> Plotkin et al., *supra* note 36.

<sup>38</sup> *Id.*

<sup>39</sup> Julie Milstein & Miloud Kaddar, *Managing the Effect of TRIPS on Availability of Priority Vaccines*, 84 BULL. WORLD HEALTH ORG. 360, 362 (2006).

<sup>40</sup> Plotkin et al., *supra* note 36.

<sup>41</sup> *See id.* (discussing the challenges associated with developing and processing vaccines).

<sup>42</sup> Rele, *supra* note 32, at 1124 (stating that eighteen of the most developed vaccines that were undergoing preclinical and clinical testing, including Moderna and Pfizer’s, were mRNA vaccines).

<sup>43</sup> *See* Thomas Schlake et al., *Developing mRNA-Vaccine Technologies*, 9 RNA BIOLOGY 1319, 1319 (2012) (providing that mRNA-vaccine technologies have the immunological properties of a standard protein vaccine and are characterized by great flexibility in production and application).

<sup>44</sup> *Id.* at 1326.

<sup>45</sup> Norbert Pardi et al., *mRNA Vaccines — A New Era in Vaccinology*, 17 NATURE REV. DRUG DISCOVERY 261, 273 (2018).

### 1. *The Conflict Over Components Between Moderna and Arbutus*

This pressure came into the public spotlight in 2019 when Moderna Inc. and Arbutus Biopharma Corporation—two of the largest pharmaceutical companies in North America—went to court over IP rights protecting a vaccine component. mRNA vaccines require a crucial mechanism known as a lipid nanoparticle (“LNP”) delivery system, for which the U.S. Patent and Trademark Office (“USPTO”) granted Arbutus Biopharma Corporation several patents between 2011 and 2016.<sup>46</sup> Many vaccine developers, including Moderna, rely on LNPs to ensure that the mRNA in their mRNA vaccines is properly administered to develop the required antibodies.<sup>47</sup> Although Moderna licensed an LNP based mRNA delivery technology from a Canadian company called Acuitas, Arbutus was the patent holder, not Acuitas.<sup>48</sup> Arbutus promptly terminated Acuitas’ license because Acuitas’ sublicense to Moderna was improper and obtained a preliminary injunction against Acuitas in Canada, preventing it from sublicensing the LNP technology to any other entities.<sup>49</sup>

Acuitas and Arbutus settled and stipulated that Acuitas has no further right to the LNP technology.<sup>50</sup> Also included was a stipulation that Moderna only has access to the LNP technology for four non-exclusive vaccine sublicenses for vaccines to target predetermined viral targets.<sup>51</sup> A day earlier, Moderna filed a petition at the USPTO for an *inter partes* review (“IPR”) against Arbutus’ U.S. Patent No. 9,404,127, which protects an element of the LNP technology.<sup>52</sup> The goal was to try to get the USPTO to invalidate Arbutus’ patent. Moderna prevailed, and the Patent Trial and Appeal Board (“PTAB”) rendered a Final Written Decision that invalidated all of the patent’s claims.<sup>53</sup> Two other IPRs against two of Arbutus’s other patents protecting the LNP technology failed partially or completely.<sup>54</sup>

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<sup>46</sup> Rele, *supra* note 33, at 3; *see also* U.S. Patent No. 8,058,069 (issued Nov. 15, 2011); U.S. Patent No. 9,364,435 (issued Jun. 14, 2016); and U.S. Patent No. 9,404,127 (issued Aug. 2, 2016).

<sup>47</sup> *Moderna Loses Key Patent Challenge*, 38 NATURE BIOTECH. 1009 (2020).

<sup>48</sup> Derek Lowe, *Formulating RNA – and Owning It*, SCI. TRANSLATIONAL MED. (July 24, 2020), <https://blogs.sciencemag.org/pipeline/archives/2020/07/24/formulating-rna-and-owning-it> [<https://perma.cc/LGK5-5EKY>].

<sup>49</sup> Nathan Vardi, *Moderna’s Mysterious Coronavirus Vaccine Delivery System*, FORBES (July 29, 2020, 7:51 AM), <https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/?sh=b8a040c62d9c> [<https://perma.cc/FY37-8H6F>].

<sup>50</sup> *Arbutus Settles Litigation, Terminating Acuitas’ Rights to LNP Technology*, ARBUTUS BIOPHARMA CORP. (Feb. 22, 2018), <https://investor.arbutusbio.com/index.php/node/14131/pdf> [<https://perma.cc/ME66-NXWL>].

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

<sup>52</sup> *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics Inc.*, No. IPR2018-00680 (P.T.A.B. Sept. 10, 2019).

<sup>53</sup> *Id.*

<sup>54</sup> *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics Inc.*, No. IPR2018-00739 (P.T.A.B. Sept. 11, 2019) (holding that Moderna’s second IPR against Arbutus, which challenged U.S. Patent No. 9,364,435, led the PTAB to invalidate some claims and upholding the validity of others); *Moderna Therapeutics, Inc., v. Arbutus Biopharma Corp.*, No. IPR2019-00554 (P.T.A.B. July 23, 2020) (holding that Moderna’s third IPR against Arbutus, which challenged U.S. Patent No. 8,058,069, led

### C. Roadblocks to Domestic and International Vaccine IP Sharing

Moderna and Arbutus's dispute over vaccine components is one example of a roadblock that prevents outright sharing, both in the U.S. and globally. Real property rights in the U.S., especially as they pertain to IP and vaccine development, are a source of constant consternation for lawmakers. Juggling the countervailing interests and goals of vaccine developers and citizens is a tall order, especially when certain situations require that one group be disadvantaged to benefit the other. A 2020 Special 301 Report prepared by the Office of the U.S. Trade Representative underscored the major issues surrounding the intersection of health policy and IP interests.<sup>55</sup> Despite initiatives promoting international collaboration during the COVID-19 crisis, true IP sharing remains to be seen. Nations look to protect their citizens, and pharmaceutical companies look to protect their IP and investment. These prevailing interests often conflict when nations look to pharmaceutical companies for treatment and either want to protect their native pharmaceutical industries or prioritize treatment for their citizens. This dissonance grows stronger when one considers that LMICs and developed nations, at times distinguished based on their Gross National Income ("GNI"),<sup>56</sup> also have conflicting views on priority treatment. Two distinct phenomena have presented significant challenges to global treatment programs during the current pandemic: (1) vaccine nationalism and (2) resistance to the "anti-capitalistic" behaviors that are IP sharing and compulsory licensing.

#### 1. *The Rise of Vaccine Nationalism*

During difficult times, it is natural human instinct for people to focus inward and prioritize efforts to best help themselves. This is, in effect, a survival mechanism borne out of the fact that humans are not gifted with an automatic method or tool of survival that would save them from having to actively work to preserve their own lives.<sup>57</sup> Vaccine nationalism extends this concept on the international level that occurs when countries seek to obtain preferential treatment for their citizens either by buying new vaccines first or by refusing to sell vaccines or license vaccine technology until their citizens have been served.<sup>58</sup> Not only does this lead to bidding wars where wealthier countries have more leverage to induce vaccine developers to help their citizens first, this also encourages a lack of cooperation and sharing of research and resources.<sup>59</sup> Desperate governments may risk long-term damage to their diplomatic, economic, and strategic interests in exchange for short-term deals for vaccines or their

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the PTAB to uphold all twenty-two claims of Arbutus' patent).

<sup>55</sup> Robert E. Lighthizer, OFF. OF THE U.S. TRADE REP., 2020 SPECIAL 301 REPORT 36 (2020), [https://ustr.gov/sites/default/files/2020\\_Special\\_301\\_Report.pdf](https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf) [<https://perma.cc/7MB4-44KJ>].

<sup>56</sup> Espen Beer Prydz & Divyanshi Wadhwa, *Classifying Countries by Income*, WORLD BANK (Sept. 9, 2019), <https://datatopics.worldbank.org/world-development-indicators/stories/the-classification-of-countries-by-income.html> [<https://perma.cc/2RZX-AQ6Y>].

<sup>57</sup> AYN RAND, THE VIRTUE OF SELFISHNESS, at 6 (1961) (ebook).

<sup>58</sup> Bollyky & Bown, *supra* note 35, at 96–97.

<sup>59</sup> *Global Governance for COVID-19 Vaccines*, 395 LANCET 1751, 1751 (2020).

technology.<sup>60</sup>

World leaders such as French President Emmanuel Macron, UN Secretary-General António Guterres, and Chinese President Xi Jinping have tried to combat this instinct by calling vaccines global public goods that are a resource that should be available to all people regardless of nationality.<sup>61</sup> In November 2020, the G-20 signatory countries recognized “extensive immunization as a global public good,” and reaffirmed their resolution to “ensure affordable and equitable access [of the vaccine] for all people.”<sup>62</sup> Although they have expressed intentions of ensuring that the stock and use of vaccines in any one country would not interfere with its use in another, initial supply compared to the global demand show that view to be idealistic.<sup>63</sup> Earlier that year, the CEO of Sanofi—one of the world’s largest pharmaceutical companies—stated that the U.S. should have the right to the largest pre-order of its COVID-19 vaccine because it contributed significant funding for research.<sup>64</sup> It only reversed that position in the face of worldwide condemnation and criticism.<sup>65</sup> A short while later, in March 2021, Italy blocked the export of 250,000 AstraZeneca doses to Australia, citing a need to vaccinate citizens in-country first.<sup>66</sup> The European Commission, at Australia’s request, investigated the situation and backed Italy amid growing concerns that European-based pharmaceutical companies were helping countries outside the bloc without first properly addressing Europe’s needs.<sup>67</sup>

Unsurprising as the desire to receive preferential treatment for vaccine distribution is, it is increasingly detrimental to global stability, economic growth, and

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<sup>60</sup> Bollyky & Bown, *supra* note 35, at 97.

<sup>61</sup> Anna Marie Merlo, *Macron to WHO: ‘The Vaccine is a Global Public Good’*, IL MANIFESTO (May 20, 2020), <https://global.ilmanifesto.it/macron-to-who-the-vaccine-is-a-global-public-good/> [<https://perma.cc/A46B-27ZJ>]; Corinne Gretler, *Xi Vows China Will Share Vaccine and Gives WHO Full Backing*, BLOOMBERG (May 18, 2020, 6:00 AM), <https://www.bloomberg.com/news/articles/2020-05-18/china-s-virus-vaccine-will-be-global-public-good-xi-says> [<https://perma.cc/X32R-KU4N>]; *UN Chief: COVID-19 Vaccine Must Be Affordable and Available to All*, UN NEWS (Sept. 16, 2020), <https://news.un.org/en/story/2020/09/1072522> [<https://perma.cc/5RLU-BRS4>].

<sup>62</sup> Raya Jalabi et al., *G20 Leaders Seek to Help Poorest Nations in Post-COVID World*, REUTERS (Nov. 21, 2020, 8:43 AM), <https://www.reuters.com/article/uk-g20-saudi-idUSKBN2810JD> [<https://perma.cc/43WE-TWLQ>].

<sup>63</sup> Bollyky & Bown, *supra* note 35, at 98.

<sup>64</sup> James Patton et al., *U.S. Likely to Get Sanofi Vaccine First if It Succeeds*, BLOOMBERG (May 13, 2020, 4:34 PM), <https://www.bloomberg.com/news/articles/2020-05-13/u-s-to-get-sanofi-covid-vaccine-first-if-it-succeeds-ceo-says> [<https://perma.cc/7ZP2-HGSC>].

<sup>65</sup> James McAuley, *France Angered by Suggestion U.S. Would Get First Access to Coronavirus Vaccine by French Pharma Company Sanofi*, WASHINGTON POST (May 14, 2020, 2:13 PM), [https://www.washingtonpost.com/world/europe/coronavirus-vaccine-sanofi/2020/05/14/821c7c12-95e2-11ea-87a3-22d324235636\\_story.html](https://www.washingtonpost.com/world/europe/coronavirus-vaccine-sanofi/2020/05/14/821c7c12-95e2-11ea-87a3-22d324235636_story.html) [<https://perma.cc/FG35-4QR5>].

<sup>66</sup> Colin Packham et al., *Australia Asks EU to Review Block of AstraZeneca Vaccine*, REUTERS (Mar. 4, 2021, 9:42 PM), <https://www.reuters.com/article/us-health-coronavirus-australia/australia-asks-european-commission-to-review-italys-vaccine-block-idUSKCN2AX07H> [<https://perma.cc/U2MW-4A9V>].

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

stability.<sup>68</sup> IP stability and international collaboration that guarantees a rapid global vaccine rollout might alleviate pressures from competitive practices and increase public trust in vaccines.

2. *Resistance to Compulsory Licensing Due to the Conception that Such Provisions are Incompatible with Capitalist Economies*

The other major roadblock to IP sharing is the interplay between compulsory licensing (or IP sharing) and capitalism. In the U.S. and other capitalist economies, pharmaceutical R&D is mainly funded and carried out by the private sector. It comes as no surprise that the focus is on profitability, which can be achieved through treatments that heal maladies affecting more people and service more customers. As a result, vaccine development for diseases that mainly affect people who lack the financial ability to pay for costly medications is often put on hold in favor of medicines that target people who can afford the costly medications. Over the past two decades, there has been little to no private-sector research into diseases that run rampant in LMICs, such as onchocerciasis, leishmaniasis, and schistosomiasis.<sup>69</sup> Many of those infected by these “neglected infectious diseases” cannot afford to pay hundreds, let alone thousands, of dollars for a name-brand patented drug.<sup>70</sup> Even though these diseases cause epidemics that affect millions more people than COVID-19, pharmaceutical companies do not consider curing them profitable enough to warrant research.<sup>71</sup>

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<sup>68</sup> Marco Hafner et al., *The Global Economic Cost of COVID-19 Vaccine Nationalism* 1 (RAND Corp., Research Brief No. RB-A769-1, 2020), <https://doi.org/10.7249/RBA769-1>. The research brief concluded that:

- (1) vaccine nationalism could cost the global economy up to \$1.2 trillion a year in GDP;
- (2) as long as there is no vaccine against the disease, the global cost associated with COVID-19 and its economic impact could be \$3.4 trillion a year;
- (3) if the poorest countries cannot access vaccines, the world could still lose between \$60 billion and \$340 billion a year in GDP; and
- (4) for every \$1 spent on supplying poorer countries with vaccines, high-income countries would get back about \$4.80.

<sup>69</sup> See generally Germán Velásquez, *Trade Agreements, Intellectual Property and Access to Medicines: An Introduction*, in INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES, WORLD HEALTH ORG. 1 (2010) (discussing the lack of research and the widening gap on health care inaccessibility); see also *Neglected Tropical Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION (last visited Feb. 21, 2021), <https://www.cdc.gov/globalhealth/ntd/diseases/index.html>. The three diseases listed, along with fourteen others are known as neglected tropical diseases (“NTDs”) because of the lack of treatment available because of unfavorable cost-benefit analyses. The CDC estimates that six NTDs could be controlled or eliminated through targeted vaccine programs.

<sup>70</sup> See *Neglected Infectious Diseases, Leishmaniasis*, PAN AM. HEALTH ORG. & WORLD HEALTH ORG. (Feb. 21, 2021), <https://www.paho.org/hq/dmdocuments/2017/2017-cha-leishmaniasis-factsheet-work.pdf> (discussing Leishmaniasis as a one of the top neglected infectious diseases that result in thousands of deaths each year).

<sup>71</sup> *Id.*; see also Jens Aagard-Hansen & Claire Lise Chaignat, *Neglected Tropical Diseases: Equity and Social Determinants*, in EQUITY, SOCIAL DETERMINANTS AND PUBLIC HEALTH PROGRAMMES 135, 136, 148–50 (Erik Blas & Anand Sivasankara Kurup eds., 2010) (discussing the cyclical nature of poverty in relation to NTDs and the need for greater subsidization of costs).

In light of this capitalistic pragmatism, it is understandable that American pharmaceutical companies would balk at compulsory licensing provisions and decry them as anti-competitive and anti-capitalistic.

Additionally, IP rights encourage the development of new medicines and provide the stability necessary to innovate without fear of wrongful takings.<sup>72</sup> Such bedrock protections often make one wary of abridging those rights, no matter the emergency.

The dire circumstances of the COVID-19 pandemic encouraged many U.S. lawmakers to consider those risks. In a February 2020 letter, forty-six members of Congress implored former President Donald J. Trump to use every tool at his disposal to ensure that vaccines were accessible and affordable.<sup>73</sup> Notably, this letter requested that the President deny private manufacturers exclusive licenses to COVID-19 vaccine or treatment IP, and that he authorize the Department of Health and Human Services (“HHS”) to step in if a manufacturer priced the byproducts of that innovation unreasonably.<sup>74</sup> These entreaties, and every other since then have met with no success and no federally mandated licenses.

Balancing capitalist principles, Constitutional rights, and global health needs to develop an equitable solution is a concept that will be further explored in Part IV.

### III. Existing Initiatives

IP licensing is not a novel concept. Lawmakers in the U.S. and worldwide have developed a variety of licensing frameworks that grant rights-holders varying levels of control over their IP and the rights they grant licensees. Legal experts categorize licenses into two categories—non-voluntary and voluntary licenses—based on a rights-holder’s control over the license.

Non-voluntary licenses, sometimes referred to as compulsory licenses, allow rights-holders the least control over the terms of the license.<sup>75</sup> Rights-holders cannot usually control who the IP is licensed to, nor can they generally set the terms of the license.<sup>76</sup> Given the extent to which non-voluntary licenses abrogate a rights-holder’s

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<sup>72</sup> U.S. CONST. amend.V. “No person shall be . . . deprived of life, liberty , or property, without due process of law; nor shall private property be taken for public use, without just compensation.”

U.S. Const. amend. XIV, § 1. “No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law . . .”

<sup>73</sup> Letter from Jan Schakowsky, Senator, et al. to President Trump (Feb. 20, 2020), <http://freepdfhosting.com/20bf1d75af.pdf>.

<sup>74</sup> *Id.* at 1.

<sup>75</sup> Mark W. Lauroesch, *General Compulsory Patent Licensing in the United States: Good in Theory, But Not Necessary in Practice*, 6 SANTA CLARA HIGH TECH. L.J. 41, 41, 48 (1990).

<sup>76</sup> See Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 350–54 (1993) (discussing various legal schemes where compulsory licensing takes place).

property rights, they are almost exclusively issued by governments and find legal justification in the State's federal legislation.<sup>77</sup>

Voluntary licenses, on the other hand, are a form of contract between a rights-holder and a pharmaceutical company, which authorizes the licensee to produce the patented technology within certain parameters and conditions.<sup>78</sup> As the International Federation of Pharmaceutical Manufacturers & Associations notes,

[t]he license usually sets quality requirements and defines the markets in which the licensee can sell the product . . . [and] can be tailored to account for many factors, including the nature of the epidemic/disease, social factors, economic considerations, and the capacity of the licensee to meet and maintain quality standards for the product .<sup>79</sup>

Rights-holders can also use voluntary licenses to define a remuneration plan, such as a royalty, which the licensee would pay to continue to use the IP.<sup>80</sup>

This Part will analyze existing non-voluntary and voluntary licensing schemes in effect in the U.S. and abroad as well as their applications thus far to the COVID-19 pandemic. These schemes range from federal legislation to independent initiatives aimed at incentivizing IP sharing.

#### A. Non-Voluntary Licensing (Compulsory Licensing)

Compulsory licensing is one of the most powerful tools a government can use to increase production and distribution of a product when needed and demand outstrips supply—such as during a public emergency. Governments generally authorize compulsory licenses when a patentee exhibits disagreeable behavior, such as anti-competitive or uncooperative inhibitory practices, during a time of public need.<sup>81</sup> By forcing the patentee to license the patent to the government, a license acts as an “unwilling contract between a willing buyer and an unwilling seller imposed and enforced by the state,” which can affect market exclusivity directly and market price indirectly.<sup>82</sup> Compulsory licenses generally authorize the willing buyer to manufacture, use, or distribute the patented invention without the unwilling seller's consent.<sup>83</sup>

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<sup>77</sup> See *id.* (discussing the relationship between the state and the inventory)

<sup>78</sup> *Voluntary Licenses and Non-Assert Declarations*, INT'L FED'N OF PHARM. MFRS. & ASS'NS (July 28, 2010), <https://www.ifpma.org/resource-centre/voluntary-licenses-and-non-assert-declarations/> [<https://perma.cc/85SB-JAAM>].

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

<sup>80</sup> *Voluntary Licenses and Access to Medicines*, MÉDECINS SANS FRONTIÈRES 6, 11 (Oct. 2020), [https://msfaccess.org/sites/default/files/2020-10/IP\\_VoluntaryLicenses\\_full-brief\\_Oct2020\\_ENG.pdf](https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf) [<https://perma.cc/Y743-QQHK>].

<sup>81</sup> Julian-Arnold, *supra* note 76, at 350–54.

<sup>82</sup> Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 782 (2004) (quoting Paul K. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes* (Economic Council of Canada 1981)).

<sup>83</sup> *Id.* at 782–83.

1. *Relevant U.S. IP Legislation Affecting Pharmaceuticals*

The U.S., likely due to its strong regard for property rights and its desire for a clear delineation of government power, has one of the most robust and well-defined compulsory licensing schemes. Two provisions allow the federal government to issue a compulsory license: 28 U.S.C. § 1498 and 35 U.S.C. §§ 200–212, also known as the Bayh-Dole Act.

a. 28 U.S.C. § 1498

Of the two, 28 U.S.C. § 1498 is the broadest and grants the government the greatest powers over domestic IP.<sup>84</sup> Originally conceived in 1910 with wartime urgency in mind, the statute grants the U.S. Government, as a function of its sovereign immunity, the absolute right to practice any U.S. patent without fear of an injunction.<sup>85</sup> Congress intentionally gave the government such sweeping authority “to stimulate contractors to furnish what was needed for the War, without fear of becoming liable themselves to inventors or the owners or assignees of patents.”<sup>86</sup> This purpose was manifested in a 1918 amendment to the 1910 Act, per which the only recourse available to an infringed patent owner is to sue the U.S. in the U.S. Court of Federal Claims.<sup>87</sup> However, even if they were to do so, § 1498 only entitles them to the recovery of reasonable and entire compensation for the infringing use.<sup>88</sup>

The statute’s strength comes from the eminent domain aspects, which allow the government to expropriate IP without fear of injunctions that might halt development at a critical juncture. Congress originally drafted § 1498 under the lens of dealing with recalcitrant patent holders in a time of war, where speed is essential to ensuring an adequate response. Certain distinct parallels, including that need for a rapid response, can be drawn between a war and other major crises, such as a public health emergency. This is particularly important in a situation like a global pandemic, where the federal research collective needs to move fast to control the outbreak by developing and rolling out vaccines without worrying about getting bogged down in the judicial system.

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<sup>84</sup> Act of June 25, 1910, Pub. L. No. 61-305, 36 Stat. 851 (1910); *see also* *Zoltek Corp. v. U.S.*, 442 F.3d 1345, 1368–69 (2006) (discussing the Act of 1910 as a precursor to § 1498 and the purpose of the Act).

<sup>85</sup> *Richmond Screw v. United States*, 275 U.S. 331, 345 (1928); David S. Bloch, *Alternatives to March-in Rights*, 18 VAND. J. ENT. & TECH. L. 247, 261 (2016).

<sup>86</sup> *Richmond Screw*, 275 U.S. at 345.

<sup>87</sup> Act of July 1, 1918, Pub. L. No. 65-182, 40 Stat. 704, 705; ); *see also* *Zoltek Corp.*, 442 F.3d at 1369–70 (discussing the 1918 amendment to the 1910 Patent Act to not only state that a suit against the United States in the Court of Federal Claims is the only recourse, but also stating that compensation is to be the only recovery granted. This amendment was later incorporated into 28 U.S.C. §1498(a) when the act was re-codified by the Act of June 24, 1948, Pub. L. No. 80-773, 62 Stat. 869, 941 (1948)).

<sup>88</sup> 28 U.S.C. §1498(a).

b. The Bayh-Dole Act of 1980 and 35 U.S.C. § 203

The Bayh-Dole Act of 1980<sup>89</sup> also contains compulsory licensing provisions and was a retroactive attempt by Congress to address a decline in American innovation.<sup>90</sup> With new patent filings going down year after year, Congress was concerned that rapidly decreasing domestic technological innovation would put the U.S. behind foreign competitors.<sup>91</sup> West Germany and Japan, in particular, were going through innovation booms that concerned legislators considering their industrial might and the power they brought to bear in the previous World War.<sup>92</sup> Congress was also concerned that recent scientific breakthroughs were not being developed and commercialized properly.<sup>93</sup> This was because the majority of the scientific research was either funded or conducted by the federal government.<sup>94</sup> Congress wished for the federal government to have the ability to leverage the results of the research it funded in actionable ways that improved the country while still incentivizing innovation in the public and private sector.<sup>95</sup> The Bayh-Dole Act was Congress's attempt to encourage research and capitalize on developments made with access to federal funds.<sup>96</sup> Through it, the federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. any subject invention throughout the world . . . ."<sup>97</sup>

35 U.S.C. § 203 codifies the march-in rights conferred by the Bayh-Dole Act and applies it to patented inventions developed using government funding.<sup>98</sup> These rights allow the government to require that the contractor, assignee, or exclusive assignee (collectively "rights holder") of such a patent grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants upon terms that are reasonable under the circumstances . . . ."<sup>99</sup> The Act also allowed the government to grant the license itself if the contractor, assignee, or exclusive assignee refuses as long as one of four conditions are met.<sup>100</sup> It explicitly carved out health and

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<sup>89</sup> Patent and Trademark Amendments (Bayh-Dole) Act, 35 U.S.C. §§ 200–212 (1980).

<sup>90</sup> 126 CONG. REC. 29,897 (1980).

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> 126 CONG. REC. 29,896 (1980). *See also* U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 3 (1998) ("The purpose of this act was to reform U.S. patent policy related to government-sponsored research. At the time, fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed . . . .").

<sup>94</sup> 126 CONG. REC. 29,898 (1980).

<sup>95</sup> *Id.*

<sup>96</sup> U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES 3 (1998).

<sup>97</sup> 35 U.S.C. § 202(c)(4).

<sup>98</sup> 35 U.S.C. § 203.

<sup>99</sup> 35 U.S.C. § 203(a).

<sup>100</sup> 35 U.S.C. § 203(a)(1)–(4). § 203 provides these four conditions, any one of which permits the government to issue a license:

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

safety provisions that allowed for licensing, which although relevant to many types of inventions, is of particular relevance based on its coverage of pharmaceuticals.<sup>101</sup>

It is important to note several distinctions between the Bayh-Dole Act and 28 U.S.C. § 1498 to show the overlap between the two. Although both laws allow the rights holder to appeal to the Court of Federal Claims,<sup>102</sup> unlike for an issuance under § 1498, which cannot be halted, the Court of Federal Claims can affirm, reverse, remand, or modify a government’s license granted under the Bayh-Dole Act.<sup>103</sup> For cases in which march-in rights are asserted on the grounds of § 203 (1) or (3)<sup>104</sup>, that power may not be exercised until the rights holder has exhausted all available appeals or petitions.<sup>105</sup> Additionally, the “terms that are reasonable” language of § 203 implies a royalty to the original rights holder, which § 1498 does not grant when the government leverages a patent.<sup>106</sup> A rights holder whose patent was exercised under § 1498 may only seek compensation.<sup>107</sup> Finally, § 203’s march-in rights may only be used on patents developed using government funding, while § 1498(a) has a broader coverage and applies to all U.S. patents.<sup>108</sup> These differences between § 1498 and the Bayh-Dole Act give the federal government flexibility in approaching a potential compulsory licensing situation.

c. Historical Pandemics in the U.S. and the Attempts to License IP

Although Congress conceived two pieces of legislation that allowed the government to use patents when needed, they have seen little to no use. The federal government only threatened to invoke § 1498 for a pharmaceutical patent once.<sup>109</sup> The Bayh-Dole Act has never been used, despite at least six petitions to do so since its enactment in 1980.<sup>110</sup> In each of those situations, the National Institute of Health (“NIH”) declined to exercise the march in rights against the patent holders. For three of the petitions, *In re Norvir I*, *In re Xalatan*, and *In re Norvir II*, the NIH stated that the Bayh-Dole Act does not allow agencies to control drug prices if the drugs are widely

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- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
  - (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
  - (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

<sup>101</sup> 35 U.S.C. § 203(a)(2).

<sup>102</sup> 28 U.S.C § 1498(a); 35 U.S.C. § 203(b).

<sup>103</sup> 28 U.S.C § 1498(a); 35 U.S.C. § 203(b).

<sup>104</sup> 35 U.S.C. § 203(a)(1), (3).

<sup>105</sup> 35 U.S.C. § 203(b).

<sup>106</sup> 35 U.S.C. § 203(a); 28 U.S.C § 1498(a).

<sup>107</sup> 28 U.S.C. §1498(a).

<sup>108</sup> 35 U.S.C. § 203(a); 28 U.S.C § 1498(a).

<sup>109</sup> See *infra* Part III.A.1.c.ii.

<sup>110</sup> JOHN R. THOMAS, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (Cong. Research. Serv. 2016).

available to physicians or clients, or if the patentee “has taken reasonable steps to achieve practical commercialization.”<sup>111</sup> Similar march-in petition requests in 2001 for Ciprofloxacin after the anthrax scare and in 2018 for Gilead Sciences’ prophylactic HIV treatment Truvada fizzled out before even reaching the NIH.<sup>112</sup>

*i. 2001 U.S. Anthrax Outbreak*

The 2001 anthrax outbreak is one of the most compelling examples of when compulsory licensing rights could have been used but were not. The outbreak occurred shortly after the deadliest terrorist attack in American history and stemmed from a string of letters that were sent to news outlets and congressional offices.<sup>113</sup> These letters contained pores of the deadly airborne pathogen anthrax and caused over twenty-two infections within a several-week window.<sup>114</sup> The pharmaceutical company Bayer held the patent for the antibiotic prophylactic Ciprofloxacin.<sup>115</sup> Bayer sought to use the widespread panic to leverage the federal government into severely overpaying for the hundred million doses it wished to purchase.<sup>116</sup> After futile negotiations, Bayer only conceded after the Secretary of Health and Human Services at the time, Tommy Thompson, threatened to override Bayer’s exclusivity rights by licensing the formula to a generics<sup>117</sup> manufacturer.<sup>118</sup> The Bayer incident set a precedent that gained traction during other health crises and resulted in other incidents where state governments declared an explicit intention to invoke 28 U.S.C. § 1498 to lower drug prices during a time of need.

*ii. Louisiana 2017 Hepatitis C Outbreak*

Similarly, in 2017, Louisiana was struck by a Hepatitis C outbreak that affected nearly 35,000 uninsured and Medicaid-dependent residents.<sup>119</sup> Gilead’s antiviral drugs would have cost an uninsured individual an estimated \$85,000 each, at a total

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<sup>111</sup> Bloch, *supra* note 85, at 255-57.

<sup>112</sup> *Id.* at 258; Shefali Luthra, *In the Battle to Control Drug Costs, Old Patent Laws Get New Life*, KHN (Oct. 5, 2018), <https://khn.org/news/in-the-battle-to-control-drug-costs-old-patent-laws-get-new-life/> [<https://perma.cc/TR7Y-5MPZ>].

<sup>113</sup> Daniel B. Jernigan et al., *Investigation of Bioterrorism-Related Anthrax, United States, 2001: Epidemiological Findings*, 8 EMERGING INFECTIOUS DISEASES 1019, 1019 (2002).

<sup>114</sup> *Id.*

<sup>115</sup> Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 175 (2003).

<sup>116</sup> *Id.*

<sup>117</sup> See generally *Generic Drug Facts*, FOOD & DRUG AGENCY (Feb. 22, 2021), <https://www.fda.gov/drugs/generic-drugs/generic-drug-facts> [<https://perma.cc/32MJ-33C9>]. (The U.S. Food and Drug Agency (“FDA”) defines a generic pharmaceutical as “a medication created to be the same as an existing approved brand name-drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.”).

<sup>118</sup> Thomas F. Mullin, *AIDS, Anthrax and Compulsory Licensing: Has the United States Learned Anything – A Comment on Recent Decisions on the International Intellectual Property Rights of Pharmaceutical Patents*, 9 ILSA J. INT’L & COMP. L. 185, 200–01 (2002).

<sup>119</sup> Sarah Jane Tribble, *Louisiana Proposes Tapping a Federal Law to Slash Hepatitis C Drug Prices*, KHN (May 4, 2017), <https://khn.org/news/louisiana-proposes-tapping-a-federal-law-to-slash-hepatitis-c-drug-prices/> [<https://perma.cc/Y547-6DCV>].

untenable cost of \$764 million to the state.<sup>120</sup> Interestingly enough, Louisiana's Secretary of Health, Dr. Rebekah Gee, was also able to force a concession from Gilead to provide the drugs at a subscription rate by publicizing an intention to invoke § 1498.<sup>121</sup> What was most surprising about this concession, however, was that another coalition's similar initiative to persuade the NIH to exercise march-in rights and license pharmaceutical company AbbVie's patent on another Hepatitis C drug for similar reasons failed only four years earlier.<sup>122</sup> Apart from focusing on local inaccessibility because of the exorbitant prices, the coalition also focused on the pricing disparities in different countries based on the differences in healthcare.<sup>123</sup> The NIH found this argument to be unpersuasive: "the extraordinary remedy of march-in is not an appropriate means of controlling prices of drugs broadly available to physicians and patients."<sup>124</sup>

## 2. *Compulsory Licensing Provisions Worldwide*

Compulsory licenses are not a new phenomenon, nor are they a unique feature of American capitalism. Many countries, like the U.S.,<sup>125</sup> developed their own provisions, while others, like Thailand,<sup>126</sup> used international treaties as a template. While many different types of compulsory licensing schemes exist across the world, this Article will specifically focus on those that impact pharmaceuticals, including those of the five largest pharmaceutical exporters by dollar value<sup>127</sup> and some of the largest generic pharmaceutical exporters<sup>128</sup> by volume. All compulsory licensing schemes have the same general components, but this Section will focus on some notable differences. This Section will also cover the most binding resolution on global compulsory licensing provisions: the TRIPS Agreement.

Unsurprisingly, as heavy exporters of pharmaceuticals or generics, France,<sup>129</sup>

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<sup>120</sup> See Brian R. Edlin, *Access to Treatment for Hepatitis C Virus Infection: Time to Put Patients First*, 16 LANCET INFECTIOUS DISEASES e196, e196 (2016) ("The list prices for 12-week regimens for HCV genotype 1 range from US\$83 320 to \$94 500").

<sup>121</sup> Tribble, *supra* note 119.

<sup>122</sup> Charlotte Harrison, *NIH Denies March-In Rights on Norvir Patent*, 12 NATURE REV. DRUG DISCOVERY 898 (2013).

<sup>123</sup> *In the Case of Norvir Manufactured by AbbVie*, (Nat'l Inst. of Health, 2013) (determination), <https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf>.

<sup>124</sup> *Id.*

<sup>125</sup> See *supra* Part III.A.1.

<sup>126</sup> Patent Act B.E. 2522 [Patent Act 1979], , last amended by Patent Act (No. 3) B.E. 2542 [Patent Act (No. 3) 1999] (Thai.),

<sup>127</sup> See Daniel Workman, *Drugs and Medicine Exports by Country*, WORLDS TOP EXPORTS (Feb. 25, 2021), <https://www.worldstopexports.com/drugs-medicine-exports-country/> (Germany is the largest exporter of pharmaceuticals, and its compulsory licensing provisions are explored in Part III.C.4.).

<sup>128</sup> See Hepeng Jia, *Chinese Manufacturers Vie for Piece of Outsourcing Pie*, 25 NATURE BIOTECH. 1337, 1137 (2007) ("China . . . is already the world's largest supplier of bulk drug materials, according to the China Pharmaceutical Industry Association").

<sup>129</sup> Code de la Propriété Intellectuelle [I.P.C.] [French Intellectual Property Code] art. L613-11 - L613-22 (Fr.) [hereinafter French Compulsory Licensing Provisions].

Germany,<sup>130</sup> China,<sup>131</sup> Switzerland,<sup>132</sup> and the Netherlands<sup>133</sup> all have strong compulsory licensing schemes that clarify the reasons for granting a license, the entities that have the power to grant that license, and terms of the license (including the scope, duration, and remuneration). Of those elements, countries differ most on the reason for granting a license. Although all allow for licensing for public interest reasons<sup>134</sup>, Germany's patent law takes this to an extreme and allows the Federal Government or Federal Ministry of Health the power to invalidate patents where "the invention is to be used in the interest of public welfare."<sup>135</sup> Germany and Switzerland's patent laws include specific carve-outs for pharmaceutical patents, insofar as to allow them to be licensed to be produced for export to beneficiary countries that have insufficient capabilities to deal with public health crises.<sup>136</sup> Finally, although many countries allow licenses where a patent has not been exercised for a certain time period, France allows licenses where a rights holder does not start to exploit the patent or makes preparations to exploit it in another country.<sup>137</sup> The judicial court or government ministry that hears the case must determine whether this burden is met.<sup>138</sup>

#### a. TRIPS Agreement Between WTO Members

Much of the differences in applying these provisions disappeared with the

<sup>130</sup> Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 4 of the Act of 8 October 2017 (Federal Law Gazette I p. 3546)[hereinafter German Patent Act].

<sup>131</sup> Patent Law of the People's Republic of China (promulgated by the Standing Comm'n Nat'l People's Cong., Mar. 12, 1984, rev'd, Oct. 17, 2020, effective Jun. 1, 2021) [hereinafter Chinese Patent Law]; Measures for Compulsory Licensing of Patent Implementation (promulgated by the Order of the Dir. of State Intell. Prop. Off. No. 64, May 1, 2012, effective March 15, 2012) [hereinafter Chinese Compulsory Licensing Provisions]; Amendment to the Patent Law of the People's Republic of China (promulgated by the Standing Comm'n Nat'l People's Cong., Oct. 17, 2020, effective Jul. 1, 2021), [http://www.gov.cn/xinwen/2020-10/18/content\\_5552102.htm](http://www.gov.cn/xinwen/2020-10/18/content_5552102.htm) (Mar. 3, 2021) [hereinafter 2020 Chinese Patent Amendment].

<sup>132</sup> Legge Federale sui Brevetti d'Invenzione [LBI] [Federal Act on Patents for Inventions], Dec. 31, 1955, RU 1955 (Switz.) [hereinafter Swiss Patent Act].

<sup>133</sup> Rijksocrooiwet 1995 [Kingdom Patents Act 1995] (Neth.), *translated in* KINGDOM ACT OF 15 DECEMBER 1994, CONTAINING RULES IN RESPECT OF PATENTS (THE DUTCH PATENTS ACT) (Sept. 18, 2009), [https://english.rvo.nl/sites/default/files/2013/12/ROW95\\_ENG\\_niet\\_officiele\\_vertaling\\_0.pdf](https://english.rvo.nl/sites/default/files/2013/12/ROW95_ENG_niet_officiele_vertaling_0.pdf). <https://perma.cc/A963-BX8E> [hereinafter Dutch Patents Act].

<sup>134</sup> French Compulsory Licensing Provisions, *supra* note 129, L613-17 - L613-18 (allowing for license for public interest or national economy); German Patent Act, *supra* note 130, § 24(1); Chinese Patent Law, *supra* note 131, art. 49; Swiss Patent Act, *supra* note 132, art. 40; Dutch Patents Act, *supra* note 133, art. 57, 59(1) (allowing for licenses for public interest or national defense).

<sup>135</sup> German Patent Act, *supra* note 130, § 13(1). *See also* Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite, Bevölkerungsschutzgesetz [Civil Protection Act], Mar. 27, 2020, BUNDESGESETZBLATT JAHRGANG Teil I [BGBl. I] § 5(2) no. 5, last amended by Gesetz [G], Nov. 18, 2020, BGBl. I at 18 2397 (Ger.), <https://www.buzer.de/gesetz/13847/index.htm> [hereinafter German COVID Act] (granting the Federal Ministry of Health the power to issue licenses under the § 13(1) of the German Patent Act).

<sup>136</sup> German Patent Act, *supra* note 130, § 85(a); Swiss Patent Act, *supra* note 132, art. 40(d).

<sup>137</sup> French Compulsory Licensing Provisions, *supra* note 129, L613-11.

<sup>138</sup> *Id.* L613-12.

signing of the TRIPS Agreement in 1995. The Agreement, which was one of the keystone accomplishments of the 1986-1994 Uruguay Round, was the first to bind all of the World Trade Organization (“WTO”) Member States<sup>139</sup> to a universal compulsory licensing scheme.<sup>140</sup> This scheme set out minimum standards of IP protection and enforcement.<sup>141</sup> It also gave the countries flexibility and freedom in how they went about making their laws TRIPS compliant, as well as in how they implemented and practiced the Agreement’s provisions, provided that they met those minimum standards.<sup>142</sup>

Articles 8, 30, and 31 of the Agreement are relevant to compulsory licensing. Article 8 allows members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance . . . .”<sup>143</sup> Article 30 grants signatory governments the power to abridge patent rights in limited ways in some cases.<sup>144</sup> Article 31 is the most significant as it contains most of the compulsory licensing provisions.<sup>145</sup> It explicitly allows member countries to issue non-exclusive, non-assignable, licenses for patented technology without the authorization of the rights holder as long as the country pays adequate remuneration.<sup>146</sup> It also requires that the entity seeking the license first try to obtain a voluntary license from the rights holder.<sup>147</sup> However, Article 31 waives this requirement “in the case of a national emergency or other circumstances of extreme urgency or cases of public non-commercial use,” as long as the entity seeking the license notifies the rights holder as soon as reasonably practical.<sup>148</sup> Article 31*bis*, an addition to Article 31, also allows nations that need patented pharmaceuticals but are unable to manufacture them to employ compulsory licenses to import them from a producing country while remaining compliant with other TRIPS provisions.<sup>149</sup>

A significant challenge the WTO faced was how to balance the inequities of the effects of patents on LMICs and the losses suffered by innovators who had their IP

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<sup>139</sup> *Members and Observers*, WORLD TRADE ORG. (Feb. 24, 2020), [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) [<https://perma.cc/H7VB-P94T>] (“164 members since 29 July 2016”).

<sup>140</sup> LIGHTHIZER, *supra* note 55, at 37.

<sup>141</sup> *Id.* at 36.

<sup>142</sup> COMM’N ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH, WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 21 (2006), <https://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1> [<https://perma.cc/7G3F-94W8>].

<sup>143</sup> TRIPS Agreement, *supra* note 3, at art. 8. *See also* Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979, 1008–10 (2009).

<sup>144</sup> TRIPS Agreement, *supra* note 3, art 30.

<sup>145</sup> *Id.* art. 31.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> TRIPS Agreement, *supra* note 3, art. 31*bis*.

stolen.<sup>150</sup> On one hand, requiring WTO members to actively enforce patents and patent holders' exclusive marketing rights encourages innovation and development by helping innovators and protecting property.<sup>151</sup> On the other hand, it hurts individuals and countries with restricted purchasing power that cannot afford expensive, patented technology.<sup>152</sup> This inequity is especially prevalent in pharmaceuticals, and while compulsory licensing allowed countries to increase accessibility through compulsory licenses, the process to do so is difficult and often very convoluted.<sup>153</sup> The WTO sought to balance these countervailing interests at a Ministerial Conference in Doha, Qatar at the turn of the century.<sup>154</sup>

*i. The Doha Declaration*

The Doha Declaration, a product of the Fourth Ministerial Conference of the WTO in 2001, is an amendment to the TRIPS Agreement that went into effect in 2005.<sup>155</sup> It reflected the WTO's intent to "promote access to medicines once and for all" and address difficulties that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector" faced to protect the global public health.<sup>156</sup> The WTO did so by (1) revitalizing compulsory licensing provisions by including allowances for countries to import and produce generic versions of patented pharmaceuticals<sup>157</sup> and by (2) empowering WTO signatories to exert them when needed.<sup>158</sup>

Sections 4 and 5 of the Declaration have the greatest effect on the TRIPS Agreement's existing compulsory licensing scheme.<sup>159</sup> Section 4 emphasizes that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health."<sup>160</sup> It grants them the flexibility to interpret the Agreement in a way that supports the goal of protecting public health and promoting public access.<sup>161</sup> Section 5 elaborates on some of those flexibilities, most notably granting each Member the right and freedom to grant compulsory licenses as they see fit.<sup>162</sup> It also

<sup>150</sup> COMM'N ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH, *supra* note 142, at 21 ("Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs.").

<sup>151</sup> Hilary Wong, *The Case for Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 1, 2 (2020).

<sup>152</sup> COMM'N ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH, *supra* note 142, at 22.

<sup>153</sup> Velásquez, *supra* note 69, at 3.

<sup>154</sup> Doha Declaration, *supra* note 4.

<sup>155</sup> *Id.*

<sup>156</sup> *Id.* at ¶¶ 4, 6.

<sup>157</sup> WORLD HEALTH ORG., PROGRESS ON GLOBAL ACCESS TO HIV ANTIRETROVIRAL THERAPY: A REPORT ON "3 BY 5" AND BEYOND 60 (2006).

<sup>158</sup> Doha Declaration, *supra* note 4, ¶ 4.

<sup>159</sup> *See id.* ¶¶ 4, 5 (providing members with flexible options for licensing).

<sup>160</sup> *Id.* ¶ 4.

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* ¶ 5. *See also* Carlos M. Correa, *Implementation of the WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, INTELL. PROP. AND ACCESS TO MEDICINES:

allows Members to determine what qualifies as a national emergency to invoke the national emergency provisions of TRIPS Article 31.<sup>163</sup>

International treaties like the TRIPS Agreement and the Doha Declaration were the first major steps to synchronize the demands of the pharmaceutical industry and the needs of the developing world. Neither side got what they wanted out of it because although pharmaceutical companies received more IP rights and protections, much of that was diminished by the Doha Declaration. On the other hand, although LMICs and their pharmaceutical industries were certainly inhibited by the TRIPS Agreement, which deprived them of the free rein they enjoyed for many decades, the Doha Declaration restored to those countries the broad latitude to protect their citizens and manufacture generics during emergencies. Analyzing an LMIC with a strong generics industry would be practical to properly gauge the effects of this legislation.

### 3. *The Effects of Compulsory Licensing and IP Protections on Global Collaboration and Vaccine Distribution*

Like the various national IP regimes discussed above,<sup>164</sup> the TRIPS Agreement imposed a set of guidelines and restrictions that set out a framework for how to protect intellectual property, albeit on a grander scale that bound all signatory countries of the WTO.<sup>165</sup> The Doha Declaration later amended the TRIPS Agreement and added in flexibilities, including broader compulsory licensing provisions, that allowed LMICs to act during emergencies.<sup>166</sup> This Section will analyze the impact and effectiveness of these pieces of legislation, both historically, and with respect to the COVID-19 global pandemic.

#### a. Use of the National Emergency Provision of the Doha Declaration

Since the Doha Declaration's ratification in 2001, many countries' health ministries have discreetly sought to use compulsory licenses or the threat of imposing compulsory licenses to decrease local prices of vital medicines.<sup>167</sup> In the decade following the ratification alone, seventeen countries have tried to avail themselves of its

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PAPERS AND PERSPECTIVES, WORLD HEALTH ORG. 75, 75–81 (2010). Paragraph 5 extended broad flexibilities which expanded Member States' powers to grant compulsory licenses during emergencies. It removed the TRIPS § 31(f) limitation on exports of generics that were obtained under a compulsory license and also expanded parallel importation provisions. The section also allowed for unrestricted imports of generics of patented drugs if they were imported by the Member government for public and non-commercial use if the government negotiated and paid reasonable compensation to the rights holder.

<sup>163</sup> Doha Declaration, *supra* note 4, ¶ 5.

<sup>164</sup> *See supra* Part III.A.2.

<sup>165</sup> *See supra* Part III.A.2.a.

<sup>166</sup> *See supra* Part III.A.2.a.i.

<sup>167</sup> Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 249–50 (2009).

compulsory licensing provisions.<sup>168</sup> This has mainly come in the form of licenses or declarations of licenses issued under the authority of TRIPS Article 31.<sup>169</sup> In November 2006, Thailand's Ministry of Public Health issued a five-year compulsory license for the AIDS antiretroviral drug Efavirenz.<sup>170</sup> This allowed the government to import the drug from India and produce a generic version of the drug despite the pharmaceutical company Merck having an active patent that was valid in Thailand.<sup>171</sup> This was just the first of several compulsory licenses that the Thai government issued following the Doha Declaration's enactment under the justification of protecting public health as a WTO member.<sup>172</sup> A year later, Brazil followed by issuing a compulsory license for the same drug to combat a rapidly spreading AIDS epidemic.<sup>173</sup> That same year, Rwanda also issued a license on similar drugs to receive assistance from Canada.<sup>174</sup> Although these three incidents may appear to be isolated, there are dozens of similar issuances from more than twenty countries across the world.<sup>175</sup>

As common as demonstrations of the power of the Doha Declaration are, albeit everywhere but the U.S., many governments have found that merely threatening to enact a compulsory license framework based on the Doha Declaration is just as effective.<sup>176</sup> Between 2003 and 2006, several countries including Indonesia, India, Vietnam, and South Korea threatened to enforce TRIPS-based compulsory licenses against Roche Holding AG to gain access to the anti-viral influenza drug Oseltamivir.<sup>177</sup> The threat alone was enough to compel Roche to increase production and select partners to produce the drug under non-exclusive licenses.<sup>178</sup>

#### b. Effects on LMICs

The TRIPS Agreement and its compulsory licensing provisions have had positive and negative effects on LMICs. Historically, the TRIPS Agreement has largely hindered a rapid resolution to pressing health crises. By forcing LMICs to undertake strenuous obligations to respect foreign IP rights, TRIPS made many drugs

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<sup>168</sup> Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1, 4 (2012).

<sup>169</sup> Reichman, *supra* note 167, at 250.

<sup>170</sup> Robert Steinbrook, *Thailand and the Compulsory Licensing of Efavirenz*, 356 NEW ENG. J. MED. 544, 544 (2007).

<sup>171</sup> *Id.*

<sup>172</sup> *Id.* at 546.

<sup>173</sup> Reichman, *supra* note 167, at 250.

<sup>174</sup> Gorik Ooms & Johanna Hanefeld, *Threat of Compulsory Licenses Could Increase Access to Essential Medicines*, BMJ 1, 2 (2019).

<sup>175</sup> JAMES PACKARD LOVE, RECENT EXAMPLES OF THE USE OF COMPULSORY LICENSES ON PATENTS (Knowledge Ecology Int'l., Research Note 2, 2007).

<sup>176</sup> Ooms & Hanefeld, *supra* note 174.

<sup>177</sup> Reichman, *supra* note 167, at 250.

<sup>178</sup> Tove I. S. Gerhardsen, *Roche Seeks Deals on Bird Flu Drug as Compulsory Licenses Loom*, INTELL. PROP. WATCH (Oct. 20, 2005), <https://www.ip-watch.org/2005/10/20/roche-seeks-deals-on-bird-flu-drug-as-compulsory-licenses-loom/> [<https://perma.cc/9ASQ-FZ64>]. See also Reichman, *supra* note 167, at 250.

unattainable for average citizens in those countries.<sup>179</sup> South Africa and Brazil are two examples of countries whose governments have struggled to reconcile compliance with the TRIPS Agreement with the need to protect their citizens from diseases such as AIDS.<sup>180</sup> Before joining the WTO, these and other similarly situated countries could develop or import generic products at a fraction of the cost to consumers as a patented equivalent would cost, thus developing a strong market for generic pharmaceuticals.<sup>181</sup> Before TRIPS, there would have been little to no repercussions for this behavior, which pharmaceutical companies considered to be little more than common IP theft.<sup>182</sup> Therefore, it is unsurprising that TRIPS quickly sought to stifle these generic markets by providing safeguards, which, if broken, could subject the infringing country to fines and sanctions.<sup>183</sup> In 1997, the South African Parliament tried to override patent rights and allow compulsory licensing to make AIDS pharmaceuticals more accessible amid an AIDS epidemic.<sup>184</sup> As a response, the U.S. threatened trade sanctions under TRIPS and only relented in the midst of mounting public political pressure.<sup>185</sup>

That being said, however, the Doha Declaration went a long way towards righting the imbalance in power that the original TRIPS Agreement gave developed countries over their less developed neighbors. As mentioned in the previous Section, these countries have successfully used TRIPS Article 31 within the past two decades to issue compulsory licenses and bring down costs for critical drugs during severe health crises like the AIDS epidemic.<sup>186</sup> Additionally, a slew of LMICs have found ways to successfully grow their generics manufacturing industries in compliance with the TRIPS regime. Brazil, India, and China all leveraged their infrastructure and experience to increase their R&D capabilities and world standing as pharmaceutical exporters.<sup>187</sup> Collaboration between Oxford, AstraZeneca and Serum Institute of India to

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<sup>179</sup> See Jaime B. Herren, *TRIPS and Pharmaceutical Patents: The Pharmaceutical Industry vs. the World*, 14 INTEL. PROP. L. BULL. 43, 60 (2009) (discussing how Least-Developed Nations “are unable to utilize compulsory licenses in the traditional sense”); Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of Patent Laws of Various Countries*, 30 INT’L L. 835, 845 (1996) (“Production in a particular country is problematic in the pharmaceutical industry because production involves environmental, safety, and regulatory problems.”).

<sup>180</sup> Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT’L L. REV. 191, 209–11 (2002).

<sup>181</sup> Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1701 (2008).

<sup>182</sup> Ronald J. T. Corbett, *Protecting and Enforcing Intellectual Property Rights in Developing Countries*, 35 INT’L L. 1083, 1085 (2001).

<sup>183</sup> See Stiglitz, *supra* note 181 (arguing “one of the main reasons the pharmaceutical industry was pushing for TRIPS was that they wanted to reduce access to generic medicines”).

<sup>184</sup> Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 952–53 (2000).

<sup>185</sup> *Id.* at 955–56.

<sup>186</sup> See *supra* Part III.A.3.a.

<sup>187</sup> Swathi Padmanabhan et al., *Intellectual Property, Technology Transfer and Manufacture of Low-*

mass produce a COVID-19 vaccine is only the latest example of that growth.<sup>188</sup>

c. Global Attempts to License COVID-19 IP

The 2020 COVID-19 pandemic caused one of the most dramatic global policy shifts in IP in many decades. Many countries that had either shunned implementing compulsory licensing provisions in the past, or had skirted over the Doha Declaration since its enactment began looking for ways to federalize vaccine research. France,<sup>189</sup> Germany,<sup>190</sup> Chile,<sup>191</sup> Ecuador,<sup>192</sup> and Canada<sup>193</sup> were just some examples of countries whose lawmakers began rolling out resolutions or legislation in early 2020 to support a compulsory license push for vaccine technology. All adhere to the general framework laid out in TRIPS Article 31 in that they grant the government the power to issue compulsory licenses during an emergency on public health grounds.<sup>194</sup>

The key difference between these pieces of legislation and the emergency compulsory licensing provisions laid out in TRIPS and the codes of the U.S., United Kingdom, and India is that, while functionally similar, they are reactionary in posture and stem from an active emergency.<sup>195</sup> As a result, they tend to err on the side of giving more absolute power to the government. Ecuador's resolution, for example, which the Committee of the National Assembly passed, requires that their President and Minister of Health provide free or affordable access to COVID-19 related technology through compulsory licensing.<sup>196</sup> Germany's Act on the Protection of the Population in Case of Epidemic Situation of National Significance, which modified the original German Infection Protection Act and German Patent Act, gave the government broad powers to act in the interest of "public welfare or in the interest of the security of the Federal Republic of Germany."<sup>197</sup> France and Canada's acts are similar albeit a little

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*Cost HPV Vaccines in India*, 28 NATURE BIOTECH. 671, 671 (2010); COMM'N ON INTELL. PROP. RIGHTS, INNOVATION & PUB. HEALTH, *supra* note 142, at 26.

<sup>188</sup> *Agreements with CEPI and Gavi and the Serum Institute of India Will Bring Vaccine to Low-and-Middle Income Countries and Beyond*, ASTRAZENECA (Jun. 4, 2020), <https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html> [<https://perma.cc/ELF9-QKCM>].

<sup>189</sup> Code de la santé publique [C.S.P.] [Public Health Code] art. L3131-15 (Fr.) [hereinafter French COVID Act].

<sup>190</sup> German COVID Act, *supra* note 135.

<sup>191</sup> Proyecto de Resolución N° 896, Marzo 17, 2020, Cámara de Diputadas y Diputados [Chamber of Deputies] (Chile) [hereinafter Chilean Resolution].

<sup>192</sup> Resolution for Compulsory Licensing of Patents Relating to Coronavirus art. 2, Marzo 20, 2020, Comisión Especializada Permanente de Educación, Cultura y Ciencia y Tecnología de la Asamblea Nacional [Education, Culture, Science and Technology Commission of the National Assembly] (Ecuador) [hereinafter Ecuadorian Resolution].

<sup>193</sup> COVID-19 Emergency Response Act, S.C. 2020, c 5, pt. 12 (Can.) [hereinafter Canadian COVID Act].

<sup>194</sup> TRIPS Agreement, *supra* note 3, art. 31.

<sup>195</sup> See *supra* Part III.

<sup>196</sup> Ecuadorian Resolution, *supra* note 192, art. 1.

<sup>197</sup> German COVID Act, *supra* note 135, art. 1 ¶¶ 4–5.

more specific through use of limiting language like “health disaster”<sup>198</sup> and “public health emergency”<sup>199</sup> to define the boundaries of the provisions. The power of these loosely worded provisions could prove to be daunting to lawmakers interested in implementing them, which provides an impediment to collaboration.

d. India/South Africa Joint Waiver Request

The India/South Africa Waiver to the TRIPS Agreement, which was submitted to the WTO’s Council for Trade-Related Aspects of Intellectual Property Rights in October 2020, is an example of a drastic measure.<sup>200</sup> In it, India and South Africa requested that the WTO temporarily suspend IP rights related to COVID-19 technology to expedite vaccine, technology, and medicine development and ensure equitable distribution.<sup>201</sup> Rather than limiting the use of IP to the few rights holders, the suspension would allow entities across the world the ability to innovate simultaneously and share developments freely.<sup>202</sup>

Predictably, while this declaration found support among LMICs, high-income countries like Japan, Canada, Australia, and Switzerland resisted almost immediately and requested evidence of the TRIPS Agreement and Doha Declaration’s ineffectiveness in resolving the issue.<sup>203</sup> The European Union declared that while the TRIPS Agreement could resolve this issue without a waiver, implementing compulsory licensing provisions would be harder to do than envisioned.<sup>204</sup>

Opposition to the India/South Africa Waiver largely disappeared when many countries, including the U.S., France, China, and Japan announced their support for an IP waiver in May 2021.<sup>205</sup> This policy reversal coincided with a host of other

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<sup>198</sup> French COVID Act, *supra* note 189, ¶¶ 8–10.

<sup>199</sup> Canadian COVID Act, *supra* note 193, pt. 12.

<sup>200</sup> Request for Waiver by India & South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> [<https://perma.cc/A6F3-Q57M>] [hereinafter India/South Africa Waiver].

<sup>201</sup> *Id.* at ¶¶ 12–13.

<sup>202</sup> Ann Danaiya Usher, *South Africa and India Push for COVID-19 Patents Ban*, 396 LANCET P1790, P1790 (2020).

<sup>203</sup> *Id.*; *As Vaccine Roll-Out Begins, WTO Members Intensify Debate Over Policy Solutions*, IISD SDG KNOWLEDGE HUB (Dec. 21, 2020), <https://sdg.iisd.org/commentary/policy-briefs/as-vaccine-roll-out-begins-wto-members-intensify-debate-over-policy-solutions/> [<https://perma.cc/5KPB-KFMV>].

<sup>204</sup> *Id.*

<sup>205</sup> Andrea Shalal et al., *U.S. Reverses Stance, Backs Giving Poorer Countries access to COVID Vaccine Patents*, REUTERS (May 5, 2021, 2:10 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/biden-says-plans-back-wto-waiver-vaccines-2021-05-05/> [<https://perma.cc/385X-NNKL>]; Matthias Blamont, *Macron Backs Waiving IP Rights for COVID-19 Vaccines*, REUTERS (May 6, 2021, 7:11 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/macron-backs-waiving-ip-rights-covid-19-vaccines-2021-05-06/> [<https://perma.cc/Q399-DC78>]; David Lawder & Sonali Patel, *APEC Ministers Pledge to Expedite Transit of COVID-19 Vaccines, Related Goods*, REUTERS (Jun. 5, 2021), <https://www.reuters.com/world/asia-pacific/apec-debate-proposal->

nations joining India and South Africa to present a revised waiver.<sup>206</sup> The revised waiver differed from the new waiver in a key respect: it limited the effective duration of the waiver conditions to three years, subject to an extension if necessary at that three-year mark.<sup>207</sup> The previous waiver waived IP rights “until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”<sup>208</sup> This indefinite abrogation of rights was a key sticking point for many of the opponents of the original waiver.<sup>209</sup>

The India/South Africa Waiver is just the latest example of LMICs trying to reconcile IP protections and their desire to protect their citizens. In a discussion about the COVID-19 pandemic, LMICs expressed frustration towards high-income countries’ self-serving approach to the pandemic.<sup>210</sup> They specifically highlighted that the same high-income countries that, on one hand, were buying up as much of the vaccine as they could, were also opposing initiatives that could increase global manufacturing and benefit LMICs in a timely and affordable manner.<sup>211</sup> Unfortunately this assertion describes a behavior known as vaccine nationalism<sup>212</sup> which has been observed many times during the COVID-19 pandemic.<sup>213</sup> Addressing it will require changes in policy and legislation, both in the U.S. and around the world. Part IV will present and discuss proposals to bring about that change.

### B. Existing Voluntary Licensing Frameworks

Voluntary licensing is a catch-all term that covers a wide spectrum of licensing frameworks including paid-up and open licenses—which will be discussed here. The key commonality between these licenses that makes them voluntary is that the rights-holder can *voluntarily* choose if and when they enter the license, and whom they enter it with.<sup>214</sup>

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remove-tariffs-covid-vaccines-medical-prodcuts-2021-06-05/ [https://perma.cc/BSL4-33K4].

<sup>206</sup> Communication from the African Group et al. Council for Trade-Related Aspects of Intellectual Prop. Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/669/Rev.1 (May 25, 2021), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W669R1.pdf&Open=True> [https://perma.cc/BS9Y-DPSM].

<sup>207</sup> *Id.*

<sup>208</sup> India/South Africa Waiver, *supra* note 200, ¶ 13.

<sup>209</sup> Arjun Padmanabhan, *People or Patents? The COVID-19 IP Waiver & Property Rights During a Pandemic*, COLUM. J. TRANSNAT’L L. BULL. (July 14, 2021), <https://www.jtl.columbia.edu/bulletin-blog/people-or-patents>.

<sup>210</sup> *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 – Responses to Questions*, WORLD TRADE ORG., (Jan. 14, 2021), <https://docs.wto.org> (click “Search” in menu bar; then enter “IP/C/W/672” in the “Document symbol” field; then click the “Search” button; then follow the provided hyperlink for the document).

<sup>211</sup> *Id.* ¶ 25.

<sup>212</sup> See *supra* Part II.C.1.

<sup>213</sup> Ingrid T. Katz et al, *From Vaccine Nationalism to Vaccine Equity — Finding a Path Forward*, THE NEW ENG. J OF MED. (Apr. 8, 2021), <https://www.nejm.org/doi/full/10.1056/NEJMp2103614>

<sup>214</sup> See Daniel D. Kim, *Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing*, 8 AM. U. INTEL. PROP. BRIEF 63, 80–82 (2016) (discussing the leverage voluntary licensing

The key differences between a paid-up license and an open license are remuneration and restrictions a licensee is subject to. As its name suggests, a paid-up license “does not require further royalties because some consideration [such as cash] has been given in advance.”<sup>215</sup> Paid-up licenses are also known as royalty-free licenses.<sup>216</sup> Open licenses, on the other hand, grant licensees permission to access and redistribute intellectual property with few or no restrictions.<sup>217</sup> Many restrictions that a rights-holder can impose on a licensee in a paid-up licensing agreement are not applicable in an open licensing agreement. For example, an open license generally allows for reproductions, modifications, and derivative works, and for licensees to distribute them as they would the original work.<sup>218</sup> Additionally, the open licenses can neither restrict licensees from selling or otherwise giving away the work, nor can they require royalties or fees.<sup>219</sup> Interestingly, innovators and would-be licensees made use of both types of licenses during the early stages of the pandemic.

### 1. *Paid-Up and Open Licenses*

Through the aforementioned legislation and independent initiatives, the global community has found several ways to collaborate and share vaccine IP through voluntary licenses. These initiatives typically focus on encouraging technology sharing without enforcing IP protections like patents that might hinder development. Pledges to not enforce IP rights during the pandemic for vaccine-related technology gained popularity once the WHO expressed an interest in forming a patent pool in May 2020.<sup>220</sup> Around that time, the WHO and Costa Rica launched the COVID-19 Technology Access Pool (C-TAP) to help make health technologies effective against COVID-19 accessible to all.<sup>221</sup> The initiative encourages voluntary participation in the “one-stop shop for scientific knowledge, data and intellectual property” as a sign of social solidarity.<sup>222</sup> Participating in C-TAP entails licensing relevant technology to

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grants the pharmaceutical company during contract negotiations).

<sup>215</sup> Lydia Steck, *THE BASICS OF LICENSING*, 20 (Carla Blackman ed., 2009), <https://cdn.ymaws.com/members.lesusacanada.org/resource/resmgr/Docs/publications/BasicsofLicensing.pdf> [<https://perma.cc/B26N-WXTM>].

<sup>216</sup> *Id.*

<sup>217</sup> Andrés Guadamuz-González, *The License/Contract Dichotomy in Open Licenses: A Comparative Analysis*, 30 *U. LA VERNE L. REV.* 296, 296 (2009).

<sup>218</sup> *Id.*

<sup>219</sup> Christian H. Nandan, *Open Source Licensing: Virus or Virtue*, 10 *TEX. INTELL. PROP. L. J.* 349, 352 (2002).

<sup>220</sup> *Making the Response to COVID-19 a Public Common Good: Solidarity Call to Action*, WORLD HEALTH ORG. (Jun. 1, 2020), [https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d\\_4](https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d_4) [<https://perma.cc/RAR2-GJWD>].

<sup>221</sup> *International Community Rallies to Support Open Research and Science to Fight COVID-19*, WORLD HEALTH ORG. (May 29, 2020), <https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19> [<https://perma.cc/C98Q-8572>]

<sup>222</sup> *Id.*

the Medicines Patent Pool<sup>223</sup> and promoting open innovation models and technology transfer initiatives like the Open COVID Pledge.<sup>224</sup> More than forty WHO Member States indicated support for C-TAP and the Solidarity Call to Action.<sup>225</sup>

Like the Medicines Patent Pool, the Open COVID Pledge is a repository for vaccine-related IP that rights holders can license to the repository through an “Open COVID License 1.0.”<sup>226</sup> Under this license, the pledgor grants a “non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense)” for the “sole purpose of ending the ‘COVID-19 Pandemic’. . . and minimizing the impact of the disease, including without limitation the diagnosis, prevention, containment, and treatment of the COVID-19 Pandemic.”<sup>227</sup> The license also precludes the pledgor from asserting regulatory exclusivity use of the licensed IP, and from seeking injunctive or regulatory relief for the same purpose.<sup>228</sup> Dozens of international corporations, including Facebook, Amazon, IBM, Intel, Microsoft, and NASA JPL agreed to license their IP under these terms.<sup>229</sup>

Notably absent from the abovementioned list are pharmaceutical companies. Patent pools and IP pledges hold great appeal among LMICs, but not so much among wealthier countries such as the U.S. and not among pharmaceutical companies. The IFPMA opposed patent pools and pledges in May and October 2020 when it determined those initiatives to be misguided and an attack on IP rights.<sup>230</sup> Instead, these

<sup>223</sup> *Launch of the COVID-19 Technology Access Pool (C-TAP)*, MEDS. PATENT POOL (May 29, 2020, 5:00-6:30 PM), <https://medicinespatentpool.org/news-publications-post/launch-of-the-covid-19-technology-access-pool-c-tap/> [<https://perma.cc/J7DD-J8W9>].

<sup>224</sup> WORLD HEALTH ORG., *supra* note 222. Two of C-TAP’s stated goals are to (1) “Licen[s] any potential treatment, diagnostic, vaccine, or other health technology to the Medicines Patent Pool – a United Nations-backed public health body that works to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries” and (2) “[Promote] open innovation models and technology transfer that increase local manufacturing and supply capacity, including through joining the Open Covid Pledge and the Technology Access Partnership (TAP).”

<sup>225</sup> *Endorsements of the Solidarity Call to Action*, WORLD HEALTH ORG. (Oct 1, 2021), <https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action>

<sup>226</sup> *About Us*, OPEN COVID PLEDGE (Sept. 30, 2021), <https://opencovidpledge.org/about/>.

<sup>227</sup> *Open COVID License 1.0 March 31, 2020*, OPEN COVID PLEDGE (Mar. 31, 2020), <https://opencovidpledge.org/v1-0/> [<https://perma.cc/8L4Q-4U9H>].

<sup>228</sup> *Id.*

<sup>229</sup> Diana Peters & Eric Steuer, *Creative Commons Is Now Leading the Open COVID Pledge—Here’s What That Means*, CREATIVE COMMONS (Aug. 27, 2020), <https://creativecommons.org/2020/08/27/cc-ocp/> [<https://perma.cc/3NCD-26SZ>]. *See also Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020, 6:39 AM), <https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19> [<https://perma.cc/67C4-CMVA>]. Moderna made a similar independent pledge to license its intellectual property.

<sup>230</sup> *IFPMA Statement on “Intellectual Property and COVID-19”*, INT’L FED’N OF PHARM. MFRS. & ASSOCS. (Oct. 16, 2020), <https://www.ifpma.org/resource-centre/ifpma-statement-on-intellectual-property-and-covid-19/> [<https://perma.cc/48BU-WQVB>]; *IFPMA Statement on the “Solidarity Call to Action to Realize Equitable Global Access to COVID-19 Health Technologies Through Pooling of Knowledge, Intellectual Property and Data”*, INT’L FED’N OF PHARM. MFRS. & ASSOCS. (May 28,

pharmaceutical companies and developed countries have turned to procurement initiatives such as COVAX.<sup>231</sup>

On June 4, 2020, the Coalition for Epidemic Preparedness Innovations (CEPI), in partnership with the Global Vaccine Alliance (Gavi), launched COVAX.<sup>232</sup> COVAX is a pillar of the Access to COVID-19 Tools (ACT) Accelerator that works in partnership with over 172 developed and LMICs to speed up the search for an effective vaccine for all countries.<sup>233</sup> It is the only global initiative partnering with governments and manufacturers to deliver vaccines to both higher-income and lower-income countries worldwide.<sup>234</sup> Like the other patent pools, COVAX has a mechanism through which it procures IP related to vaccines to ensure fair and equitable access to the vaccines for each participating economy: the COVAX Facility.<sup>235</sup> Where the COVAX Facility differs, however, is that it is a subset of a larger organization (COVAX) that acts as a procurement mechanism for countries to get the vaccine, rather than just a pledge or license facilitator.<sup>236</sup> COVAX has likely received more support than the Open COVID Pledge and C-TAP because it provides more protections for IP rights and does not simply take rights away from the rights holders.

The COVAX initiative represents a step in the right direction, but the most important question is how to make organizations like COVAX more efficient to ensure quicker responses to future pandemics. Although the WHO declared the COVID-19 outbreak to be a pandemic on March 11, 2020,<sup>237</sup> the Vaccine Alliance only launched the precursor fundraising instruments for COVAX three months later, on June 4.<sup>238</sup>

In fact, even if COVAX had been formed on the same day the WHO declared COVID-19 to be a pandemic, it would still have been long overdue. This is because before March 11, significant time and resources that could have been used in

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2020), <https://www.ifpma.org/resource-centre/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-in-tellectual-property-and-data/> [<https://perma.cc/X63R-3P87>].

<sup>231</sup> Maria Serebrov, *Biopharma Opts for Collaboration, Not Patent Pools*, BIOWORLD (Aug. 25, 2020), <https://www.bioworld.com/articles/496984-biopharma-opts-for-collaboration-not-patent-pools> [<https://perma.cc/EG3Z-VAUM>].

<sup>232</sup> Steve Usdin, *COVAX Created to Try to Avoid Global Bidding Frenzy for COVID-19 Vaccines*, BIOCENTURY (Jun. 16, 2020), <https://www.biocentury.com/article/305466/covax-created-to-try-to-avoid-global-bidding-frenzy-for-covid-19-vaccines> [<https://perma.cc/6AAZ-LKA6>].

<sup>233</sup> *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (Aug. 24, 2020), <https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> [<https://perma.cc/P396-WFRD>].

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

<sup>235</sup> *Id.*

<sup>236</sup> Serebrov, *supra* note 231.

<sup>237</sup> *Timeline of WHO's Response to COVID-19*, WORLD HEALTH ORG. (Oct. 18, 2020), <https://www.who.int/news/item/29-06-2020-covid-timeline> [<https://perma.cc/4Y8X-G2PE>].

<sup>238</sup> Usdin, *supra* note 232.

international collaborative efforts had already been expended.<sup>239</sup> Prior to the formation of COVAX, the U.S. had spent more than \$2.1 billion supporting Johnson & Johnson, Moderna, and AstraZeneca's vaccine efforts.<sup>240</sup> While it is hard to say whether the result would have been different, it can be argued that contributing \$2.1 billion towards a concerted and collaborative international initiative would have likely yielded actionable results far sooner than spreading the investment across three companies.

## 2. Current COVID-19 Alliances

In recognition of the existential threat COVID-19 posed to Asia, the Association of Southeast Asian Nations (ASEAN), comprising of Indonesia, Philippines, Vietnam, Thailand, Myanmar, Malaysia, Cambodia, Laos, Singapore, and Brunei, along with China, Japan and Korea, convened the "Special ASEAN Plus Three (APT) Summit on the Coronavirus Disease 2019" in mid-April 2020.<sup>241</sup> In a Declaration, the Association expressed its commitment to

[f]urther strengthen public health cooperation measures to contain the pandemic and protect the people, including, inter alia, through timely and transparent exchange of information on real time situation and pandemic response measures taken by Member States, sharing of experience and best practices in epidemiological research and development, clinical treatment, joint research and development of vaccines and anti-viral medicines, enhancing capacity for the public health systems of ASEAN Member States while protecting and ensuring the safety of public health workers.<sup>242</sup>

The Association also expressed an intent to consider creating a standard operating procedure for public health emergencies and bolster national and regional epidemic preparedness and response by creating a network of experts, a network of emergency operations teams, and a biological pathogen response center.<sup>243</sup> Unfortunately, seven of the ten members of ASEAN are categorized as lower or lower-middle income economies by COVAX.<sup>244</sup> These countries lack the capital and infrastructure

<sup>239</sup> See *supra* Part II (indicating that significant vaccine research began in January 2020 when Chinese researchers published COVID-19's genetic sequence. Over 115 vaccine candidates were in various stages in development less than a month after COVAX was formed, and most of those had expended significant resources before the formation of COVAX).

<sup>240</sup> *Explaining Operation Warp Speed*, U.S. DEP'T OF HEALTH AND HUM. SERVS. (Dec. 12, 2020), <https://www.hhs.gov/sites/default/files/fact-sheet-operation-warp-speed.pdf> [<https://perma.cc/U78D-N72T>].

<sup>241</sup> See *generally Joint Statement of the Special ASEAN Plus Three Summit on Coronavirus Disease 2019 (COVID-19)*, ASSOC. OF SE. ASIAN NATIONS (Apr. 14, 2020), <https://asean.org/storage/2020/04/Final-Joint-Statement-of-the-Special-APT-Summit-on-COVID-19.pdf> [<https://perma.cc/2PNW-YD69>].

<sup>242</sup> *Declaration of the Special ASEAN Summit on Coronavirus Disease 2019 (COVID-19)*, ASSOC. OF SE. ASIAN NATIONS, ¶ 9(i) (Apr. 14, 2020), <https://asean.org/storage/2020/04/FINAL-Declaration-of-the-Special-ASEAN-Summit-on-COVID-19.pdf> [<https://perma.cc/22L5-DBNF>] [hereinafter ASEAN Declaration].

<sup>243</sup> *Id.*

<sup>244</sup> *AMC-Eligible Economies*, COVAX, 5 (Dec. 15, 2020, 9:00 AM), [https://www.gavi.org/sites/default/files/covid/pr/COVAX\\_CA\\_COIP\\_List\\_COVAX\\_PR\\_15-12.pdf](https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_15-12.pdf) [<https://perma.cc/3ZFG-AEKS>]. 92 *Low- and Middle-Income Economies Eligible to get Access to COVID-19 Vaccines*

to develop their own vaccines, so while they can implement safety protocols, they depend on the rest of the world for the vaccine.<sup>245</sup> This forces them to rely on the goodwill of the nations actually developing the vaccine to inoculate their citizens.<sup>246</sup>

Also of note are collaborative initiatives between international pharmaceutical developers and generics manufacturers. In June 2020, British-Swedish pharmaceutical giant AstraZeneca contracted with the world's largest vaccine manufacturer, Serum Institute of India, to supply one billion doses of its vaccine, Covishield, to low-and-middle-income countries.<sup>247</sup> As mentioned above, this initiative has already seen results, with India shipping out millions of Covishield vaccines to over a dozen countries in January 2021 alone.<sup>248</sup>

While these different initiatives have their merits, the lack of a centralized response presents a particular problem that, paired with the pharmaceutical industries' reluctance to weaken IP rights, has LMICs looking for more drastic means of licensing crucial technology.

#### IV. Proposals for New Licensing Schemes to Address Future Pandemics

According to chair of the Gavi Board, Dr. Ngozi Okonjo-Iweala, the COVID-19 pandemic has caused “the most severe contraction of the global economy since World War Two,” with a resultant “terrible impact on the poorest and emerging economies.”<sup>249</sup> As this is a global pandemic, the response to it must also be global. International collaboration is critical to resolving the crisis as soon as possible by ensuring that all countries have access to the vaccine. However, global access to the vaccine is only the first step, because, while that may resolve this particular pandemic, it does not protect the world from being held hostage by the next global health emergency.

This Section will discuss the merits of five proposals aimed at improving international collaboration and vaccine distribution for this and future pandemics: (1) forming a Trilateral council that can implement TRIPS compulsory licensing provisions, (2) enhancing state “march-ins” during domestic emergencies, (3) retroactively remunerating R&D costs, (4) incentivizing voluntary licensing as an alternative to

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*through Gavi COVAX AMC*, GAVI (July 31, 2020), <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc> [https://perma.cc/4DHZ-UYAW].

<sup>245</sup> GAVI, *supra* note 249.

<sup>246</sup> *Id.*

<sup>247</sup> ASTRAZENACA, *supra* note 188.

<sup>248</sup> Sanjeev Miglani, *Vaccine Diplomacy: India Seeks to Rival China with Broad Shipments*, REUTERS (Feb. 7, 2021), <https://www.reuters.com/article/us-health-coronavirus-india-diplomacy-idUSKBN2A70C8> [https://perma.cc/V86V-5HLD].

<sup>249</sup> *92 Low- and Middle-Income Economies Eligible to get Access to COVID-19 Vaccines through Gavi COVAX AMC*, GAVI (July 31, 2020), <https://www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc> [https://perma.cc/4DHZ-UYAW].

compulsory licensing, and (5) increasing competition through non-exclusive voluntary licenses. Proposals #1 and #2 relate to non-voluntary licensing because the rights holders don't choose when a government would abrogate their rights. Proposals #3, #4, and #5 are alternatives to compulsory licensing that allow the rights holders the ability to decide when they license their IP.

#### A. Non-Voluntary Licensing Proposals

Despite the plethora of compulsory licensing provisions available to them including the TRIPS Agreement, developed countries' governments rarely issue compulsory licenses, and have only done so a scant few times for pharmaceuticals. As collaborative as the process to create TRIPS was, there is still fierce opposition to implementing TRIPS compulsory licensing provisions. The U.S. leads the charge against TRIPS compulsory licensing.<sup>250</sup> This is primarily because it believes that compulsory licensing disincentivizes the research and development of new technologies, which will diminish new medicine creation and availability in the future.<sup>251</sup> Critics of the provisions, who succeed at blocking compulsory licensing schemes more often than not, also view government-sanctioned infringement of IP rights as a slippery slope that could lead to governments being more willing to abrogate property rights in the future.<sup>252</sup>

These are valid concerns. The decades following the TRIPS Agreement's enactment have provided ample evidence of a trend that suggests that governments, especially in LMICs, are becoming more cavalier with their use of TRIPS compulsory licensing provisions.<sup>253</sup> The flexibilities in the Doha Declaration that allowed countries to choose how and when to implement compulsory licenses directly empowered this uptick in use. Having the ability to issue a compulsory license and actually issuing that license are two different matters entirely, and history has shown that governments flexing that power frequently encounter adverse consequences. For seven decades between 1923 and 1993, Canada had a compulsory licensing scheme that granted compulsory licenses for all patented medicines in the country.<sup>254</sup> Unsurprisingly, this had a marked negative effect on pharmaceutical development. Pharmaceutical innovators stopped patenting inventions in Canada because generics manufacturers would

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<sup>250</sup> Bass, *supra* note 180, at 200.

<sup>251</sup> *Id.* See also Serebrov, *supra* note 231 (“IFPMA Director General Thomas Cueni said expecting companies to give up their intellectual property for SARS-CoV-2 vaccines showed a lack of understanding. ‘In the history of IP, there’s never been a need for compulsory licensing of vaccine patents,’ he noted. ‘IP is a fundamental part of our industry.’ AstraZeneca plc Executive Director and CEO Pascal Soriot agreed. ‘And if you don’t protect IP, then essentially there’s no incentive for anybody to innovate.’”).

<sup>252</sup> See generally 145 CONG. REC. H6027–30 (daily ed. July 21, 1999). See also Siraprapha Khim Rungpary, *Compulsory Licensing Issues and Trends in Asia*, 2 PHARM. PAT. ANALYST 681, 681 (2013).

<sup>253</sup> See *supra* Part III.A.3.a.

<sup>254</sup> Sheldon Burshtein, *Sublicense or Supply Agreement? Supreme Court of Canada Interpretation Benefits Generic Pharmaceutical Industry*, 54 FOOD & DRUG L.J. 73, 74–75 (1999).

take the most lucrative formulas from the patents and outcompete the inventors.<sup>255</sup> This practice ceased only when Canadian lawmakers recognized that the provision clashed with the newly signed North American Free Trade Agreement (NAFTA) and Article 31 of the TRIPS Agreement.<sup>256</sup>

It is important to note, however, that effective as the Canada compulsory licensing scheme is at serving as a warning of the perils of issuing compulsory licenses recklessly, it was a unique situation. Studies have shown no link, apart from rare situations like this one, between using compulsory licenses and a decline in R&D or innovation.<sup>257</sup> In fact, to the contrary, a study of German patents and inventions following World War I found that new or renewed patents increased year-over-year in fields with licensing and decreased year-over-year in fields without licensing.<sup>258</sup> Similar increases in innovation, or a lack of a decrease in innovation, also occurred in other countries following their implementation of a compulsory licensing scheme.<sup>259</sup> While this certainly should not serve as an endorsement for governments to enforce compulsory licenses often and with reckless abandon, it should help assuage the concerns of lawmakers who are more circumspect in their willingness to enforce such provisions. It is clear, however, that no two situations or crises are the same, and a one-size-fits-all approach to abridging IP rights will cause more problems than it resolves. Proposals for improving collaboration therefore must be flexible and adaptable to the specific situation at hand.

*1. Proposal #1: Form an International Council that Can Implement TRIPS Provisions*

Although the TRIPS Agreement includes provisions for dealing with crises, no provisions dictate how to formulate a global response to a worldwide health disaster like COVID-19. It is therefore on individual countries and alliances to determine how best to unify to challenge the threat. This approach is flawed, and the lack of bright-line rules and guidance results in countries handling the threat in their own ways, rather than as a global collective. It is therefore imperative that the WHO work with other intergovernmental organizations to form a governing body that can address worldwide disasters and coordinate a united response against them. In June 2021, the WHO, WTO, and World Intellectual Property Organization (“WIPO”) announced an

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<sup>255</sup> *Id. See id.* (stating that “innovators complained that the compulsory licensing system resulted in inadequate compensation . . . and discouraged pharmaceutical research in Canada.”)

<sup>256</sup> Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L. MED. & ETHICS 222, 226 (2009).

<sup>257</sup> See generally Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853 (2003) (concluding based on many case studies from the U.S. and abroad that compulsory licensing does not harm innovation).

<sup>258</sup> Joerg Baten et al., *Does Compulsory Licensing Discourage Invention? Evidence from German Patents After WWI 16–19* (Nat’l Bureau of Econ. Research, Working Paper No. 21442, 2015).

<sup>259</sup> Chien, *supra* note 257, at 857.

intensified partnership to tackle COVID-19.<sup>260</sup> This proposal advances a more robust collaboration effort between those organizations, and others, with broader latitude of authority during pandemics.

COVAX has yielded significant results in a relatively short time frame, which by itself proves the benefit and need for similar initiatives for future outbreaks. To maximize their efficiency, these organizations must be formed and operational far before a virus reaches pandemic proportions. The ASEAN Special Summit Declaration was a faster response, but ASEAN lacked the resources to seize on its foresight.<sup>261</sup> Although the Doha Declaration of TRIPS empowers individual member states to grant compulsory licenses and determine what constitutes a national emergency, the Declaration falls short by failing to include provisions to unite the world in situations that would constitute an international emergency, such as the COVID-19 outbreak.<sup>262</sup> A method of remedying this shortcoming would first be to establish a council that has the mandate to form a global initiative and enact TRIPS provisions. Second, this council would have the power to declare a pandemic to be an international emergency that warrants compulsory licensing and collaboration.

#### a. Future Initiatives

While the TRIPS Agreement has the foundation to facilitate compulsory licensing strategies that can help the world during global health crises, the WHO lacks a governing body that can implement them efficiently when such crises do arise.<sup>263</sup> The Doha Declaration empowers member states to make decisions regarding compulsory licensing without providing provisions to assist in forming international initiatives like COVAX.<sup>264</sup>

The international community could largely remedy this deficiency by modifying the TRIPS Agreement to form a body that can act and implement compulsory licensing provisions to collate research initiatives from around the world once a pandemic has been identified. COVAX and the ASEAN Special Summit are examples of ongoing initiatives that can serve as templates for a permanent body that achieves the same goal. As of now, 194 states have accepted the WHO's Constitution and become Member States that are bound by it and the TRIPS Agreement.<sup>265</sup> The Agreement could be

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<sup>260</sup> *Directors General of the WHO, WIPO, and the WTO Agree on Intensified Cooperation in Support of Access to Medical Technologies Worldwide to Tackle the COVID-19 Pandemic*, WORLD HEALTH ORG. (Jun. 24, 2021), <https://www.who.int/news/item/24-06-2021-directors-general-of-who-wipo-and-the-wto-agree-on-intensified-cooperation-in-support-of-access-to-medical-technologies-worldwide-to-tackle-the-covid-19-pandemic> [https://perma.cc/R23K-QKZS].

<sup>261</sup> See *supra* Part III.B.2.

<sup>262</sup> See Doha Declaration, *supra* note 4 (recognizing the rights to grant compulsory licenses and determine what constitutes a national emergency, but remaining silent as to international emergencies).

<sup>263</sup> See generally TRIPS Agreement, *supra* note 3 (providing a framework for handling compulsory licensing).

<sup>264</sup> See Doha Declaration ¶ 5(b), *supra* note 4 (explicitly recognizing each members "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted").

<sup>265</sup> *Countries*, WORLD HEALTH ORG. (Jan. 10, 2021), <https://www.who.int/countries/>

modified to include a provision that forms a body with intentions like those laid out in the ASEAN Special Summit Declaration<sup>266</sup> and mechanisms of meeting those goals like those of COVAX and Gavi.<sup>267</sup>

To act effectively, the body would first need to determine whether a given emergency qualifies as a pandemic. The Centers for Disease Control and Prevention (CDC) defines an epidemic as, “an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area.”<sup>268</sup> A pandemic is an epidemic or multiple epidemics that occur over a wide area and cross international boundaries to usually affect a large number of people.<sup>269</sup> Next, rather than wait for the WHO to analyze data from different countries, countries could bring forward motions to categorize public health emergencies as pandemics to trigger compulsory licensing provisions. This would be analogous to an Article 5 Resolution in the North Atlantic Treaty Organization (NATO).<sup>270</sup> In an Article 5 Resolution proceeding, a signatory country may bring forward an incident or situation and the North Atlantic Council can determine whether it qualifies as an armed attack that requires a collective defense from every member.<sup>271</sup> Invocation of Article 5 requires the unanimous consent of all twenty-eight signatories.<sup>272</sup> Following the 2001 attack on the World Trade Center in New York, the U.S. invoked Article 5 and NATO agreed to eight measures to help the U.S., including its first ever anti-terror operation using assets from thirteen signatory countries.<sup>273</sup>

Global pandemics are attacks against all countries that plague the world as a whole. Thus, a united and common defense is paramount. With a TRIPS addendum like Article 5, countries could present their health ministries’ data on growing public health threats and request an international response that could be analyzed by member countries based on their own epidemic data and voted on accordingly. The biggest

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[<https://perma.cc/CSL4-KRNH>].

<sup>266</sup> ASEAN Declaration, *supra* note 242 ¶ 9(i).

<sup>267</sup> *172 Countries and Multiple Candidate Vaccines Engaged in COVID-19 Vaccine Global Access Facility*, WORLD HEALTH ORG. (Aug. 24, 2020), <https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility> [<https://perma.cc/P396-WFRD>].

<sup>268</sup> OFFICE OF WORKFORCE AND CAREER DEV., CTRS. FOR DISEASE CONTROL AND PREVENTION, *PRINCIPLES OF EPIDEMIOLOGY IN PUBLIC HEALTH PRACTICE*, 1-72 (3d ed. 2012), <https://www.cdc.gov/csels/dsepd/ss1978/SS1978.pdf> [<https://perma.cc/9HSP-P68U>].

<sup>269</sup> *Id.* See also *Pandemic*, A DICTIONARY OF EPIDEMIOLOGY (6th ed. 2014).

<sup>270</sup> See North Atlantic Treaty art. 5, Apr. 4, 1949, 63 Stat. 2244, 34 U.N.T.S. 243 (allowing each country “in an exercise of the right of individual or collective self-defense” the ability to take actions it deems necessary to “restore and maintain the security of the North Atlantic area”).

<sup>271</sup> *Id.*

<sup>272</sup> *The Mechanics of NATO’s Collective Self-Defense*, STRATFOR WORLDVIEW (Mar. 25, 2015, 8:00 AM), <https://worldview.stratfor.com/article/mechanics-natos-collective-self-defense> [<https://perma.cc/L3J8-J7GZ>].

<sup>273</sup> *Collective Defense – Article 5*, NORTH ATLANTIC TREATY ORG. (Nov. 25, 2019, 11:12 AM), [https://www.nato.int/cps/en/natohq/topics\\_110496.htm](https://www.nato.int/cps/en/natohq/topics_110496.htm) [<https://perma.cc/EX6J-MACR>].

hurdle to invoking Article 5 is the requirement that consent be unanimous.<sup>274</sup> This would be nearly impossible in an organization with 194 members; however, in this situation, a simple majority might suffice to invoke a common-health defense. In the instances in which such a resolution was invoked, or the WHO declared the emergency to be a pandemic, the body would have the power to implement compulsory licensing provisions across all signatories and form a task force to handle the specific threat.

2. *Proposal #2: Empower U.S. States to Exercise March-In Rights During Domestic Emergencies*

As previously mentioned, march-in rights have never been used successfully in the U.S.<sup>275</sup> Whether this is because of a lack of precedent or a learned helplessness where legislators feel no desire to fight a prolonged battle with large pharmaceutical companies, the fact remains that key IP legislation is not being used at a time when it is needed.

Although an obscure power, states should use sovereign immunity to enforce “march-in” rights during public health crises. Sovereign immunity and government federalism, as general principles guaranteed to state governments under the Constitution, prevent states from being liable for patent infringement so long as they offer sufficient compensation.<sup>276</sup> In the landmark case *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, the Supreme Court upheld these protections and struck down Congressional attempts to limit them.<sup>277</sup> In 1992, Congress passed the Patent and Plant Variety Protection Remedy Clarification Act and amended U.S. Code to strip states of their sovereign immunity and Eleventh Amendment protections during patent infringement suits.<sup>278</sup> Although the Federal Circuit agreed with Congress on the matter,<sup>279</sup> the Supreme Court determined that Congress had exceeded its Article I authority<sup>280</sup> and that

a State’s infringement of a patent, though interfering with a patent owner’s right to exclude others, does not by itself violate the Constitution. Instead, only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result.<sup>281</sup>

This holding invalidated 35 U.S.C. § 296(a) and secured states’ rights to sovereign immunity after exercising march-in rights. Despite this, these rights have never

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<sup>274</sup> STRATFOR WORLDVIEW, *supra* note 272.

<sup>275</sup> See *supra* Part III.A.1.c.

<sup>276</sup> Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 643 (1999).

<sup>277</sup> *Id.* at 630.

<sup>278</sup> Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230, 4230 (1992); 35 U.S.C. § 296(a) (1994), *invalidated by* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999).

<sup>279</sup> Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 148 F.3d 1343, 1347 (Fed. Cir. 1998), *aff’g* 131 F.3d 353 (3d Cir. 1997), *rev’d*, 527 U.S. 627 (1999).

<sup>280</sup> Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. at 636.

<sup>281</sup> *Id.* at 643.

been used, not even by Louisiana during the 2017 Hepatitis C scare.<sup>282</sup> Encouraging states to enforce these rights *within reason*, or at least look into doing so, during public health crises would relieve pressure from the federal government. Doing so would also allow states to respond to unique situations, such as a surge in infections in their state, on a situation-by-situation basis so that crisis hotspots are addressed quickly with tailored solutions. Finally, during crises like the COVID-19 pandemic, granting local manufacturers licenses obtained from enforcing march-in rights might bring relief to beleaguered state economies.

### B. Voluntary Licensing Proposals

Voluntary licensing is another option that, if leveraged properly, can achieve the same goal as compulsory licenses while avoiding much of the ill will associated with a government having to step in and infringe on a citizen's property rights. The three following proposals are designed to encourage rights-holders to issue licenses voluntarily for compensation or as a method to stay competitive in a capitalist economy.

#### 1. *Proposal #3: Retroactive Remuneration of R&D Costs for Proportional Licensing Rights*

Proposal #3, which builds on economic remuneration theories, would incentivize licensing through funding already completed research using a subscription plan. Subscription plans, like the "Netflix subscription model," guarantee an unlimited supply of a product in return for a fixed reimbursement.<sup>283</sup> Although implementing such an arrangement in an IP-related matter may seem ill advised, the idea has merit and has been successful thus far.<sup>284</sup> In 2019, Louisiana, the first state to successfully launch such an initiative to treat Hepatitis C, signed an agreement with Asegua, a Gilead subsidiary.<sup>285</sup> Asegua agreed to provide the state with an unlimited amount of the drug Epclusa for five years at a set price.<sup>286</sup> Washington followed suit later that year by signing a contract with AbbVie for a similar drug following a blind bidding process.<sup>287</sup> Other pharmaceutical companies, including Merck & Co. and Gilead, also bid.<sup>288</sup>

This suggestion advocates for allowing the government to apply the Netflix subscription model to retroactively pay for a portion of the R&D costs the patent holders

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<sup>282</sup> See *supra* Part III.A.1.c.ii.

<sup>283</sup> Mark R. Trusheim et al., *Alternative State-Level Financing for Hepatitis C Treatment—The "Netflix Model"*, 320 J. AM. MED. 1977, 1977 (2018).

<sup>284</sup> JoNel Aleccia et al., *Pharma Sells States on "Netflix Model" to Wipe Out Hep C*, SCI. AM. (Oct. 31, 2019), <https://www.scientificamerican.com/article/pharma-sells-states-on-netflix-model-to-wipe-out-hep-c/> [<https://perma.cc/F3HL-8RRM>].

<sup>285</sup> *Hepatitis C Innovative Payment Model Contract with Asegua Therapeutics LLC*, LA. DEP'T OF HEALTH & DEP'T. OF CORR. 1, 2 (effective July 1, 2019).

<sup>286</sup> *Id.* at 10.

<sup>287</sup> JoAleccia et al., *supra* note 284.

<sup>288</sup> *Id.*

incurred in developing the relevant IP. In return, the government could license the patent to manufacturers to populate a proportional market share of the patented technology. To illustrate, assume that Company X spent \$1 billion to develop the drug “Xcure.” The proposed plan would allow the government to pay a fixed amount, say 30% of the \$1 billion in a subscription plan over a predetermined period. In return, the government would be allowed to license Xcure technology to other manufacturers. The main restriction on the license would be that the total produced pharmaceuticals across all the licensees are capped at 30% of the market share. If Company X signed a contract with the government to vaccinate 80% of the population, the licensees could collectively vaccinate 30% of that 80%. Similarly, if the government contracted Company X to produce 1,000,000 doses of Xcure, the license would allow the licensees to produce 300,000 of those 1,000,000 doses.

This system would benefit the government in that it could pay for proven and successful research over a period of time. It would also allow the government to act as a licensor, thereby allowing it to set price caps for the licensee manufacturer(s), which would defray the remuneration costs. The public would benefit from a faster product rollout from multiple manufacturers working on the same product. Finally, although the patent holders would lose opportunity costs of profiting off that percentage of the market, remuneration of the R&D costs would ensure that it did not completely lose those initial investments.

## 2. *Proposal #4: Incentivize Voluntary Licensing as an Alternative to Compulsory Licensing*

Although the Trilateral Initiative from Proposal #1 would have the power to implement compulsory licensing provisions across all signatory countries, patent rights holders should have a way to adjust their business models to collaborate during a health crisis without being forced to do so by the proposed governing body. This Article advances a proposed “inducement package” of three incentives that a rights holder would be guaranteed should they voluntarily license their IP during a global health crisis.

First, should a rights holder choose to issue a non-exclusive voluntary license, they would have a guarantee that their IP would be used in good faith by reputable<sup>289</sup> licensees. Unlike an Open COVID Pledge license,<sup>290</sup> the license would be restricted to reputable licensees. These licensees would be actors that the WIPO vetted and approved based on a history of respecting IP rights and dealing in good faith with other rights holders. Because potential licensees would need to be approved to receive the license, the license would be non-sublicensable. Licensees would also be subject to unscheduled audits or inspections to ensure that the rights holder’s IP is protected and leveraged properly. The WIPO would essentially act in a function like the National

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<sup>289</sup> Reputable in this context would refer to licensees who deal in good faith and could be trusted to not violate the terms of the licensing agreement.

<sup>290</sup> See *supra* Part III.A.3.c.

Intellectual Property Administration of China (CNIPA) in its handling of open licenses,<sup>291</sup> although the WIPO would have a greater remit to enforce IP rights' protections across the world. As a method of enforcement, the WIPO would be able to strip a licensee of its license in the case of non-compliance with those protections.

Second, the WTO would facilitate favorable terms for the rights holder to procure raw materials for research and for its own vaccine production network. Consistently procuring suitable raw vaccine components is a challenge, and failure to do so inhibits vaccine development and manufacturing.<sup>292</sup> Raw materials and vaccine components must be available and consistent for long periods of time to ensure that the vaccine is available long enough to not only recover research and development costs, but also net the developer a profit.<sup>293</sup> For this reason, pharmaceutical companies generally wait until the vaccine passes clinical trials and is approved by the relevant regulatory body before establishing resource supply lines and product delivery chains.<sup>294</sup> Even though Pfizer and its German partner BioNTech SE started mass production well before the U.S. Food and Drug Administration ("FDA") approved the vaccine in December 2020, material bottlenecks prevented the companies from meeting their end-of-year goal of delivering 100 million doses of its COVID-19 vaccine by fifty million doses.<sup>295</sup> If a rights holder were to voluntarily license IP relevant to the present crisis, the WTO would work with countries that source the raw components to ensure a steady pipeline of consistent raw materials. The WTO would also negotiate to decrease the cost of those materials to increase profit margins and provide a competitive benefit to that particular rights holder over others who did not opt to voluntarily license. This increase in profit margins would also help offset the rights holder's lost opportunity cost from not exclusively servicing the entire market.

Finally, the WHO would, as a function, compensate the rights holder for its research and development costs and pay a royalty for the license. Research and development costs drive up the prices of vaccines.<sup>296</sup> Those high costs are also why companies are reluctant to share IP.<sup>297</sup> This final incentive should help alleviate that concern by providing the rights holder a guaranteed method of receiving a return on its investment. Because research and development costs are so high, the WHO might be best served by paying in installments in a plan like the previously discussed Netflix model.<sup>298</sup> It would also pay a flat royalty fee, like those granted by other countries,

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<sup>291</sup> 2020 Chinese Patent Amendment, *supra* note 131, ¶¶ 16–18.

<sup>292</sup> Plotkin et al., *supra* note 36.

<sup>293</sup> *Id.*

<sup>294</sup> Costa Paris, *Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target*, WALL ST. J. (Dec. 3, 2020), <https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787> [https://perma.cc/LHE8-ZDFN].

<sup>295</sup> *Id.*

<sup>296</sup> *See supra* Part II.B.

<sup>297</sup> *See supra* Part II.B.1.

<sup>298</sup> *See supra* Part IV.B.1.

throughout the term of the license.<sup>299</sup> The question becomes who would pay for the rights holder's R&D compensation and royalty. Nobel Peace Prize winner Dr. James Orbinski once suggested a tax on international drug sales to fund a public research body.<sup>300</sup> While this would seem feasible, an international defense fund is a tried and tested solution for which there already is precedent. Each year, NATO's member countries agree to a civil and military budget which they fund according to an "agreed cost-sharing formula based on Gross National Income."<sup>301</sup> This idea of an annual budget, supported by member states contributing a percentage of their GNI, would be easily adaptable to create an international health defense fund where all members of the WHO contribute a percentage of their GNI to support research initiatives during a health crisis.

Together, these three incentives would protect a potential licensor's IP rights from illegal infringement, increase profitability by decreasing production costs, and subsidize research and development costs. This would make a strong case for a licensor to voluntarily license relevant IP during a crisis rather than risk a government enforcing a compulsory license against them. This is also a better option than differential pricing, where pharmaceutical companies price the same drug differently across markets, which various industries have found to be unfeasible in the past.<sup>302</sup> If this inducement package fails, a strong council with the ability to enforce global compulsory licensing provisions—as discussed earlier in this Part—would still ensure that collaboration is the primary directive during a health crisis.

### 3. *Proposal #5: Increase Competition Through Non-Exclusive Voluntary Licenses*

The final proposal models a framework that promotes open licenses during public emergencies and would achieve a similar goal as compulsory licensing *would* without forcefully infringing on IP rights. Nonexclusive licenses already exist as a function of current IP schemes and allow a rightsholder to grant licenses to multiple actors.<sup>303</sup> Gilead granted eleven Indian companies nonexclusive voluntary licenses to produce the HIV/AIDS drug Tenofovir in return for a 5% royalty on sales.<sup>304</sup> For the current pandemic, Gilead granted nonexclusive licenses to generics manufacturers in

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<sup>299</sup> Steinbrook, *supra* note 170. See also 35 U.S.C. § 203(a).

<sup>300</sup> Velásquez, *supra* note 69, at 5.

<sup>301</sup> *NATO Agrees 2021 Civil and Military Budget*, N. ATL. TREATY ORG. (Dec. 17, 2020, 8:21 AM), [https://www.nato.int/cps/en/natohq/news\\_180185.htm#:~:text=NATO%20Allies%20have%20agreed%20the,%E2%82%AC1.61%20billion%20for%202020](https://www.nato.int/cps/en/natohq/news_180185.htm#:~:text=NATO%20Allies%20have%20agreed%20the,%E2%82%AC1.61%20billion%20for%202020) [<https://perma.cc/2YBB-B62J>].

<sup>302</sup> See Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence, and Emerging Issues*, 36 PHARMACOECONOMICS 1395, 1401, 1404 (2018) (“[I]n LMICs where most consumers pay out of pocket for drugs, simple differential pricing appears to fail”). See also Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT’L J. HEALTH CARE FIN. & ECON. 183, 193, 201 (2003) (concluding that “actual price differentials are not optimal”).

<sup>303</sup> *Understanding Non Exclusive Licensing*, LAWS (Dec. 23, 2019), <https://patent.laws.com/patent-protection/non-exclusive-licensing> [<https://perma.cc/YAD6-8FWN>].

<sup>304</sup> Steinbrook, *supra* note 170, at 546.

Egypt, India, and Pakistan to develop the Hepatitis C drug Remdesivir, which has been successful at treating COVID-19, for distribution in 127 low-income and lower-middle-income countries.<sup>305</sup> Voluntary licenses like Gilead’s are uncommon because it is far more profitable for pharmaceutical developers to sell their own brand-name drugs.<sup>306</sup> In fact, Gilead made the COVID-19 Remdesivir licenses royalty-free until the WHO ends the Public Health Emergency of International Concern, or “until a pharmaceutical product other than Remdesivir or a vaccine is approved to treat or prevent COVID-19, whichever is earlier.”<sup>307</sup> One distinction, however, between Remdesivir and other COVID-19 research is that, although Gilead obtained a patent for the drug’s uses against coronavirus,<sup>308</sup> Remdesivir is a repurposed drug—it was originally developed for Hepatitis C in 2009, and is effective against several families of viruses.<sup>309</sup> Thus, it would be reasonable to think that income from Remdesivir’s uses against other viruses, which are not royalty free and not subject to voluntary licenses, may have offset the loss of income from the royalty-free non-exclusive COVID-19 licenses. This would make the Remdesivir license framework an anomaly, not the norm, and would indicate the lack of incentives for another pharmaceutical company to adopt this approach regarding its COVID-19 related IP.

China recognized the unpalatability of non-exclusive licenses for innovators and developed an open-license framework that incentivized innovators to open their licenses for non-exclusive use. In a 2020 amendment to its patent legislation, the fourth since it was enacted in 1984, the National People’s Congress approved an open license system for patents.<sup>310</sup> Under this system, if a patent holder expressed to the government a willingness to license its patent to anyone who asked, it could set the terms of the fees and would receive government support to openly license the patent.<sup>311</sup> Other entities could then pay the fees and use the license.<sup>312</sup> Most importantly,

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<sup>305</sup> *Voluntary Licensing Agreements for Remdesivir*, GILEAD (Mar. 4, 2021), <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir> [<https://perma.cc/UT6X-KUF4>]. (Gilead promotes using voluntary licenses and has expressed an intent to continue doing so throughout the COVID-19 pandemic).

<sup>306</sup> Cf. Press Release, Daniel O’Day, Chairman & CEO, Gilead Sciences, An Open Letter from Daniel O’Day (Jun. 29, 2020), <https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/an-open-letter-from-daniel-oday-chairman—ceo-gilead-sciences> [<https://perma.cc/78U2-GUGB>] (stating that a five-day treatment of Remdesivir would cost developed country governments \$2,340 per patient) with Andrew Hill, *Minimum Costs to Manufacture New Treatments for COVID-19*, 6 J. OF VIRUS ERADICATION no. 2, 2020, at 61, 62 (estimating a five-day treatment of Remdesivir, sans non-drug components such as saline, would cost manufacturers \$4.65).

<sup>307</sup> GILEAD, *supra* note 305.

<sup>308</sup> U.S. Patent No. US 10,251,898 B2 (filed Feb. 22, 2018).

<sup>309</sup> Michael K. Lo et al., *GS-5734 and Its Parent Nucleoside Analog Inhibit Filo-, Pneumo-, and Paramyxoviruses*, 7 SCI. REPS. 1, 2 (2017).

<sup>310</sup> 2020 Chinese Patent Amendment, *supra* note 131, ¶¶ 16–18.

<sup>311</sup> *Id.* ¶¶ 16–17 (explaining that the patent holder must be willing to grant issue a voluntary license to anyone who asked and accepted the patent holder’s fee terms to be granted an open license).

<sup>312</sup> *Id.* ¶ 17.

however, the Amendment encourages patent holders to issue open licenses by promising a reduction or exemption of annual fees for those who do.<sup>313</sup>

Proposal #5 advocates for introducing legislation that permits federal governments to encourage non-voluntary licensing of pharmaceutical IP during predetermined situations of national emergency. The legislation would first allow for automatic implementation when the government declares a national health emergency. At that point provisions would allow patent holders to request the federal government's support in regulating an open license of the relevant patents until the emergency was resolved, or, like in the Gilead Remdesvir licenses, until another technology was developed that better addressed the situation. The government would also encourage patent holders to seek those licenses, regardless of the lost opportunity cost of not exploiting the technology themselves. These incentives would vary depending on the situation but could include annual patent fee exemptions, retroactive remuneration of research costs, or tax concessions. Patent holders would still retain their rights, and although they would suffer opportunity costs, incentives would make open licenses more palatable than compulsory licenses.

## V. Conclusion

There is a lot of uncertainty surrounding compulsory licensing provisions and how to use them. State and national governments often consider compulsory licensing to be a nuclear option, and rightly so. The decision to abridge an individual's rights to their property should not be taken lightly, especially in a democracy that protects those rights in every other regard. However, in an increasingly interconnected world where hostile pathogens can traverse sovereign borders, the initiatives to fight them must be able to do the same. COVID-19 and other public health disasters do not wait for anyone, nor do they discriminate in who they strike down: rich or poor, American, French, or Indian. Prevailing over these diseases, requires input from the best and brightest each country has to offer.

Science has come so far in the past few centuries, and breakthroughs are happening now at a rate far faster than ever before. Before COVID-19, the mumps vaccine was the fastest vaccine ever developed, taking four years from initial research to licensing in 1967.<sup>314</sup> The COVID-19 vaccine took just under a year to undergo the same process and begin rolling out on a massive scale.<sup>315</sup> Despite all this development, the question remains, "how can we do better?" As monumental and historic as the COVID-19 vaccine race was, it may have ended faster if the international community had shared research and IP sooner. It is understandable that innovators should laud IP protections and curse compulsory licensing schemes. It is also understandable

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<sup>313</sup> *Id.* ¶ 17.

<sup>314</sup> Nsikan Akpan, *Why a Coronavirus Vaccine Could Take Way Longer than a Year*, NAT'L GEOGRAPHIC (Apr. 10, 2020), <https://www.nationalgeographic.com/science/2020/04/why-coronavirus-vaccine-could-take-way-longer-than-a-year/#close>. [<https://perma.cc/Z9RH-ATN8>].

<sup>315</sup> Sandy Cohen, *The Fastest Vaccine in History*, UCLA HEALTH (Dec. 10, 2020), <https://connect.uclahealth.org/2020/12/10/the-fastest-vaccine-in-history/> [<https://perma.cc/JYK2-WHPW>].

that LMICs and the disadvantaged should do just the opposite. However, there is a way to find equitable solutions that do not altogether disadvantage one side in favor of the other. While the TRIPS Agreement and the IP frameworks LMICs used before TRIPS reflected a bias towards one side or the other, it is important to recognize how far those types of legislation have come. The amended TRIPS Agreement certainly reflects an intent to seek middle ground.

That spirit of cooperation must continue, and must transcend legal policy into reality. Fostering IP exchanges to collaborate against health disasters like COVID-19 must be the world's primary directive going forward. Whether it be through encouraging voluntary licenses, enforcing compulsory licenses, or another method, global actors like countries and private pharmaceutical developers must be prepared to engage in discourse to share knowledge and information pertaining to treatment or cures. While there is no telling when the next global pandemic will emerge, there is one certainty: it will come, and a rapid, unified response must meet it. Only by examining and learning from the plagues of the present can we preserve the health of our future.