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## Compulsory Licensing of Patents in Times of Public Health Emergency

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**COMPULSORY LICENSING OF PATENTS IN TIMES OF  
PUBLIC HEALTH EMERGENCY**

*Kelsey Truglio\**

**ABSTRACT**

In March 2020, the United States shut down to avoid the continued spread of the COVID-19 virus as it spread globally. In December 2020, the first COVID-19 vaccines were granted emergency usage authorization in the United States. Wealthy nations were able to quickly purchase and hoard vaccines for public distribution, leaving many third-world countries and developing nations struggling to continue to survive the pandemic without vaccination.

Compulsory licensing should be allowed on otherwise patented or patentable new technology in times of global health emergency, regardless of which entity creates the technology. This will enable governments of countries spanning all wealth levels to manufacture and distribute technology without the obstacles of the high cost of paying the full royalty rate to the patent owner or an excessive wait period while the patent's monopoly period runs.

## I. INTRODUCTION

Moderna and the National Institutes of Health (NIH), once partners in the invention of a COVID-19 vaccine, are now warring in court over its long term distribution rights, management, and potential billions of dollars in profits.<sup>1</sup> The court's decision in this patent dispute will set a precedent that will change the way private companies collaborate with the United States government in the future.<sup>2</sup> In filing its COVID-19 vaccine patent, Moderna only credited its own scientists for the invention, allegedly leaving out three NIH scientists who critically collaborated with the private pharmaceutical company.<sup>3</sup> Several NIH scientists contributed to the creation of the Moderna mRNA vaccine after a four-year collaboration between Moderna and the NIH, the United States government's biomedical research agency.<sup>4</sup> The exclusion allegedly blindsided the NIH.<sup>5</sup> However, Moderna now asserts that its scientists were the sole creators of the vaccine, and therefore, filed its vaccine patent application to reflect that assertion. This ongoing patent dispute persists while millions are still unvaccinated against COVID-19 around the world and populations are still struggling to combat the disease and its effects – including widespread death and instances of long-term illness. During public health emergencies, the global community needs to follow a

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<sup>1</sup> Sheryl Gay Stolberg & Rebecca Robbins, *Moderna & U.S. Odds Over Vaccine Pat. Rts.*, N.Y. TIMES, Nov. 9, 2021 (updated Nov. 11, 2021), <https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>; Julie Steenhuisen, *Moderna COVID-19 Vaccine Pat. Disp. Headed Ct.*, REUTERS (Nov. 11, 2021 2:07 AM), <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-covid-19-vaccine-patent-dispute-headed-court-us-nih-head-says-2021-11-10/>.

<sup>2</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>3</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>4</sup> Stolberg & Robbins, *supra* note 1.

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

consistent, efficient, and collaborative system to waive patent protections and prioritize innovation and distribution of treatments, vaccinations, and other life-saving technologies.

Despite its surface appearance, the Moderna lawsuit is not merely a petty squabble over who will get credit for the vaccine.<sup>6</sup> The main issue is the lasting and possibly devastating impact this could have on vaccine access moving forward, both domestically and internationally.<sup>7</sup> If the patent application is approved the way it is, Moderna will have a developmental monopoly on the COVID-19 vaccine, not only collecting royalties on sales but also controlling and managing the production, distribution, and licensing of the vaccination technology.<sup>8</sup> If Moderna credited the NIH, the government agency would likely not need Moderna's permission to license the vaccine to other companies or organizations for mass production and distribution.<sup>9</sup> With this stake in ownership, the NIH could secure national access to at least one type of vaccine which has been proven effective against COVID-19.<sup>10</sup> Without the stake, there are other alternatives - but none of them as assured as credit on the patent itself.<sup>11</sup>

Although Moderna has publicly announced that it will not exercise patent rights during the pandemic period, it may change its mind at any time with virtually no consequence or restrictions imposed by governments or the market.<sup>12</sup> That is where compulsory licensing presents a solution. A compulsory license from the government would provide firm legal reassurance to government officials and manufacturers to allow vaccine production after the pandemic emergency period.<sup>13</sup> A license would add a force of law behind Moderna's promise.

The process of compulsory licensing for patents in the public health field should be changed to address a wider scope of major health

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<sup>6</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>7</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>8</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>9</sup> Stolberg & Robbins, *supra* note 1.

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

<sup>11</sup> *Id.*

<sup>12</sup> Stolberg & Robbins, *supra* note 1; MODERNA, STATEMENT BY MODERNA ON INTELL. PROP. MATTERS DURING COVID-19 PANDEMIC (Oct. 2020), <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx>.

<sup>13</sup> Stolberg & Robbins, *supra* note 1.

problems. Specifically, the requirements that compulsory licenses can only be issued after a government has attempted to convince a patent holder to issue a voluntary license, and then only to meet a specific emergency and for specific periods of time, is no longer appropriate for a post-COVID-19-pandemic world. We now see that some public health issues do not dissipate as quickly as expected or hoped by the public. As of the current date, there are over ten named COVID-19 variants in existence, with BA.5 making up more than 50% of cases in the United States as of the beginning of July 2022.<sup>14</sup>

This Note will argue that compulsory licensing should be allowed on otherwise patented or patentable new technology in times of medical emergency, regardless of which entity, private or government, creates the technology. This will enable governments of low income, middle, and high-income countries to manufacture and distribute these innovations without the obstacles of the cost of paying the full royalty rate to the patent owner or an excessive wait period while the patent's monopoly period runs. Allowing such compulsory licensing will permit governments to address public health issues continuously and respond to emergencies and health issues quickly. Without trying to predict how long an emergency will last, more lives may be preserved and a more equitable approach to public health on

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<sup>14</sup> CTR. DISEASE CONTROL PREVENTION, *Delta Variant*, (updated Aug. 26, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>; CTR. DISEASE CONTROL PREVENTION, *Omicron Variant*, (updated Dec. 20, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html>; CTR. DISEASE CONTROL PREVENTION, *What You Need Know About Variants*, (updated Dec. 13, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html>; CTR. DISEASE CONTROL PREVENTION, *Understanding Variants*, (updated Aug. 6, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/understanding-variants.html>; WORLD HEALTH ORG., *Tracking SARS-CoV-2 Variants*, (updated Jan. 24, 2022), <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>; Kathy Katella, *Omicron, Delta, Alpha & More*, YALE MED (update July 5, 2022), <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron>; Elizabeth Mahase, *Covid-19: What Have We Learnt About New Variant In UK*, BRIT. MED. J. (Dec. 23, 2020), <https://doi.org/10.1136/bmj.m4944>; John R. Mascola, MD, Barney S. Graham, MD, PhD & Anthony S. Fauci, MD, *SARS-CoV-2 Viral Variants—Tackling a Moving Target*, J. AM. MED. ASS'N (Feb. 11, 2021), [https://jamanetwork.com/journals/jama/fullarticle/2776542?guestAccessKey=9e0c2f1d-0a51-444d-b3a4-cf1b84766df1&utm\\_source=TrendMD&utm\\_medium=cpc&utm\\_campaign=Journal\\_of\\_American\\_Medical\\_Association\\_TrendMD\\_1&utm\\_content=olf&utm\\_term=021121](https://jamanetwork.com/journals/jama/fullarticle/2776542?guestAccessKey=9e0c2f1d-0a51-444d-b3a4-cf1b84766df1&utm_source=TrendMD&utm_medium=cpc&utm_campaign=Journal_of_American_Medical_Association_TrendMD_1&utm_content=olf&utm_term=021121).

an international level may be established. A factor that contributes to the delayed response time during public health crises, like the H1N1 outbreak or COVID-19 pandemic, is the lack of international cooperation and cohesion.<sup>15</sup> Therefore, this Note will also argue that the compulsory licensing system in the United States should be updated to match the Trade Related Intellectual Property Rights (TRIPS) agreement system that is used on an international level. Without a cohesive international system in place, there will always be a divide which will continue to contribute to trade conflicts, lack of access to patented medical technologies for low-income nations and worsening international relations.<sup>16</sup>

This Note will be divided into seven parts. Part II will discuss the recent COVID-19 pandemic and how it has changed the public views on global health and technology. Part III will explain the background and history of patents, ultimately focusing on compulsory licensing and how it is used as a safeguard against intellectual property right exploitation, including patent protections that block public health interests. Part IV will discuss the argument for strengthening compulsory licensing procedures, including the merits of building an internationally cohesive system. Part V will address the main arguments against removing patent protections from public health innovations. Part VI will analyze the issues and argue that a compulsory licensing system serves the interests of progress and global health by providing lifesaving medicine to lower income

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<sup>15</sup> Andrew Green, *COVID-19: Countries Race to Strengthen Compulsory Licensing Legis.*, DEVEX (June 30, 2020), <https://www.devex.com/news/covid-19-countries-race-to-strengthen-compulsory-licensing-legislation-97595>; Graham Dutfield, *Coronavirus*, CONVERSATION (July 1, 2020, 10:27 AM), <https://theconversation.com/coronavirus-it-is-morally-indefensible-for-a-nation-to-keep-life-saving-drugs-for-itself-141734>; Olga Gurgula & Wen H. Lee, *COVID-19, IP & Access*, J. GENERIC MEDICINES (June 6, 2021), <https://doi.org/10.1177/1741134321993182>; Ana Santos Rutschman, *How 'Vaccine Nationalism' Could Block Vulnerable Pop.'s Access COVID-19 Vaccines*, CONVERSATION (June 17, 2020, 8:16 AM), <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689>.

<sup>16</sup> Markus Overdiek & Thomas Rausch, *World Class Pats. Cutting-Edge Tech.: N. Am.*, BERTELSMANN STIFTUNG'S GLOB. ECON. DYNAMICS PROJECT (July 3, 2020), <https://ged-project.de/digitization-and-innovation/world-class-patents-in-cutting-edge-technologies-north-america/#:~:text=The%20US%20E2%80%93%20A%20class%20of,eight%20%20takes%20second%20place.>

nations. Ultimately, this Note will conclude that changing compulsory licensing for public health innovations will help public health interests internationally without negatively affecting individual and corporate motivation to innovate and research groundbreaking solutions and treatments.

## II. THE PANDEMIC, VACCINES, DISTRIBUTION, AND MANUFACTURING

A significant reason that the COVID-19 pandemic dragged on for as long as it did was the nature of the virus and its remarkable ability to mutate and create variants. For a brief period of time at the end of 2020, it appeared as if COVID-19 was on its way toward becoming endemic, with the emergent variants differing only slightly from the original strain of the virus.<sup>17</sup> The vaccines appeared to be working properly against the Alpha and Beta strains and it appeared that the global and national shutdowns were a thing of the past.<sup>18</sup> Then,

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<sup>17</sup> “Endemic” means that a disease is commonly found in an area. For a pandemic to become endemic, “enough people will gain immune protection from vaccination and from natural infection such that there will be less transmission and much less...hospitalization and death, even as the virus continues to circulate.” Karen Feldscher, *What Will It Be Like When COVID-19 Becomes Endemic?*, HARVARD SCH. PUB. HEALTH (Aug. 11, 2021), <https://www.hsph.harvard.edu/news/features/what-will-it-be-like-when-covid-19-becomes-endemic/>; Hannah Miao, *Pfizer Exec. Covid Could Become Endemic By 2024*, CONSUMER NEWS BUS. CHANNEL (Dec. 17, 2021), <https://www.cnbc.com/2021/12/17/pfizer-executives-say-covid-could-become-endemic-by-2024.html>; Sigal Samuel, *Despite Omicron, Covid-19 Will Become Endemic*, VOX, (Jan. 1, 2022), <https://www.vox.com/future-perfect/22849891/omicron-pandemic-endemic>; CTR. DISEASE CONTROL PREVENTION, *Identifying Source Outbreak*, (updated July 1, 2020), [https://www.cdc.gov/coronavirus/2019-ncov/science/about-epidemiology/identifying-source-outbreak.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fabout-epidemiology%2Fidentifying-source-outbreak.html](https://www.cdc.gov/coronavirus/2019-ncov/science/about-epidemiology/identifying-source-outbreak.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fabout-epidemiology%2Fidentifying-source-outbreak.html).

<sup>18</sup> Hannah Beech & Livia Albeck-Ripka, *Delta Variant Surges, Outbreaks Return Many Parts of the World*, NY TIMES (June 30, 2021), <https://www.nytimes.com/2021/06/30/world/asia/virus-delta-variant-global.html>; WHITE HOUSE BRIEFING ROOM, *Pres. Biden Announces New Actions Protect Ams. Against Delta & Omicron Variants* Dec. 2, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/>; Aya Alamroussi,

enter Delta. The Centers for Disease Control and Prevention (CDC) as well as the World Health Organization (WHO) first called attention to the Delta variant, which was initially identified in India in late 2020.<sup>19</sup> The Delta variant threw off the course to endemic status as it was twice as contagious as previous variants. Delta introduced the first concerns about breakthrough infections in vaccinated individuals and spiking cases, hospitalizations, and deaths in unvaccinated individuals.<sup>20</sup> In many countries, Delta launched a step back into restrictions and mask mandates, with wealthy countries exploring booster doses of the vaccines.<sup>21</sup>

Delta was later overshadowed by the panic surrounding the Omicron variant, which was initially identified in South America in November 2021.<sup>22</sup> Omicron is the more recent strain, and it has posed some serious issues. First, Omicron is more transmissible than Delta and all of the previous strains of COVID-19 thus far.<sup>23</sup> Since more than thirty of Omicron's mutations are on the virus's spike protein, part of its enhanced transmissibility may come from its ability to evade some immune responses, especially in individuals who were previously infected but not vaccinated.<sup>24</sup> The mutations have also

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*Delta Variant 'Covid-19 On Steroids,'* CABLE NEWS NETWORK (July 9, 2021), <https://www.cnn.com/2021/07/08/health/us-coronavirus-thursday/index.html>; Rob Stein, *Fauci Warns Dangerous Delta Variant Greatest Threat U.S. COVID Efforts*, NAT'L PUB. RADIO (June 22, 2021), <https://www.npr.org/sections/health-shots/2021/06/22/1008859705/delta-variant-coronavirus-unvaccinated-u-s-covid-surge>; *Delta Variant*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>19</sup> *Delta Variant*, *supra* note 14; *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>20</sup> *Delta Variant*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>21</sup> *Delta Variant*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>22</sup> *Delta Variant*, *supra* note 14; *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>23</sup> *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mascola et al., *supra* note 14.

<sup>24</sup> *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mascola et al., *supra* note 14.



changed the symptoms that have shown up in the general population when infected with Omicron. The Omicron variant in particular has posed some difficulty because Omicron symptoms can look similar to a common cold in vaccinated individuals – but can still be spread by those with mild or no symptoms.<sup>25</sup>

The emergence of these variants demonstrated two major points. First, that “emergency conditions” can last much longer than the compulsory licensing system currently considers.<sup>26</sup> Second, that global health emergencies no longer consider borders and that nationally divided measures will do little to stop the spread of diseases – even with precautions and travel bans or restrictions.

Regarding the COVID-19 vaccine, many also believe that relief from patent protection will not help the global distribution problem.<sup>27</sup> Instead, pharmaceutical companies, healthcare researchers, and some governments point to low manufacturing capacity, not patents, as the biggest impediment to global vaccination efforts.<sup>28</sup> This point may have held some truth in the past, but recent developments have changed the market costs. The vaccines that have been created thus far are complex to produce and difficult to maintain after production. In the United States, the available vaccine brands are Moderna, Pfizer, Johnson & Johnson, and, as of July 2022, Novavax.<sup>29</sup>

<sup>25</sup> Bob Curley, *Omicron Symptoms*, HEALTHLINE, (Jan. 14, 2022), <https://www.healthline.com/health-news/omicron-symptoms-how-they-compare-with-other-coronavirus-variants?c=456499417593>; Priya Joi, *Top 5 Omicron Symptoms Aware*, GLOB. ALL. VACCINES IMMUNIZATIONS, (Jan. 18, 2022), <https://www.gavi.org/vaccineswork/top-5-symptoms-be-aware-omicron>; U. CAL. DAVIS HEALTH, *Omicron Variant*, (updated Jan. 28, 2022), <https://health.ucdavis.edu/coronavirus/covid-19-information/omicron-variant>.

<sup>26</sup> Broadly, these licenses will expire after one year or earlier if the emergency has ended. World Trade Org., Ministerial Declaration of 14 November 2001, WTO Doc. T/MIN(01)/DEC/1, 41 ILM 746 (2002).

<sup>27</sup> James Bacchus, *Unnecessary Proposal*, CATO INST. (Dec. 16, 2020), <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>; William A. Reinsch et al., *Compulsory Licensing*, CTR. FOR STRATEGIC & INT’L STUDIES (May 2020), <https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure>; Reto Hilty et al., *10 Arguments Against Waiver Of Intell. Prop. Rts.*, U. OXFORD FAC. L. (June 29, 2021), <https://www.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights>.

<sup>28</sup> Bacchus, *supra* note 27; Hilty, *supra* note 27.

<sup>29</sup> Mark Terry, *UPDATED Comparing COVID-19 Vaccines*, BIOSPACE (Oct. 8, 2021), <https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/>; WORLD HEALTH

Outside of the United States, the AstraZeneca-University of Oxford vaccine is widely distributed, with Novavax also being a popular option in the European Union.<sup>30</sup> AstraZeneca decided to request full approval in the U.S rather than emergency use authorization.<sup>31</sup> The Moderna and Pfizer vaccines are mRNA technology-based, Johnson & Johnson and AstraZeneca-University of Oxford vaccines use adenovirus technology, and the Novavax COVID-19 vaccine contains the SARS-CoV-2 spike protein and a matrix-M adjuvant.<sup>32</sup>

The mRNA technology used by Moderna and Pfizer works by introducing a small piece of single-stranded RNA that is complementary to a section of the virus's genetic material.<sup>33</sup> The mRNA complements a spike protein sequence, which is a protein on the surface of the virus.<sup>34</sup> The vaccines suspend the mRNA sequence in a nanolipid to introduce the code to the host's cells.<sup>35</sup> By introducing the spike protein sequence to the vaccinated subject, the body develops a response with specialized antibodies and learns to recognize the virus ahead of time.<sup>36</sup> Then, if the subject comes into contact with the virus, the body will be able to launch the antibodies and head off severe illness.<sup>37</sup> The potent immune response elicited from mRNA vaccines, along with the capacity for rapid development and potential for low-cost manufacture and safe administration, makes them a major player in future research prospects, and of course, a major breakthrough in the fight against the COVID-19 pandemic.<sup>38</sup> The two

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ORG., *The Novavax Vaccine Against COVID-19: What You Need to Know*, (June 13, 2022), <https://www.who.int/news-room/feature-stories/detail/the-novavax-vaccine-against-covid-19-what-you-need-to-know>.

<sup>30</sup> *Id.*; Terry, *supra* note 29.

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

<sup>32</sup> *Id.*; James Shea, *Johnson & Johnson Vaccine*, VCU HEALTH (May 2021) <https://www.vcuhealth.org/news/covid-19/johnson-and-johnson-vaccine-how-is-it-different>; U.S. FOOD AND DRUG ADMIN., *Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted*, (July 13, 2022), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted>.

<sup>33</sup> Terry, *supra* note 29; Norbert Pardi et al., *MRNA Vaccines — New Era Vaccinology*, 17 NATURE REVIEWS DRUG DISCOVERY 261 (2018), <https://www.nature.com/articles/nrd.2017.243>.

<sup>34</sup> Terry, *supra* note 29.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*; CTR. FOR DISEASE CONTROL, MYTHS & FACTS ABOUT COVID-19 VACCINES (Oct. 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>.

<sup>37</sup> *Id.*; Terry, *supra* note 29.

<sup>38</sup> *Id.*; Pardi et al., *supra* note 33.

mRNA vaccines boast high performance, with Moderna's vaccine demonstrating approximately ninety-five percent efficacy in adults in phase III trials and Pfizer's vaccine demonstrating ninety-five percent immunity in phase III trials.<sup>39</sup> Pfizer's vaccine received full FDA approval on August 23, 2021, while Moderna's vaccine received full approval on January 31, 2022.<sup>40</sup>

The cost of manufacturing these vaccines is estimated to be \$19.50 per dose for the Pfizer brand and between \$23 and \$25 per dose for the Moderna brand.<sup>41</sup> Since these vaccines require two doses, the cost per individual is between approximately \$39 and \$50.<sup>42</sup> Pfizer reported sales its COVID-19 vaccine to be \$36.8 billion in 2021, and Moderna reported \$17.7 billion the sales of 807 million doses of the vaccine in 2021.<sup>43</sup>

The initial difficulty in implementing the mRNA vaccines was storage and shipment concerns.<sup>44</sup> Due to the nature of the vaccine components, namely the mRNA suspended in nano-lipids, the mRNA vaccines needed to be stored at low temperatures.<sup>45</sup> Additionally, with two doses required for the mRNA vaccines to be effective, twice the number of doses needed to be manufactured and shipped.<sup>46</sup> The Pfizer vaccine was developed to be stored at negative ninety-four degrees Fahrenheit.<sup>47</sup> However, Moderna later revealed that its vaccine is stable at thirty-six to forty-six degrees Fahrenheit, about the temperature of a standard refrigerator, for up to 30 days. The Moderna vaccine can also be stored for up to six months at negative four degrees Fahrenheit, about the temperature of a freezer set to extra cold.<sup>48</sup>

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<sup>39</sup> Terry, *supra* note 29.

<sup>40</sup> *Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2022), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>; Terry, *supra* note 29.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

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

<sup>45</sup> *Id.*; MODERNA, *supra* note 12.

<sup>46</sup> *Id.*; Pardi et al., *supra* note 33.

<sup>47</sup> Terry, *supra* note 29.

<sup>48</sup> Berkeley Lovelace Jr., *Moderna COVID Vaccine Remain Stable Refrigerated Temperatures 3 Months*, CNBC HEALTH & SCI. (Apr. 29, 2021) <https://www.cnbc.com/2021/04/29/moderna-covid-vaccine-can-remain-stable-at-refrigerated-temps-for-3-months.html>.

Therefore, the major cost obstacles of storing and distributing an mRNA vaccine are avoidable.

In contrast to the mRNA vaccines, the Johnson & Johnson and AstraZeneca-University of Oxford vaccines are a disabled adenovirus vaccine.<sup>49</sup> It takes a different virus - not COVID-19 - that is disabled to deliver the COVID-19 protein information to the body's immune system. The disabled, coded virus is detected by the immune system to create the antibodies needed for immunity.<sup>50</sup> Like any other adenovirus vaccine, the Johnson & Johnson vaccine needs to be stored in a refrigerator between thirty-six and forty-six-degrees Fahrenheit.<sup>51</sup> However, the CDC has stated that the Pfizer and Moderna vaccines are preferred over the Johnson & Johnson's Janssen vaccine due to safety concerns and lack of effectivity against some prevalent variants.<sup>52</sup>

### III. THE PATENT SYSTEM: BACKGROUND AND HISTORY

The current United States patent system has changed and grown tremendously from its early beginnings. It was originally established by Article 1, Section 8, Clause 8 of the U.S. Constitution and was included largely through the efforts of Thomas Jefferson.<sup>53</sup> Ironically, Thomas Jefferson himself was an inventor and is credited for several inventions, yet never filed a patent for a single invention.<sup>54</sup> He strongly opposed patents and considered them an unfair monopoly, believing instead that knowledge should be freely available to the public to work with and build on.<sup>55</sup> Indeed, the entire U.S. patent

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<sup>49</sup> Terry, *supra* note 29; Shea, *supra* note 32.

<sup>50</sup> Terry, *supra* note 29; CTR. FOR DISEASE CONTROL, *supra* note 36; Shea, *supra* note 32.

<sup>51</sup> Terry, *supra* note 29; Shea, *supra* note 32.

<sup>52</sup> Terry, *supra* note 29; Shea, *supra* note 32; CTR. DISEASE CONTROL PREVENTION, *Johnson & Johnson's Janssen COVID-19 Vaccine: Overview and Safety*, (updated July 14, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html>.

<sup>53</sup> U.S. CONST. art. I, § 8, cl. 8; Adam Mossof, *Who Cares What Thomas Jefferson Thought About Pat. - Reevaluating Pat. Privilege Hist. Context*, 92 CORNELL L.R. 954, 954-56 (2007), <https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=3067&context=clr>.

<sup>54</sup> Mossof, *supra* note 53.

<sup>55</sup> Mossof, *supra* note 53.

system is predicated on the idea that humanity needs incentives to create inventions and promote progress.<sup>56</sup>

At the height of the global AIDS crisis in 2001, governments whose citizens were dying because they could not afford life-saving medicines pressured the World Trade Organization (WTO) to confront the battle between intellectual property and public health.<sup>57</sup> The resulting Doha Declaration ruled that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) “should not prevent members from taking measures to protect public health.”<sup>58</sup>

In 2017, the TRIPS agreement was amended to improve access to affordable medicines for developing countries lacking drug manufacturing capacity and large-scale purchase power.<sup>59</sup> The newly added Article 31*bis* replaces a previous temporary waiver that gave the legal basis for WTO members to grant special compulsory licenses for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their national need.<sup>60</sup>

At the time of the amendment, no one could have seen what was coming. In January 2020, the United States experienced its first confirmed COVID-19 case and in March, the country shut down to avoid the continued spread of the disease while further research was done to find treatments and cures and hospitals and intensive care units were overwhelmed with patients, often without enough space or

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<sup>56</sup> PETER S. MENELL ET AL., INTELL. PROP. NEW TECH. AGE: 2020 156 (2020); Brink Lindsey, *Why Intell. Prop. & Pandemics Don't Mix*, BROOKINGS INST., (June 3, 2021), <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>; Russ Slifer, *U.S. Broken Pat. Sys. Getting Worse*, THE HILL, (Aug. 14, 2019, 06:15 PM), <https://thehill.com/blogs/congress-blog/technology/457476-the-united-states-broken-patent-system-is-getting-worse>.

<sup>57</sup> Green, *supra* note 15.

<sup>58</sup> World Trade Org., Ministerial Declaration of 14 November 2001, WTO Doc. T/MIN(01)/DEC/1, 41 ILM 746 (2002).

<sup>59</sup> WORLD TRADE ORG., AGREEMENT ON TRADE-RELATED ASPECTS INTELL. PROP. RTS. (as amended on Jan. 23, 2017), [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm); Hilary Wong, *Case Compulsory Licensing During COVID-19*, 10 J. GLOB. HEALTH 010358 (2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/>; Eduardo Urias & Shyama V. Ramani, *Access Med. After TRIPS*, J. INT'L BUS. POL'Y 1–18 (2020). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7468182/>.

<sup>60</sup> WORLD TRADE ORG., *supra* note 59.

equipment for proper treatment.<sup>61</sup> In December 2020, the Food and Drug Administration (FDA) approved emergency usage authorization of several vaccine brands in the United States, and the first COVID-19 vaccine was administered in the United States.<sup>62</sup> Soon after, other nations purchased or funded vaccines, including the AstraZeneca-Oxford University Vaccine in the United Kingdom and Sputnik vaccine in Russia.<sup>63</sup> The United States and other first-world countries were able to quickly purchase vaccines for public distribution, leaving many third-world countries and developing nations struggling to continue to survive the pandemic without vaccination.<sup>64</sup>

In May 2021, President Joe Biden surprised the world when he publicly backed waiving patents on COVID-19 vaccines to allow broad generic manufacture of the vaccines for global markets.<sup>65</sup> The move simultaneously prioritized public health and put Biden directly at odds with big pharmaceutical companies, including Pfizer, Moderna, and Johnson & Johnson.<sup>66</sup> It also opened a debate into the nature of patents in general and whether the theory behind patents is the best way to drive innovation and support public health. Many are left questioning the statutory safety measures that exist for emergencies, including compulsory licensing.

COVID-19 is not the first nor the last public health emergency, and it has shed light on the impact of wealth on health outcomes globally.<sup>67</sup> The capitalist focus of patent protection may not have a

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<sup>61</sup> CONG. RSCH. SERV., OPERATION WARP SPEED CONTS. FOR COVID-19 VACCINES & ANCILLARY VACCINATION MATERIALS (Mar. 2021), <https://crsreports.congress.gov/product/pdf/IN/IN11560>.

<sup>62</sup> Terry, *supra* note 29.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> Anshu Siripurapu, *Debate Over Pat. Waiver for COVID-19 Vaccines*, COUNCIL ON FOREIGN REL. (May 26, 2021) <https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know>.

<sup>66</sup> Lindsey, *supra* note 56.

<sup>67</sup> U.N., *COVID-19 & Hum. Rts.*, (Apr. 2020), [https://www.un.org/victimsofterrorism/sites/www.un.org.victimsofterrorism/files/un\\_-\\_human\\_rights\\_and\\_covid\\_april\\_2020.pdf](https://www.un.org/victimsofterrorism/sites/www.un.org.victimsofterrorism/files/un_-_human_rights_and_covid_april_2020.pdf); Gurgula & Lee, *supra* note 15; Richard Milne & David Crow, *Why Vaccine 'Nationalism' Could Slow Coronavirus Fight*, FIN. TIMES (May 14, 2020), <https://www.ft.com/content/6d542894-6483-446c-87b0-96c65e89bb2c>; Maria Cheng & Christina Larson, *Race for Virus Vaccine Could Leave Some Countries Behind*, ASSOC. PRESS (June 18, 2020), <https://apnews.com/article/united-nations-health-us-news-ap-top-news-virus-outbreak-4b93252bb290874c7c295cd2cb1a620c>; Santos Rutschman, *supra* note 15; Dutfield, *supra* note 15; Malik Peiris & Gabriel M. Leung, *What Can We Expect*

place in the world of health as this disparity continues to grow and more and more people die without access to life-saving technology that cannot be widely distributed due to patent protection.<sup>68</sup>

Though the patent waiver is now backed by President Biden, it was opposed by many Democratic and Republican politicians and leaders in intellectual property law as it was seen as a way to undermine intellectual property rights rather than a move to strengthen public health.<sup>69</sup> Additionally, a formal waiver process needs to pass through the WTO to be globally effective and help low and medium-income nations afford vaccine costs for free public distribution.<sup>70</sup> However, the WTO notoriously moves slowly, and other world powers including the European Union (EU) and the United Kingdom (UK) have been reluctant to support intellectual property waivers.<sup>71</sup>

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*From First-Gen. COVID-19 Vaccines?*, LANCET (Sept. 21, 2020), [https://doi.org/10.1016/S0140-6736\(20\)31976-0](https://doi.org/10.1016/S0140-6736(20)31976-0); Nurith Aizenman, *Why Low Income Countries Short On COVID Vaccines*, NAT. PUB. RADIO (Nov. 10, 2021, 7:11 PM), [https://www.npr.org/sections/goatsandsoda/2021/11/10/1052078529/why-low-income-countries-are-so-short-on-covid-vaccines-hint-its-not-boosters?utm\\_medium=social&utm\\_source=facebook.com&utm\\_campaign=npr&utm\\_term=nprnews](https://www.npr.org/sections/goatsandsoda/2021/11/10/1052078529/why-low-income-countries-are-so-short-on-covid-vaccines-hint-its-not-boosters?utm_medium=social&utm_source=facebook.com&utm_campaign=npr&utm_term=nprnews); Tove Iren S. Gerhardsen, *Brazil Takes Steps Import Cheaper AIDS Drug Under Trade Law*, IP WATCH (May 7, 2007, 1:50 PM), <https://www.ip-watch.org/2007/05/07/brazil-takes-steps-to-import-cheaper-aids-drug-under-trade-law/>.

<sup>68</sup> U.N., *supra* note 67; Gurgula & Lee, *supra* note 15; Milne & Crow, *supra* note 67; Cheng & Larson, *supra* note 67; Santos Rutschman, *supra* note 15; Dutfield, *supra* note 15; Peiris & Leung, *supra* note 67; Aizenman, *supra* note 67; Gerhardsen, *supra* note 67.

<sup>69</sup> Siripurapu, *supra* note 65; Lindsey, *supra* note 56.

<sup>70</sup> Green, *supra* note 15.

<sup>71</sup> Siripurapu, *supra* note 65; Enrico Bonadio & Filippo Fontanelli, *Push For COVID-19 Vaccine Pat. Waiver Panacea*, CONVERSATION (May 12, 2021) <https://theconversation.com/push-for-covid-19-vaccine-patent-waiver-isnt-a-panacea-but-it-could-nudge-companies-to-share-160802>; Bacchus, *supra* note 27. In a recently published study, intellectual property experts in Nigeria were administered a survey in which 81.2% agreed that the role of patents is to promote innovation, but 70.6% agreed that intellectual property waivers can improve access to COVID-19 vaccines. Obi Peter Adigwe & Davidson Oturu, *The role of patent waivers and compulsory licensing in facilitating access to COVID-19 vaccines: Findings from a survey among healthcare practitioners in Nigeria*, PUB. LIBR. SCI. (July 7, 2022), <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0000683>; “This study has revealed that there is a need for intellectual property rights waiver and compulsory licensing of all novel COVID-19 commodities including vaccines, as this is an important strategy that can improve access to relevant products in developing countries.” *Id.*

Compulsory licensing, a provision in the TRIPS Agreement that enables governments to supply their citizens with generic versions of patented treatments either through domestic production or imports, is a possible safeguard against strict patent protections in times of global emergency, such as is the case with COVID-19.<sup>72</sup> Title 28, section 1498 of the United States Code acts as a compulsory licensing statute since it allows patent owners to sue the federal government for compensation, but not an injunction, when the government invades their patent rights without permission.<sup>73</sup> In a pandemic situation like the COVID-19 outbreak, the government might authorize a company to manufacture patented drugs or vaccines if the patent owner is unable to meet the full market demand or if the government deems the drug prices to be too high.<sup>74</sup> Under this statute, the government cannot nullify or forcibly transfer patent titles.<sup>75</sup>

Compulsory licensing has the potential to help governments avoid the obstacles of patent protection to guarantee that public health innovations remain accessible and widely distributed. The process of compulsory licensing can and should be changed to serve as a public health safeguard to allow global distribution of life-saving technology.<sup>76</sup> However, compulsory licensing is not the only option. Absent a patent waiver, governments around the world could also begin to establish parallel importation schemes, which allow officials to import and resell patented drugs, and potentially vaccines, from another country where they may be marketed for less than the price set by the patent holder.<sup>77</sup> This would be particularly useful for low-income nations. Since the patent price has already been paid once, these arrangements do not violate international trade regulations.<sup>78</sup> However, in high-income nations like the United States, this can start WTO disputes and interrupt international relations.<sup>79</sup>

The subsequent question, of course, then becomes why should we who live in a wealthy nation like the United States care about low-

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<sup>72</sup> Wong, *supra* note 59; Lindsey, *supra* note 56.

<sup>73</sup> 28 U.S.C. § 1498; Kyung-Bok Son, *Importance Intell. Prop. Sys. Attempting Compulsory Licensing Pharmaceuticals*, BIOMED CENT.: GLOB. HEALTH 15, 42 (2019), <https://doi.org/10.1186/s12992-019-0485-7>.

<sup>74</sup> CONG. RSCH. SERV., *supra* note 61.

<sup>75</sup> 3rd Eye Surveillance, LLC v. U.S., 151 Fed. Cl. 49 (Cl. Ct. Feb. 9, 2022).

<sup>76</sup> Bonadio & Fontanelli, *supra* note 71; Bacchus, *supra* note 27.

<sup>77</sup> Urias & Ramani, *supra* note 59.

<sup>78</sup> *Id.*; Green, *supra* note 15; Siripurapu, *supra* note 65.

<sup>79</sup> Urias & Ramani, *supra* note 59; Siripurapu, *supra* note 65.



income countries affording medication or not – especially when many Americans refuse to be vaccinated at all.<sup>80</sup> There is the honorable argument that as world leaders, higher-income countries should look out for lower-income countries and their well-being to encourage equity, development, peace, and international cooperation.<sup>81</sup> However, the more practical and realistic argument, especially concerning COVID-19 and its continuously evolving and spreading variants, is that no one nation will be able to buy its way out of the pandemic and be free of the disease if other nations are still struggling and remain unvaccinated.<sup>82</sup> While other nations remain plagued, no amount of travel restrictions or quarantine time will stop the spread of the pandemic, or its mutation, as effectively as global immunity through vaccines.<sup>83</sup>

#### IV. THE ARGUMENT FOR COMPULSORY LICENSING

Compulsory licensing is the process by which a government may authorize production and distribution of a patented product without the consent of the patent owner.<sup>84</sup> The government itself need not be the producer or distributor and can pursue compulsory licensing on a third party's behalf.<sup>85</sup> This process has been a part of the TRIPS agreement since its enactment in 1995 and applies to all countries that

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<sup>80</sup> Julie Bosman et al., *Who Are Unvaccinated Americans?*, N.Y. TIMES, July 31, 2021 (updated Oct. 24, 2021), <https://www.nytimes.com/2021/07/31/us/virus-unvaccinated-americans.html>. The irony of the anti-vaccination movement in the United States while many developing nations struggle to acquire enough vaccines for their citizens who desperately want them is too painful not to note.

<sup>81</sup> Milne & Crow, *supra* note 67; Cheng & Larson, *supra* note 67; Rutschman, *supra* note 15; “Borderless open and collaborative science and the free exchange of knowledge and data will get us to vaccines and cures faster than by any other way.” Dutfield, *supra* note 15.

<sup>82</sup> Milne & Crow, *supra* note 67; Cheng & Larson, *supra* note 67; Rutschman, *supra* note 15; Dutfield, *supra* note 15; Aizenman, *supra* note 67.

<sup>83</sup> Rutschman, *supra* note 15; Dutfield, *supra* note 15; This is also true for vaccination against many diseases including smallpox, measles, and polio.

<sup>84</sup> WORLD TRADE ORG., *Compulsory Licensing Pharm. & TRIPS*, (2022), [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm); WORLD TRADE ORG., *Fact Sheet: TRIPS and Pharm. Pats. Obligations & Exceptions*, (Sept. 2006), [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm); CONG. RSCH. SERV., *Potential WTO TRIPS Waiver & COVID-19*, (Sept. 13, 2021), <https://crsreports.congress.gov/product/pdf/IF/IF11858>.

<sup>85</sup> WORLD TRADE ORG., *supra* note 84; *Fact Sheet*, *supra* note 84; CONG. RSCH. SERV., *supra* note 84.

are a part of the WTO.<sup>86</sup> The TRIPS Agreement does not specifically list the reasons that justify the use of compulsory licensing. However, the Doha Declaration confirms that countries are free to determine the grounds for granting compulsory licenses and to define what constitutes a national emergency warranting the action.<sup>87</sup>

Just as there are arguments against the limitation of intellectual property rights through compulsory licensing and other trade loopholes, there are arguments that support moving the intellectual property right balance to favor public health interests more than property rights protections.<sup>88</sup> The most prominent reasons for compulsory licensing support are reduced price of and greater access to patented goods and services that are critical for the public health of low-income countries, while still preserving the patent rights owner's stake in the product following the emergency period.<sup>89</sup> Compulsory licenses of patents generally result in lower costs of the patented product by allowing local manufacturers to produce the product or service without going through the patent owner first.<sup>90</sup> Studies place savings at around 70% with the royalty rate granted to the patent owner typically between 1% and 5%.<sup>91</sup> Sometimes, even just the threat of

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<sup>86</sup> WORLD TRADE ORG., *supra* note 84; *Fact Sheet*, *supra* note 84; CONG. RSCH. SERV., *supra* note 84.

<sup>87</sup> World Trade Org., Ministerial Declaration of 14 November 2001, WTO Doc. T/MIN(01)/DEC/1, 41 ILM 746 (2002).

<sup>88</sup> Randall Kuhn & Reed F. Beall, *Time For Pharm. Compulsory Licensing Has Expired*, NATURE MED. (Aug. 6, 2012), [https://www.researchgate.net/publication/230623521\\_The\\_time\\_for\\_pharmaceutical\\_compulsory\\_licensing\\_has\\_expired](https://www.researchgate.net/publication/230623521_The_time_for_pharmaceutical_compulsory_licensing_has_expired); Wong, *supra* note 59; Lindsey, *supra* note 56.

<sup>89</sup> Urias & Ramani, *supra* note 59; Danielle Navarro & Marcela Vieira, *Rsch. Synthesis: Compulsory Licensing*, GLOB. HEALTH CTR. GRADUATE INST., GENEVA (Feb. 2021), <https://www.knowledgeportalia.org/compulsory-licensing>; Reinsch, et al, *supra* note 27.

<sup>90</sup> Urias & Ramani, *supra* note 59; Navarro & Vieira, *supra* note 89; James Packard Love, *Recent Examples Use Compulsory Licenses Pats.*, KNOWLEDGE ECOLOGY INT'L (Mar. 8, 2007), [https://www.keionline.org/misc-docs/recent\\_cls\\_8mar07.pdf](https://www.keionline.org/misc-docs/recent_cls_8mar07.pdf); Gerhardsen, *supra* note 67.

<sup>91</sup> With even a threat of compulsory licensing, savings may sometimes higher or lower, or discounts may be applied. Urias & Ramani, *supra* note 59; Navarro & Vieira, *supra* note 89; Son, *supra* note 73; Gerhardsen, *supra* note 67. Negotiations between Merck with Brazil and Thailand for the HIV/AIDS drug Efavirenz show that the pharmaceutical companies offered their lowest prices after receiving a compulsory license. *Id.*

Brazil had achieved a price for efavirenz of \$580 per patient per year earlier when it had threatened to use compulsory license. But

compulsory license is enough to push a patent holder to work with governments to provide better access to patented products.<sup>92</sup> This can be most clearly demonstrated through Pfizer's predictions and discussion of the pricing and distribution of its COVID-19 vaccine after the pandemic emergency has passed. Pfizer's Chief Financial Officer said that "obviously," the company is "going to get more on price" after the "pandemic pricing environment."<sup>93</sup> The pharmaceutical company anticipates its earnings will increase from fifteen billion dollars in 2020 to up to three to four times more after it rescinds "pandemic pricing" and moves to continuous distribution of booster vaccines doses.<sup>94</sup> As of early 2021, Pfizer was charging the U.S. \$19.50 per dose, which the company noted is not a normal price; Pfizer would typically charge anywhere from \$150 to \$175 per dose of its vaccine.<sup>95</sup> The support of the waiver and the "pandemic pricing" conditions are factors that have pushed Pfizer to continue to allow the vaccinations to be purchased by the government for less, thereby allowing U.S. citizens to temporarily receive the vaccinations for free and extend booster doses to the public.<sup>96</sup> While no one can say for sure if Pfizer would have taken it upon itself to offer this reduced price given competing vaccines and support from President Biden, it seems very likely that the company would have skipped the "pandemic

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this was too expensive compared with the price for generics (Thailand was offered \$244 per patient per year after it issued a [compulsory license]), and thus Brazil has paid too much for too many years . . . *Id.*

Additionally, few or no licenses are issued, repeated; hollow threats of use erode the negotiating power of the compulsory license. *Id.*

<sup>92</sup> Gerhardsen, *supra* note 67. *People Over Pat.: How Govs. Preparing Make COVID-19 Med. Accessible*, PUB. CITIZEN (Aug. 10, 2020), <https://www.citizen.org/article/people-over-patents/> (hereinafter "Pub. Citizen").

<sup>93</sup> Eric Sagonowsky, *Pfizer Eyes Higher Prices For COVID-19 Vaccine After Pandemic Wanes: Exec., Analyst*, IP WATCHDOG (Feb. 23, 2021, 12:09 PM), <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>.

<sup>94</sup> *Id.*; *Edited Transcript Pfizer Inc. Earnings Call Q4-2020*, (Feb. 2, 2021, 3:00 PM GMT), [https://s21.q4cdn.com/317678438/files/doc\\_financials/2020/q4/PFE-USQ\\_Transcript\\_2021-02-02.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USQ_Transcript_2021-02-02.pdf) (hereinafter "Pfizer Earnings call").

<sup>95</sup> *Id.* Sagonowsky, *supra* note 93.

<sup>96</sup> *Id.* Seemantani Sharma, *A Survey Intell. Prop. Issues Between U.S. & India Under Special 301 Report*, N.C. J. INT'L L. (2018), <https://scholarship.law.unc.edu/cgi/viewcontent.cgi?article=2044&context=ncilj>.

pricing” for a bigger payout given the company leadership’s attitude on the subject.<sup>97</sup>

The problem of pharmaceutical companies demanding more than they are willing to accept is not just limited to the United States or to the COVID-19 vaccines. Countries including Israel, Russia, Chile, Ecuador, France, Germany, Brazil, Indonesia, and Canada have issued or proposed the issuance of compulsory licenses or similar legislative measures to ensure that COVID-19 medications and vaccines are readily available for a lower-than-market price.<sup>98</sup> The price gouging that occurs between pharmaceutical companies and governments drives higher-income countries into a frenzy where they buy out as much stock as possible, thereby preventing lower-income countries from being able to afford to purchase vaccine doses, medication, or other public-health necessities.<sup>99</sup>

However, in lower income nations even the lower cost of patented products may not be enough to utilize compulsory licensing.<sup>100</sup> While compulsory licensing may add force of law behind

<sup>97</sup> Sagonowsky, *supra* note 93; *Pfizer Earnings Call*, *supra* note 94.

<sup>98</sup> *Id.* Polina Ivanova, *Rus. Firm Seeks Produce COVID-19 Drug Remdesivir Without Pat.*, REUTERS HEALTHCARE & PHARM. (Nov. 2, 2020, 3:23 AM), <https://www.reuters.com/article/us-health-coronavirus-russia-remdesivir/russian-firm-seeks-to-produce-covid-19-drug-remdesivir-without-patent-idUSKBN27I0QH>; Ed Silverman, *Chilean Lawmakers Support Compulsory Licensing For Coronavirus Med. & Vaccines*, STAT PHARMALOT (Mar. 18, 2020), <https://www.statnews.com/pharmalot/2020/03/18/chile-compulsory-licensing-coronavirus-covid19-vaccines/>; Ed Silverman, *Ecuador Becomes Latest Country Eye Compulsory Licensing For Covid-19 Prods.*, STAT PHARMALOT (Mar. 23, 2020), <https://www.statnews.com/pharmalot/2020/03/23/ecuador-compulsory-licensing-covid19-coronavirus/>; PUB. CITIZEN, *supra* note 92.

<sup>99</sup> Aizenman, *supra* note 67.

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[S]ome countries fear retaliation both from other countries and from pharmaceutical companies. In 2007, when Thailand issued its compulsory license under Article 31, both the United States and European Union responded by censoring the country; 35 the United States also placed Thailand on its "Priority Watch List." Pharmaceutical maker Abbott announced it would not apply for licenses for seven of its new products in the Thai market, including a heat-resistant form of the ARV. Brazil's use of compulsory licensing was criticized by pharmaceutical companies, which claimed that compulsory licensing would negatively affect research for new medicines. The predictable negative reaction by pharmaceutical companies poses obvious worries for countries.

public need, it is not a panacea for the global health market in a pandemic. If the vaccine were to be licensed out to governments, there would still be difficulties with producing the vaccine in mass quantities. A license is not all inclusive and does not allocate crucial components for quickly making vaccines — including the actual formulae and the technical know-how and experience.<sup>101</sup> Private patent right owners and their governments have been very aggressive towards nations that have used compulsory licensing to get a better price for pharmaceuticals and medical technology.<sup>102</sup> For those nations, compulsory licensing may only bring on more issues later on, forcing the government to choose between affording life-saving medical technology for its citizens in the short term or maintaining trade relations with wealthier nations in the long term.<sup>103</sup> Though this retaliation has not been frequently carried through, it has been an issue of concern for several countries in the pandemic and has motivated several nations to strengthen compulsory licensing protection and prevent backlash later on.<sup>104</sup>

The threat of backlash can be resolved with a more unified approach to the TRIPS Agreement and the international approach to intellectual property rights in general. More specifically, it would

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Large pharmaceutical companies bring jobs and investments to developing countries; developing countries are thus leery.

Donald Harris, *TRIPS After Fifteen Years: Success Or Failure, Measured by Compulsory Licensing*, 18 J. INTEL. PROP. L. 367, 392 (2011), <https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1184&context=jipl>; Frederick M. Abbott & Jerome H. Reichman, *Doha Round's Pub. Health Legacy: Strategies For Prod. & Diffusion Pat. Med. Under Amended TRIPS Prov.*, 10 J. INT'L ECON. L. 90, 952-54 (2007), [https://www.researchgate.net/publication/37810482\\_The\\_Doha\\_Round's\\_Public\\_Health\\_Legacy\\_Strategies\\_for\\_the\\_Production\\_and\\_Diffusion\\_of\\_Patented\\_Medicines\\_Under\\_the\\_Amended\\_TRIPS\\_Provisions/link/0c96052803c1c2c8e3000000/download](https://www.researchgate.net/publication/37810482_The_Doha_Round's_Public_Health_Legacy_Strategies_for_the_Production_and_Diffusion_of_Patented_Medicines_Under_the_Amended_TRIPS_Provisions/link/0c96052803c1c2c8e3000000/download); Dina Halajian, *Inadequacy TRIPS & Compulsory License*, 38 BROOKLYN J. INT'L L. 1191, 1202 (2013), <https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?article=1050&context=bjil>.

<sup>101</sup> Stolberg & Robbins, *supra* note 1.

<sup>102</sup> Harris, *supra* note 100; Abbott & Reichman, *supra* note 100; Sharma, *supra* note 96; Halajian, *supra* note 100.

<sup>103</sup> Harris, *supra* note 100; Abbott & Reichman, *supra* note 100; Sharma, *supra* note 96; Halajian, *supra* note 100.

<sup>104</sup> Green, *supra* note 15.

likely benefit lower income nations to have a unified approach to compulsory licensing to reduce the risk of backlash and questions of affordability in emergency events. Rather than taking a nation's compulsory license as a slight or an attempt to steal from the patent owner, it should be taken as an attempt to preserve public health goals and expand access where a pharmaceutical company is unwilling to work with a government to achieve that end. After all, one of the stipulations of TRIPS and the U.S. compulsory licensing system is that the government must attempt to gain voluntary concession of rights from the company before filing for the license and forcing the issue.<sup>105</sup>

## V. PRO-PATENT ARGUMENTS: INCENTIVE FOR INNOVATION

Prior to the pandemic, in 2019, there was a bipartisan attempt to reform Section 101 of the United States Patent Act to favor stronger patent protections.<sup>106</sup> At the time it was proposed, the major concern was that the drafted bill would allow companies to own exclusive rights to genes, thereby granting the rights to prohibit all others from providing and developing genetic testing and pursuing research.<sup>107</sup> The argument was that the ambiguous clause in the current version of Section 101 created a restrictive patent system which failed to protect, or incentivize, groundbreaking innovations including personalized medicine, artificial intelligence or inventions of the next generations.<sup>108</sup> In the wake of the COVID-19 pandemic, this argument has predictably shifted to address the new hot topics. There are several arguments against removing patent protections from public health innovations, especially in the debate over a patent waiver for COVID-19 vaccines. Pharmaceutical companies, healthcare researchers, and some governments argue that intellectual property rules—and the profits they allow—promote the development of breakthrough technologies such as the COVID-19 vaccines.<sup>109</sup> Patent law theory is

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<sup>105</sup> Reinsch, et al., *supra* note 27.

<sup>106</sup> 35 U.S.C. § 101 (SENATE JUD. SUBCOMM. INTELL. PROP., Proposed Off. Draft, 2019), <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>; Slifer, *supra* note 56.

<sup>107</sup> Kate Ruane & Jennifer Leib, *Coalition Letter Opposing Draft Legis. Sec. 101 Pat. Act*, ACLU (June 3, 2019), <https://www.aclu.org/letter/coalition-letter-opposing-draft-legislation-section-101-patent-act>.

<sup>108</sup> Slifer, *supra* note 56.

<sup>109</sup> Bacchus, *supra* note 27; Hilty, *supra* note 27.

based on motivating innovation with short-term monopolies on the invention patented. The research process involved with creating inventions can be costly and time-consuming; patent protections reward the effort and time with a cut of the profits from the invention with exclusive rights to use and distribution for a short length of time - usually twenty years from the patent filing date.<sup>110</sup>

There is concern that weakening patent right protection through compulsory licensing or other means would eliminate or decrease the incentives that are deemed essential to inspire the innovations that make new medicines possible.<sup>111</sup> The intellectual property field strives to achieve a balance in the trade rules, providing the global community with sufficient flexibility to preserve intellectual property rights while also promoting access to life-saving medicines.<sup>112</sup> For short term periods, such as during an emergency response to a pandemic, circumventing private intellectual property rights may accelerate distribution of goods and services, principally where the novel knowledge that went into making them already exists.<sup>113</sup> Considering that the vaccines that have been created in response to the novel COVID-19 coronavirus were made using preexisting technology, it is not surprising that there have been some suits regarding the protected technology used to make them.<sup>114</sup> Even in a global emergency,

<sup>110</sup> Lindsey, *supra* note 56; MENELL, *supra* note 56.

<sup>111</sup> Bacchus, *supra* note 27; Reinsch et al., *supra* note 27; Son, *supra* note 73.

<sup>112</sup> Bacchus, *supra* note 27; Son, *supra* note 73; Hilty, *supra* note 27.

<sup>113</sup> Urias & Ramani, *supra* note 59; Bacchus, *supra* note 27; Navarro & Vieira, *supra* note 89.

<sup>114</sup> “Allele Biotechnology and Pharmaceuticals filed two lawsuits against the three drugmakers on Monday . . . alleges that Pfizer and BioNTech, with its investigational COVID-19 vaccine BNT162, and Regeneron’s REGN-COV2, were developed using Allele’s mNeonGreen fluorescent protein without the company’s permission.” Angus Liu, *Pfizer-BioNTech, Regeneron Sued Pat. Infringement With COVID-19 Prods.*, FIERCE PHARMA (Oct. 6, 2020, 10:55 AM), <https://www.fiercepharma.com/pharma/pfizer-biontech-regeneron-sued-for-infringement-allele-s-patent-their-covid-19-products>; “With respect to invalidity proceedings, Moderna has filed several inter partes reviews (IPRs), including against CureVac’s U.S. Pat. No. 8,383,340 . . . claims found unpatentable . . .; Arbutus Biopharma Corporation’s (Arbutus) U.S. Pat. No. 9,404,127 . . . claims found unpatentable . . .; Arbutus’ U.S. Pat. No. 9,364,435; and Arbutus’ U.S. Pat. No. 8,058,069 . . . no challenged claims found unpatentable.” Dan Shores et al., *MRNA IP & Competitive Landscape Through One Year COVID-19 Pandemic—Part I*, IP WATCHDOG (Apr. 11, 2021), <https://www.ipwatchdog.com/2021/04/11/mrna-ip-competitive-landscape-one-year-covid-19-pandemic-part/id=132130/>; Nathan Vardi, *Moderna’s Mysterious Coronavirus Vaccine Delivery Sys.*, FORBES (July 29,

squabbles over private rights and monetary compensation have broken out, demonstrating that the motivation for lead research and development companies is indeed compensation, rather than helping the state of public health.<sup>115</sup> Therefore, in emergency situations it may be proper and essential to avoid patent protections through uniform compulsory licensing standards, regardless of the effect it may or may not have on innovation incentives. For innovations not tied to outbreaks and emergency widespread use, the undermining of private intellectual property rights may seriously deter discovery and development of knowledge for new goods and services that the world needs by eliminating the monetary incentives.<sup>116</sup>

It is overly idealistic to believe that these companies will pour time and money into innovation for the sake of a greater good without economic incentive. Therefore, it is important to have a cohesive, international compulsory licensing system in place to ensure that research companies know what to expect when developing technology for general and emergency public health use. Setting expectations for short term need compensation and for general day-to-day compensation will ensure that these companies continue to innovate and work without fear of government interference in private intellectual property rights and with reasonable expectations of payment and distribution when cooperation is necessary in emergency situations.<sup>117</sup>

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2020, 07:51 AM), <https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/?sh=22e7d9b62d9c>; Adam Houldsworth & Joff Wild, *Moderna's Covid Vaccine Promising News, But IP Issues May*, L. BUS. RSCH. (Nov. 16, 2020), <https://www.iam-media.com/coronavirus/moderna-vaccine-ip-challenges>.

<sup>115</sup> Liu, *supra* note 114; Shores et al., *supra* note 114; Vardi, *supra* note 114; Houldsworth & Wild, *supra* note 114; Bacchus, *supra* note 27.

<sup>116</sup> Bacchus, *supra* note 27; Hilty, *supra* note 27; Lindsey, *supra* note 56; MENELL, *supra* note 56; Kuhn & Beall, *supra* note 88.

<sup>117</sup> Reinsch et al., *supra* note 27, “The Agreement is not ideal for the USA . . . though, the USA sees the TRIPS Agreement as an achievement far beyond that which was thought possible at the outset of the negotiations.” GRAIN, *U.S. Position TRIPS*, GRAIN (Nov. 10, 1998), <https://grain.org/en/article/2105-us-position-on-trips> (explaining why the U.S. did not join in the TRIPS agreement, thus fracturing intellectual property rights management on an international scale).



## VI. ANALYSIS

Considering the compelling arguments on each side of this issue, several remain most relevant. First, it is clear that the current patent system as applied to public health crisis response is imbalanced with detrimental favor toward large corporations filing patents with little to no regard for the harm to the public on a national and international scale.<sup>118</sup> The lawsuits against Moderna and the open admission by Pfizer only prove that these companies are prioritizing profit above all else – even during a global health crisis and even when contributing to the stop of the spread of a fatal disease could easily be made accessible and affordable.<sup>119</sup> Pharmaceutical companies are already making a healthy profit on vaccine and drug treatment sales and yet still plan to raise the prices by over three times the amount of “pandemic prices.”<sup>120</sup> It is a clear abuse of power and leverage to the detriment of public health and safety, which goes against the original ideology and intent of patent protections.<sup>121</sup> The goal of a patent is to advance progress, better society with innovation and promote the exchange of ideas.<sup>122</sup> Even the “quid pro quo” theory of patents recognizes that the patent filing grants a short-term monopoly in exchange for revealing the technology behind the patent, therefore allowing the patented product to be reproduced after the end of the monopoly.<sup>123</sup> What the “quid pro quo” theory does not provide for is what happens when the twenty year monopoly comes at the cost of human lives, and whether there is a moral responsibility of the government to take a larger role in sponsoring and funding such life-saving research.<sup>124</sup>

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<sup>118</sup> Kuhn & Beall, *supra* note 88; Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1.

<sup>119</sup> Stolberg & Robbins, *supra* note 1; Steenhuisen, *supra* note 1; MODERNA, *supra* note 12; Pfizer Inc. Earnings Call, *supra* note 94; Sagonowsky, *supra* note 93.

<sup>120</sup> *Id.*

<sup>121</sup> Sharma, *supra* note 96; Sagonowsky, *supra* note 93; Pfizer Earnings Call, *supra* note 94; Sean B. Seymore, *Symposium: Disclosure Function Pat. System*, 69 VANDERBILT L.R. 1455, (2016), <https://scholarship.law.vanderbilt.edu/vlr/vol69/iss6/1>; MENELL, *supra* note 56; Mossof, *supra* note 53.

<sup>122</sup> MENELL, *supra* note 56; Lindsey, *supra* note 56; Slifer, *supra* note 56.

<sup>123</sup> Seymore, *supra* note 121.

<sup>124</sup> Seymore, *supra* note 121; Gerhardsen, *supra* note 67; PUB. CITIZEN, *supra* note 92.

Of course, then, procedures to circumvent intellectual property protections and save lives should be used – but they should be built-in and well established. Without such a process, multiple pharmaceutical companies can and will take different approaches to maximizing their pay day and will do so aggressively and quickly.<sup>125</sup> As pharmaceutical companies rake in profit, the virus continues to mutate leading to prolonged global mass death and overwhelming pressure on the healthcare system.<sup>126</sup> Human health must become the focus again, and that requires creating a faster, more flexible safeguard against patent protections which currently prioritize big pharmaceutical company income over public health. The COVID-19 pandemic exposed major issues with intellectual property law from the perspective of public health<sup>127</sup> – but if it were not COVID-19, it likely would have been something else. With the global spread of COVID-19 and the resulting concern regarding public health measures and intellectual property concerns, there is now an opportunity to fix a broken system which has long prioritized capitalist reward over human life and health.<sup>128</sup>

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<sup>125</sup> Stolberg & Robbins, *supra* note 1; Steenhuysen, *supra* note 1; MODERNA, *supra* note 12; Terry, *supra* note 29; Sagonowsky, *supra* note 93; Pfizer Earnings Call, *supra* note 94.

<sup>126</sup> Eve Glicksman, *Workplace Shortages, Burnout Strain Hospital HR Staff*, SOC'Y HUM. RES. MGMT. (Jan. 10, 2022), <https://www.shrm.org/resourcesandtools/hr-topics/organizational-and-employee-development/pages/workplace-shortages-burnout-strain-hospital-hr-staff.aspx>; Dharam Kaushik, MD, *Medical Burnout: Breaking Bad*, ASS'N AM. MED. COLLS. (June 4, 2021), <https://www.aamc.org/news-insights/medical-burnout-breaking-bad>; Ed White, *COVID Beds Fill, Hospitals Struggle Burnout Among Dr., Nurses and Staff*, L.A. TIMES (Dec. 18, 2021, 6:12 PM), <https://www.latimes.com/world-nation/story/2021-12-18/hits-keep-coming-hospitals-struggle-as-covid-beds-fill>; *Delta Variant*, *supra* note 14; *Omicron Variant*, *supra* note 14; *What You Need Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>127</sup> U.N., *supra* note 67; Gurgula & Lee, *supra* note 15; Milne & Crow, *supra* note 67; Cheng & Larson, *supra* note 67; Rutschman, *supra* note 15; “Borderless open and collaborative science and the free exchange of knowledge and data will get us to vaccines and cures faster than by any other way.” Dutfield, *supra* note 15; Peiris & Leung, *supra* note 67; Aizenman, *supra* note 67.

<sup>128</sup> Jennifer Cohen & Yana van der Meulen Rodgers, *Contributing Factors Pers. Protective Equip. Shortages During COVID-19 Pandemic*, 141 ELSEVIER PREVENTATIVE MED. 106263 (Dec. 2020), <https://reader.elsevier.com/reader/sd/pii/S0091743520302875?token=9B24E313E164B5A5437E38E4E627108B76655139A76A8CBBE461E46F7B42FFBFF01C98C89AC137850ED448FC0B23C&originRegion=us-east->

Second, the use of compulsory licensing on a large scale is likely the most successful solution to the imbalance within the patent system. Compulsory licensing already exists on an international level through the WTO TRIPS agreement to facilitate access to critical medicine where intellectual property protections are a barrier.<sup>129</sup> The global community briefly came together in 2020 to work on creative solutions to circumvent the intellectual property protections and ensure information sharing.<sup>130</sup> Many other globally-spread diseases have an attached social stigma and unfortunately did not promote this level of international cooperation with HIV, AIDS, and diabetes as prime examples.<sup>131</sup> However, COVID-19 was a unique circumstance for that level of cooperation – and it did not last very long once it became clear that equity measures were still not ensuring vaccination and pharmaceutical access to low income nations.<sup>132</sup> In 2009 the H1N1 influenza<sup>133</sup> pandemic resulted in developed countries scrambling to place large advance orders of vaccines – just in case.<sup>134</sup> Wealthy nations bought practically all the output the vaccine companies could manufacture in a move of mutual greed – the companies gaining fast profit, and the nations gaining more bargaining power - and thus drove the price up while depriving low-income nations of the much needed vaccines.<sup>135</sup> With COVID-19, similar buy-outs of medical supplies by wealthy countries, including vaccines, personal protective equipment, respirators, and medical treatments, all occurred again, as if none of

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1&originCreation=20211123175834; Dutfield, *supra* note 15; Gurgula & Lee, *supra* note 15; Rutschman, *supra* note 15.

<sup>129</sup> WORLD TRADE ORG. TRIPS, *supra* note 84.

<sup>130</sup> Jorge L. Contreras, *Open COVID Pledge: Design, Implementation & Preliminary Assessment Intell. Prop. Commons*, S.J. QUINNEY COLL. L., U. UTAH (Feb. 2021), <https://dc.law.utah.edu/scholarship/268/>; WORLD HEALTH ORG., *WHO COVID-19 Tech. Access Pool*, (May 2020), <https://www.who.int/initiatives/covid-19-technology-access-pool>.

<sup>131</sup> WORLD TRADE ORG. TRIPS, *supra* note 84.

<sup>132</sup> Gurgula & Lee, *supra* note 15; Milne & Crow, *supra* note 67; Cheng & Larson, *supra* note 67; Santos Rutschman, *supra* note 15; Dutfield, *supra* note 15; Peiris & Leung, *supra* note 67; Aizenman, *supra* note 67; Gerhardsen, *supra* note 67.

<sup>133</sup> (H1N1 influenza is also colloquially referred to as Swine Flu). David P. Fidler, *Negot. Equitable Access Influenza Vaccines*: PLOS MED. J. (May 4, 2010), <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000247>.

<sup>134</sup> David Brown, *Most Any Vaccine New Flu Strain Could Be Claimed by Rich Nations' Preexisting Cont.*, WASH. POST (May 7, 2009), <https://www.washingtonpost.com/wp-dyn/content/article/2009/05/06/AR2009050603760.html>; Fidler, *supra* note 133.

<sup>135</sup> Brown, *supra* note 134; Fidler, *supra* note 133.

the countries learned anything from the 2009 H1N1 influenza outbreak.<sup>136</sup> Using compulsory licensing procedures for treatments and preventative medications can prevent price-gouging by pharmaceutical companies by forcing negotiations with less wealthy, developing government entities and speed up the availability and distribution of vaccines to therefore avoid the lethal consequences.<sup>137</sup> Strengthening the system to be uniform, flexible, and sensitive to truly global emergency events would only serve to ensure that nations with less power and money have a clear path to access new innovations in the public health market. Without such a uniform system in place, it is likely that the next health crisis will follow a similar pattern of massive over-purchasing by rich nations and lack of access for poor nations.

Third, compulsory licensing itself is insufficiently structured, leaving gaps in global protection and response to major health issues including viral pandemics like COVID-19 and HIV. Through the COVID-19 pandemic, it became clear that there was a stark divide between nations that have power and those that do not. Those with buying power will not hesitate to leave global neighbors behind in a global health struggle.<sup>138</sup> As of now, the most vaccinated nation in the world by percent of population in compliance is The United Arab Emirates, most likely due to its strategic and intensive vaccination compliance program and vaccine hoarding, which was driven toward ensuring its residents were vaccinated quickly with strict measures in place.<sup>139</sup> However, the most telling information comes from the vaccine acquisition contracts.<sup>140</sup> Wealthy nations and global powers including Canada, the United States, the United Kingdom, the European Union, Australia, and Japan, purchased excess vaccines - up

<sup>136</sup> Cohen & Rodgers, *supra* note 128; Rutschman, *supra* note 15; Aizenman, *supra* note 67; Milne & Crow, *supra* note 67; Fidler, *supra* note 133.

<sup>137</sup> Urias & Ramani, *supra* note 59; Green, *supra* note 15; Siripurapu, *supra* note 65.

<sup>138</sup> Hannah Ritchie et al., *Coronavirus Pandemic (COVID-19)*, OUR WORLD IN DATA. (updated Apr. 14, 2022), <https://ourworldindata.org/coronavirus>; Coronavirus Research Center, *Understanding Vaccination Progress*, JOHNS HOPKINS U. & MED. (updated Apr. 14, 2022), <https://coronavirus.jhu.edu/vaccines/international>.

<sup>139</sup> Duaa Mohamed Suliman, Faisal A. Nawaz, Parvathy Mohanan et al., *UAE Efforts Promoting COVID-19 Vaccination & Building Vaccine Confidence*, NAT'L LIBR. MED. (Sept. 7, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8421098/>.

<sup>140</sup> Tom Randall et al., *Covid-19 Deals Tracker: 9.6 Billion Doses Under Cont.*, BLOOMBERG (Mar. 9, 2021, 10:00 AM), <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/contracts-purchasing-agreements.html>.

to three times the amount to completely vaccinate the citizens in those nations.<sup>141</sup> Meanwhile, poor nations were forced to under-purchase what is needed for their citizens, leading to an international pattern of wealthier individuals being vaccinated at a higher rate than poor individuals regardless of national origin or vaccine cost.<sup>142</sup>

The compulsory licensing process and requirements should be altered to include a more flexible period and to address not just emergencies but larger public health issues as well. At any given moment, the world can be shut down by a new deadly illness without warning. Without adequate access to life-saving medical treatments and vaccines, hundreds of thousands, even millions, may die.<sup>143</sup> This will support progress and innovation better than the patent system, which is based on capital reward and monopoly after Patent and Trademark Office (PTO) application acceptance.<sup>144</sup>

Additionally, the global border-bound, piece-meal approach to compulsory licensing systems is outdated in a world where a virus can reach pandemic status in a matter of weeks.<sup>145</sup> Variants that are discovered oceans away reach the United States and Europe almost as quickly as they are reported, at least partially because travel restrictions and airline mask mandates are insufficient when

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<sup>141</sup> Randall et al., *supra* note 140; Duke Glob. Health Innovation Ctr., *Tracking COVID-19 Vaccine Purchases Across Globe*, LAUNCH AND SCALE SPEEDOMETER, (accessed Apr. 13, 2022), <https://launchandscalefaster.org/covid-19/vaccinepurchases>.

<sup>142</sup> Randall et al., *supra* note 140; Duke, *supra* note 141.

<sup>143</sup> WORLD HEALTH ORG., *supra* note 14.

<sup>144</sup> The prevailing view of the current United States patent system is the “quid pro quo” analysis:

A fundamental goal of the patent system is to encourage the dissemination of technical knowledge. The patent system achieves this goal through a quid pro quo-in exchange for the right to exclude, the inventor must fully disclose the technical details of the invention. As soon as a patent document publishes, there is hope that the public will use the technical details disclosed therein to improve upon the invention, to design around it, or to engage in other innovative activities. So while the patentee maintains the right to exclude others from practicing the invention until the patent expires, the technical information disclosed in the patent document has potential immediate value to the public.

Seymore, *supra* note 121.

<sup>145</sup> *Delta Variant*, *supra* note 14; *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mascola et al., *supra* note 14.

individuals and governments fail to take responsible actions to prevent spread and continue to travel internationally.<sup>146</sup> In an ideal world, with a centralized global health emergency response system in place based on the concept behind compulsory licensing, scientific advancements as well as purchasing and distribution would be universally shared with proportionate cost-sharing and allocation based on population. Private pharmaceutical companies and innovators could negotiate and deal with a globally unified front for truly global emergencies to ensure such egregious inequity in global response, and therefore a faster journey to the end of the emergency. Without such a system, it is likely that another global health emergency could cripple the global economy, block travel, and unravel the world as we know it like the COVID-19 pandemic achieved. Additionally, a unified system could potentially serve to bridge the gap in access to technology and innovations in times of emergency, which was demonstrated in the patterns of COVID-19 vaccine purchases internationally.<sup>147</sup>

## VII. CONCLUSION

Patent protections for innovations that support public health can have a major damaging effect on society by limiting manufacturing and price-gouging consumers. It is in the best interest of progress and humanity to eliminate patent protections on life-saving public health innovations during times of emergency. The world of public health on the global stage has changed dramatically in the past two decades, and it is time for the patent system to reflect that change. Without further safeguards against price gouging by pharmaceutical companies and stockpiling by wealthy nations, the risk of detrimental global pandemics and mass death will only increase. It is time for a collaborative, unified, internationally recognized system.

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<sup>146</sup> WORLD HEALTH ORG., *Update on Omicron*, (Nov. 28, 2021), <https://www.who.int/news/item/28-11-2021-update-on-omicron>; Kim Schive, *COVID-19 Updates*, MASS. INST. TECH. MED., (July 21, 2021), <https://medical.mit.edu/covid-19-updates/2021/07/are-things-different-delta>; *Delta Variant*, *supra* note 14; *Omicron Variant*, *supra* note 14; *What You Need to Know*, *supra* note 14; *Understanding Variants*, *supra* note 14; WORLD HEALTH ORG., *supra* note 14; Katella, *supra* note 14; Mahase, *supra* note 14; Mascola et al., *supra* note 14.

<sup>147</sup> Randall et al., *supra* note 140; Duke, *supra* note 141.