

5-23-2022

## International Rights Affecting the COVID–19 Vaccine Race

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### Recommended Citation

Samantha Johnson, *International Rights Affecting the COVID–19 Vaccine Race*, 53 U. MIA Inter-Am. L. Rev. 145 ()

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# International Rights Affecting the COVID–19 Vaccine Race

Samantha Johnson<sup>†</sup>

*The impact of the COVID–19 pandemic has been felt worldwide, and despite having several vaccines in the market at this point, there are still issues of accessibility for certain countries. International intellectual property law has been a breeding ground for the exploration of intellectual curiosity and creation as it provides strong protections to creators. These strong protections have allowed for the monopolization of certain goods, such as vaccines, under the concept of patents. While patents are important to incentivize pharmaceutical companies to create life–saving medicines, these protections have also become a barrier for access to medicines, especially in less–developed countries. This Note seeks to address the interplay between international intellectual property rights and the right to health under the international human rights framework. Specifically, it will discuss the two differing rights through the United States and Canada’s efforts to promote creation of COVID–19 vaccine candidates. In order to highlight the financial driver behind patent protections, this note will compare the production and patenting process of the COVID–19 vaccines, a virus that also heavily impacted developed countries, versus the under–funded Ebola virus, which predominantly effected less–developed countries. Finally, this Note will offer recommendations on how countries, and pharmaceutical*

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*companies, can take a human rights approach by utilizing patent protection exceptions in order to make COVID–19 vaccines accessible to all countries.*

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## I. INTRODUCTION

Picking up medication at the pharmacy can oftentimes be accompanied by a real sense of shock upon observing the cost of a prescription drug. Some small pills can have a list price of hundreds, if not thousands of dollars,<sup>1</sup> which leads to one lingering question: what makes these pills so special? There *must* be some secret formula to create these drugs, or the cost of production must be exorbitant. But the reality is that these formulas are often easily replicable in the form of generics,<sup>2</sup> and even taking production costs into account, the average markup on a patented drug is close to 400%.<sup>3</sup> If these drugs are simple to manufacture and inexpensive to produce, why must consumers still pay these high markups? The answer is simple, and it all boils down to one key word: patents.<sup>4</sup>

In the U.S., there have been significant increases in prescription drug prices over the years, which can partially be attributed to the strong intellectual property (IP) rights system in America.<sup>5</sup> In the U.S., the cost of prescription drugs has continued to increase at a rate higher than the country's inflation rate.<sup>6</sup> Injectable drugs have increased by a staggering 15 percent per year, while the inflation

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<sup>1</sup> Lauren Chase, *The 20 Most Expensive Prescription Drugs in the U.S.A.*, GOODRX (Sept. 7, 2021), <https://www.goodrx.com/blog/20-most-expensive-drugs-in-the-usa/>.

<sup>2</sup> Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARVARD BUS. REV. (Apr. 6, 2017), <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive>.

<sup>3</sup> Dean Baker, *Financing Drug Research: What are the Issues?* 7 CTR. FOR ECON. AND POL'Y RSCH 1, 2 (Sept. 22, 2004), [https://cepr.net/documents/publications/intellectual\\_property\\_2004\\_09.pdf](https://cepr.net/documents/publications/intellectual_property_2004_09.pdf).

<sup>4</sup> *See Abuse of the Patent System is Keeping Drug Prices High for Patients*, ASSN. FOR ACCESSIBLE MEDICINES, <https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients> (last visited Feb. 28, 2021).

<sup>5</sup> *See* Tahir Amin, *The Problem with High Drug Prices isn't 'Foreign Free-loading,' it's the Patent System*, CNBC (June 27, 2018, 9:08 AM), <https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html>.

<sup>6</sup> Yoni Blumberg, *Here's Why Prescription Drugs in the US Cost so Much—and it's not Innovation or Improvement*, CNBC (Jan. 14, 2019, 11:24 AM), <https://www.cnbc.com/2019/01/10/why-prescription-drugs-in-the-us-cost-so-much.html>.

rate within the country has only risen roughly 2 percent per year.<sup>7</sup> The Department of Health and Human Services estimates that “[A]mericans spent more than \$460 billion” on prescription drugs in 2016 alone.<sup>8</sup> On average, a single person in the U.S. is estimated to pay roughly \$1,200 per year on prescription drugs.<sup>9</sup>

Similarly, the spending rates on prescription drugs in Canada has increased at a significant rate.<sup>10</sup> Canada spent \$14.5 billion on prescription drugs in 2018.<sup>11</sup> Falling substantially below the U.S., but still worth recognizing, a Canadian citizen will spend nearly \$450 per year on prescription drugs.<sup>12</sup>

The remaining costs for prescription drugs are typically a result of the insurance systems in these two countries.<sup>13</sup> Although Canada has adopted a universal healthcare system, the system does not fully cover essential medication.<sup>14</sup> The U.S., on the other hand, has a privatized insurance system which has led to two outcomes.<sup>15</sup> First, a person who has private insurance will still likely be responsible for

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<sup>7</sup> *Id.*

<sup>8</sup> Ezekiel Emanuel, *Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up*, THE ATLANTIC (Mar. 23, 2019), <https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/>.

<sup>9</sup> Robert Langreth, *Drug Prices*, BLOOMBERG (Sept. 16, 2020, 1:13 PM), <https://www.bloomberg.com/quicktake/drug-prices>.

<sup>10</sup> Nicole Ireland, *Drug Costs Rising Fast in Canadian Health-Care Spending, Report Finds*, CBC (Nov. 9, 2017, 2:10 PM), <https://www.cbc.ca/news/health/cihi-health-costs-canada-report-prescriptions-pharmicare-1.4390945>.

<sup>11</sup> Kelly Grant, *Government Spending on Prescription Drugs Grew by 7 Percent Last Year*, THE GLOBE & MAIL (Dec. 17, 2019), <https://www.theglobeandmail.com/canada/article-government-spending-on-prescription-drugs-grew-by-7-per-cent-last-year/>.

<sup>12</sup> *Pharmacare: The Public Solution to Rising Drug Costs*, CANADIAN UNION OF PUB. EMP. (June 12, 2018), <https://cupe.ca/pharmacare-public-solution-rising-drug-costs>.

<sup>13</sup> Fiona Clement & Katherine A. Memedovich, *Drug Coverage in Canada: Gaps and Opportunities*, 43 (3) J PSYCHIATRY NEUROSCI 148, 148 (2018).

<sup>14</sup> Ashifa Kassam, *The Serious Flaw in Canada’s Healthcare System: Prescription Drugs aren’t Free*, THE GUARDIAN (Oct. 20, 2017, 6:30 AM), <https://www.theguardian.com/world/2017/oct/20/canada-national-pharmacare-prescription-drugs>.

<sup>15</sup> RYAN J. ROSSO, CONG. RSCH. SERV., IF10830, U.S. HEALTH CARE COVERAGE AND SPENDING (2021).

a portion of the cost of their prescription drugs.<sup>16</sup> These remaining costs associated with prescription medications can often mean an individual having to choose between an essential medication and their basic necessities, which can sometimes lead to death.<sup>17</sup> Second, there is a large class of people who are left uninsured and thus responsible for the entire cost of any prescription medications they may need.<sup>18</sup> In 2018, there were 27.5 million uninsured people in the U.S., which is around 9 percent of the total U.S. population.<sup>19</sup>

The expansion of patent rights into the area of pharmaceutical development is most evidently seen in the area of prescription drug prices. However, these rights also affect vaccine access and distribution worldwide.<sup>20</sup> While vaccines may be covered by insurance for some, individuals who lack insurance or lack access to medication in rural areas are often faced with an out-of-pocket cost that prevents them from accessing a particular vaccine.<sup>21</sup> Without any form of insurance, some prominent vaccines, like those for mumps, measles, and rubella, can cost anywhere from \$40 to \$200, rendering vaccines prohibitively expensive in less economically affluent areas.<sup>22</sup>

Over the last couple decades, prescription drug prices have continued to rise, and vaccine prices have followed suit.<sup>23</sup> In the last

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<sup>16</sup> Kassam, *supra* note 14.

<sup>17</sup> *Id.*

<sup>18</sup> RYAN J. ROSSO, CONG. RSCH. SERV., IF10830, U.S. HEALTH CARE COVERAGE AND SPENDING (2021).

<sup>19</sup> Katie Keith, *Uninsured Rate Rose in 2018 Says Census Bureau Report*, HEALTH AFFAIRS (Sept. 11, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190911.805983/full/>.

<sup>20</sup> See generally Michaeleen Doucleff, *What Will It Take To End The Covid-19 Pandemic?*, NPR (Jan. 5, 2021, 3:52 PM), <https://www.npr.org/sections/goatsandsoda/2021/01/05/953653373/some-experts-say-temporary-halt-on-drug-patents-is-needed-to-stop-pandemic-world>.

<sup>21</sup> Anthony Rivas, *Number of Unvaccinated Children Increasing in U.S. Despite Overall High Coverage*, ABC NEWS (Oct. 23, 2018, 4:02 PM), <https://abcnews.go.com/Health/number-unvaccinated-children-increasing-us-high-coverage/story?id=58692605>.

<sup>22</sup> *Price List*, CVS MINUTE CLINIC, <https://www.cvs.com/minuteclinic/services/price-lists> (last visited Feb. 28, 2021); see also Elisabeth Rosenthal, *The Price of Prevention: Vaccine Costs are Soaring*, NY TIMES (July 2, 2014), <https://www.nytimes.com/2014/07/03/health/Vaccine-Costs-Soaring-Paying-Till-It-Hurts.html>.

<sup>23</sup> Rosenthal, *supra* note 22.

two decades alone, vaccine prices have grown from single digits to some vaccines costing hundreds of dollars.<sup>24</sup> For example, Prevnar 13, the vaccine used to prevent pneumococcal pneumonia and invasive diseases caused by thirteen streptococcus pneumoniae strains, has “gone up an average of 6% each year since it was first approved by the Food and Drug Administration in 2010.”<sup>25</sup> These increases have put a strain on patients worldwide and have economically diminished the public health budgets for those that are uninsured.<sup>26</sup> With private insurance, the cost to fully vaccinate a child from birth to the age of 18 is nearly \$2,192.<sup>27</sup> This stark cost is mainly attributable to the excessive amounts of pharmaceutical patents which allow for companies to create a monopoly on a specific vaccine for a certain period of time, and thus the company is able to drive up the price.<sup>28</sup>

Medical patents most adversely impact individuals in developing countries, as more developed countries impose higher protections as they put IP protections above the right to health.<sup>29</sup> In order to retain profits for pharmaceutical patents, affluent countries will leverage their trade power to enforce international IP rights in developing countries.<sup>30</sup> This is most clearly seen in the U.S.’s policy on HIV/AIDS.<sup>31</sup> While the cases of HIV/AIDS in sub-Saharan Africa “account for more than 70 percent of all HIV/AIDS cases globally,” the World Health Organization noted that “50 percent of the population in developing countries lack access to essential drugs.”<sup>32</sup> This is partially attributable to excessive patenting on new drugs because these patents delay the onset of generic creation which limits

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<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> See *Generally Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, FED. TRADE COMM’N, [https://www.ftc.gov/system/files/documents/public\\_comments/2018/08/ftc-2018-0055-d-0036-155042.pdf](https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0055-d-0036-155042.pdf) (last visited Mar. 31, 2022).

<sup>29</sup> Chuan-feng Wu, *Raising the Right to Health Concerns within the Framework of International Intellectual Property Law*, 5 *ASIAN J. WTO & INT’L HEALTH L. & POL’Y* 141, 159 (2010).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 146.

<sup>32</sup> *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*, *INT’L INTELL. PROP. INST.* 1, 4, 9 (2000).

immediate accessibility in developing countries.<sup>33</sup> Despite there being three approved antiviral drugs for the treatment of HIV/AIDS, individuals in developing countries are still dying at a staggering rate due to their inability to access these necessary medications.<sup>34</sup> This article will further address these shortcomings in the international IP regime and will describe the actions taken by the World Trade Organization in response.

The United States (U.S.) and Canada both embarked on a mission to create a vaccine in response to the COVID-19 pandemic.<sup>35</sup> When it comes to accessing these vaccines, however, current national and international patent rights in this sector fail to provide adequate protection for one's right to health.<sup>36</sup> With the rapid spread of COVID-19 and the attention that was shown during the vaccine creation period, there is a need to address the interplay between the created vaccines and ways to make these vaccines available.

This article will examine how the actions of economically powerful countries, like the U.S. and Canada, during the development of the Covid-19 vaccines has and will continue to impact the ability of developing countries to access any patented vaccine. Furthermore, this article will underscore how the U.S. and Canada should take a human rights-based approach when providing patents to pharmaceutical companies who are creating COVID-19 vaccines. Part II of this note will begin with a brief background on the relevant international IP protections and right to health provisions that will be referenced throughout. Part III will then examine the patent process

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<sup>33</sup> See *Generally Intellectual Property and Access to Medicine*, OXFAM, <https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/> (last visited Mar. 31, 2022).

<sup>34</sup> *Id.* at 9.

<sup>35</sup> See generally Jaimy Lee, *These 23 Companies are Working on Coronavirus Treatments or Vaccines – Here's Where Things Stand*, MARKETWATCH (May 6, 2020, 2:50 PM), <https://www.marketwatch.com/story/these-nine-companies-are-working-on-coronavirus-treatments-or-vaccines-heres-where-things-stand-2020-03-06>; see also Emily Chung, *A Closer Look at the Vaccines Canada is Betting on to Stem the Spread of COVID-19*, CBC (Sept. 2, 2020, 4:00 AM), <https://www.cbc.ca/news/health/covid-vaccines-canada-profiles-1.5708240>.

<sup>36</sup> “*Whoever Finds the Vaccine Must Share it*” *Strengthening Human Rights and Transparency around Covid-19 Vaccines*, HUM. RIGHTS WATCH (Oct. 29, 2020), <https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency> [hereinafter *Strengthening Human Rights and Transparency around Covid-19*].

during the Ebola outbreak and parallel that process with the current state of affairs surrounding the coronavirus vaccine development. Part IV will address the actions that were taken to promote COVID-19 vaccine development in the U.S. and Canada. Part V will analyze the impact that international IP laws and the international right to health have on the COVID-19 patent process. This section will highlight the relevant exclusions and provisions asserted within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that pertain to a national health emergency. Moreover, this section will also examine the interrelated nature of IP rights within the international human rights framework. Finally, this note will briefly conclude with a recommendation for economically developed countries, in their development of COVID-19 vaccines, to allow the usage of the provisions within the TRIPS Agreement that pertain to patenting during a pandemic in order to remain in accordance with their duties under the relevant international human rights laws. These recommendations will expound upon the differing limitations that countries are permitted to impose upon patent rights during a national health crisis and will highlight which options may be best suited for ensuring that any COVID-19 vaccine is made available globally.

## II. RELEVANT INTERNATIONAL LEGAL FRAMEWORK

Patents give pharmaceutical corporations exclusive rights to a drug that they create, which in turn incentivizes them to continue engaging in research and development (R&D).<sup>37</sup> The need for patents in the pharmaceutical sector has typically been justified by the need to ensure that drug manufacturers are able to recoup the substantial investments necessary for R&D and the costs of regulatory testing.<sup>38</sup> These funds are important, given that the estimated cost of developing a new drug is \$500 million.<sup>39</sup> The creation of novel vaccines, like other inventions, provide the inventor with certain rights

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<sup>37</sup> KEVIN RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020).

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

<sup>39</sup> Omudhome Ogbru, *Why Drugs Cost so Much*, MEDICINE NET, [https://www.medicinenet.com/drugs\\_why\\_drugs\\_cost\\_so\\_much/views.htm](https://www.medicinenet.com/drugs_why_drugs_cost_so_much/views.htm) (last visited Oct. 7, 2020).

to exclusivity which allow the inventor to generate the highest profits off of their creation for a certain amount of time.

#### A. *Vaccine Patents*

Vaccines are often protected by several levels of IP rights through the granting of patents to the original vaccine creators.<sup>40</sup> While older vaccines, like the vaccine for mumps or polio, have no remaining IP barriers due to these vaccines formulations being created over 20 years ago, the vaccines that have not reached the 20-year mark still retain the same protections as the prescription drugs discussed above.<sup>41</sup> Typically, to get around these patents, pharmaceutical companies will make slight changes to the patented vaccine so they can manufacture and distribute their own version without violating the initial patent holder's right.<sup>42</sup> For example, a pharmaceutical company could improve the patented formulation, change the dosage, or alter the delivery procedure.<sup>43</sup> Furthermore, patent holders can likewise implement small changes in their patented formula to increase their exclusivity in the market.<sup>44</sup> This process, also known as "evergreening," is the practice of "applying for multiple, successive patents on minor or insignificant variants or indications of already-patented compounds to extend the period of market exclusivity."<sup>45</sup>

While making changes to a patented vaccine is a loophole to creating a similar vaccine without violating a patent holder's rights to their creation, the costs and experience needed to embark on this challenge can often keep less economically stable companies or government entities from engaging in this practice.<sup>46</sup> Changing the

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<sup>40</sup> Martin Friede, *Intellectual Property and License Management with Respect to Vaccines*, WORLD HEALTH ORG., <https://www.who.int/phi/news/Presentation15.pdf?ua=1> (last visited Mar. 18, 2022).

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

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

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

<sup>44</sup> *How is Access to Medicines a Human Rights Issue?*, HEALTH & HUM. RIGHTS RES. GUIDE, <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/> (last visited Mar. 1, 2021).

<sup>45</sup> *Id.*

<sup>46</sup> Friede, *supra* note 40.

formulation of a patented vaccine takes both time and money.<sup>47</sup> Companies attempting to do so must also have the expertise to examine the formulation of the patented vaccine and make any appropriate alterations that do not affect the overall efficacy of the vaccine.<sup>48</sup> Corporations are also responsible for financing their own research and costs associated with putting their new formulation through clinical trials, should they fail to gain private or governmental support.<sup>49</sup> The accumulation of these factors often leaves only large pharmaceutical companies exploring this loophole, and thus dominating the market by using the patent protection period to “produce the medicine and charge whatever price the market will bear, without fear of competition.”<sup>50</sup>

While R&D of vaccines is crucial to minimizing the impact and scale of major outbreaks, current international IP protections can often hinder these beneficial effects.<sup>51</sup> Specifically, the current IP regime fails to consider developing populations when producing and protecting patents for critical vaccines.<sup>52</sup> The current regime creates two main impediments to “securing widespread affordability and accessibility:”<sup>53</sup> the first is vaccine nationalism and the second is the incentivization of “price-gouging and artificial scarcity.”<sup>54</sup> The vaccine nationalist approach pits the more affluent countries against each other as they compete to gain first access to new vaccines.<sup>55</sup>

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<sup>47</sup> Stanley Plotkin et al., *The Complexity and Cost of Vaccine Manufacturing – An Overview*, 35 VACCINE 4064, 4065 (2017).

<sup>48</sup> Friede, *supra* note 40.

<sup>49</sup> *Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation, Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop Report*, NAT'L ACADEMIES PRESS 2 (2009), <https://www.ncbi.nlm.nih.gov/books/NBK50972/>.

<sup>50</sup> Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, HEALTH & HUM. RIGHTS J. (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

<sup>51</sup> Ana Santos Rutschman, *IP Preparedness for Outbreak Diseases*, 65 UCLA L. REV. 1200,1204-1206 (2018) [hereinafter IP Preparedness].

<sup>52</sup> Wu, *supra* note 29, at 146.

<sup>53</sup> *Why the World Needs a People's Vaccine*, OPEN SOC'Y FOUND., <https://www.opensocietyfoundations.org/explainers/why-the-world-needs-a-peoples-vaccine> (last updated May 2021).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

These competing interests lead to a mindset that hinders “universal access to a vaccine.”<sup>56</sup> This interrelationship between the need for vaccines and the detriments of stringent IP protections can be analyzed by looking at two often competing rights: (1) the right to IP protections, and (2) the right to health.

*B. IP Rights: Patents*

IP rights include a broad category of rights that cover a number of creative innovations and give their creators legal protections against those attempting to copy or replicate their creations.<sup>57</sup> According to the World Trade Organization, IP is defined as “creations of the mind.”<sup>58</sup> These creations can “take many forms, such as artistic expressions, signs, symbols . . . designs and inventions.”<sup>59</sup>

Patents offer creators a competitive advantage in the market by giving them rights to protect their creation against use by others.<sup>60</sup> Rights associated with patents give the inventor a legal right to exclude other individuals from making, using, or selling the inventor’s creation for a set number of years.<sup>61</sup> During these years of exclusivity, inventors in the pharmaceutical sector are guaranteed a profit because they hold the exclusive rights to a formulation of a drug that is needed in the market.<sup>62</sup> This level of exclusivity can often lead to the creation of a monopoly, permitting pharmaceutical patent holders to highly inflate the cost of the drug within the market because they are faced with no competition until another pharmaceutical company can create a new formulation of the drug that retains

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<sup>56</sup> *Id.*

<sup>57</sup> See *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., [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) (last visited Jan. 19, 2021).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> See generally Kevin Rivette et al., *Discovering New Value in Intellectual Property*, HARVARD BUS. REV. (Jan.–Feb. 2000), <https://hbr.org/2000/01/discovering-new-value-in-intellectual-property>.

<sup>61</sup> *General information concerning patents*, U.S. PAT. & TRADEMARK OFFICE (July 1, 2021), <https://www.uspto.gov/patents/basics/general-information-patents>.

<sup>62</sup> Emanuel, *supra* note 8.

efficacy.<sup>63</sup> IP rights are expounded upon in the both the international human rights system and within international trade agreements.

i. IP Under International Human Rights Law

Article 15 of International Covenant on Economic, Social and Cultural Rights (ICESCR) broadly describes a right to participate in cultural life, and in this broad language there is a right to protect one's own creations.<sup>64</sup> As written, Article 15(1)(c) states that there is a "right of everyone . . . to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."<sup>65</sup> This section from Article 15 identifies that a person's right to retain some level of protection over their creation is inherently necessary for one to engage fully in cultural life.<sup>66</sup> However, the approach to this right within Article 15 is from a human-centered perspective, as it was included to uphold the dignity of the person.<sup>67</sup>

Furthermore, General Comment 17 notes that IP rights are different from human rights, as IP rights are "generally of a temporary nature."<sup>68</sup> Explained within the general comment is the notion that IP rights can be "revoked, licensed or assigned to someone else."<sup>69</sup> The comment goes on to explain that "intellectual property rights, . . . may be allocated, limited in time and scope, traded, amended and even forfeited."<sup>70</sup> This distinction is made between the traditional idea of IP rights and human rights because the IP rights described in Article 15 of the covenant do "not necessarily coincide with what is referred to as intellectual property rights under national

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

<sup>64</sup> International Covenant on Economic, Social, and Cultural Rights art. 15, adopted Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter *ICESCR*].

<sup>65</sup> *Id.*

<sup>66</sup> Hum. Rts. Council, *Report of the Special Rapporteur in the Field of Cultural Rights*, ¶ 3, U.N. Doc. A/HRC/20/26 (May 14, 2012).

<sup>67</sup> *Id.* at ¶ 2.

<sup>68</sup> Comm. On Econ. Soc. And Cultural Rts., *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which he or she is the Author.*, ¶ 2, U.N. Doc. CESCR/C.12/GC/17 (Jan. 12, 2006) [hereinafter *CESCR General Comment No. 17*].

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

legislation or international agreements.”<sup>71</sup> Apart from the human rights system, IP rights are also heavily discussed in international trade agreements.

ii. TRIPS Agreement

The TRIPS Agreement is critical to facilitate “trade in knowledge and creativity” and to resolve “trade disputes over intellectual property.”<sup>72</sup> This agreement was created by the World Trade Organization on January 1, 1995 to ensure that WTO members had guidance and latitude to promote trade.<sup>73</sup> Thus, TRIPS is the “legal recognition of the significance of links between IP and trade.”<sup>74</sup> Before this agreement there existed large gaps between the extent of IP protections and enforcement in the varying countries.<sup>75</sup> Recognition of this discrepancy led to the creation of the WTO’s TRIPS Agreement that sought to narrow the discrepancies in how IP “rights are protected and enforced around the world, and to bring them under common international rules.”<sup>76</sup>

The TRIPS Agreement is the minimum standard of IP protections implemented internationally, however the U.S. and other sovereigns are left with the autonomy to implement higher standards of protection.<sup>77</sup> As stated in Article 1(1), “members may, but shall not be obliged to, implement in their law more extensive protection than is required” by the TRIPS Agreement, “provided that such protection does not contravene the provisions of this agreement.”<sup>78</sup> Therefore, member states are given flexibility to enact more stringent

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<sup>71</sup> *Id.*

<sup>72</sup> Intellectual Property: Protection and Enforcement, *supra* note 57.

<sup>73</sup> *Overview: The TRIPS Agreement*, WORLD TRADE ORG., [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited Jan. 20, 2021).

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

<sup>75</sup> *Id.*

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

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

<sup>78</sup> TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1984, Marrakesh Agreement Establishing the World Trade Organization, art. 1(1), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter *TRIPS Agreement*].

protections, as long as the protections do not diminish any of the protections set forth in the TRIPS Agreement.<sup>79</sup>

There are numerous sections in the TRIPS Agreement addressing the varying areas of IP, but the most relevant section for vaccine discussions is the article on patents.<sup>80</sup> Broadly described in Article 27(1), the WTO explains patentable subject matter, stating that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced.”<sup>81</sup> The protections guaranteed under a granted patent are outlined in Article 28 with patent holders being granted a set of exclusive rights to protect their patented creation.<sup>82</sup> These rights include “prevent[ing] third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or important for these purposes that produce,” and granting patent owners the “right to assign, or transfer by succession, the patent and to conclude licensing contracts.”<sup>83</sup>

### iii. The Doha Declaration

With the lack of clarity provided on what constitutes an epidemic or national emergency in the TRIPS Agreement exclusions sovereigns are left with unfettered discretion on whether or not an exclusion applies. In order to provide more clarity, the DOHA Declaration was written in an attempt to clarify the vaguely described need for governments to apply the principles of public health and the articles of the TRIPS Agreement.<sup>84</sup> Adopted on November 14, 2001, the Declaration attempted to address the issue of patent protections restricting “access to affordable medicines for populations in developing countries.”<sup>85</sup> While IP protection does serve an

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<sup>79</sup> See generally Intellectual Property: Protection and Enforcement, *supra* note 57.

<sup>80</sup> Ana Santos Rutschman, *The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks*, 118 MICH. L. REV. 170, 172 (2020) [hereinafter *IP of Vaccines*].

<sup>81</sup> TRIPS Agreement, *supra* note 78, at art. 27(1).

<sup>82</sup> *Id.* at art. 28.

<sup>83</sup> *Id.* at art. 28(1).

<sup>84</sup> The DOHA Declaration on the TRIPS Agreement and Public Health, WORLD HEALTH ORG., [https://www.who.int/medicines/areas/policy/doha\\_declaration/en/](https://www.who.int/medicines/areas/policy/doha_declaration/en/) (last visited Jan. 22, 2021) [hereinafter *DOHA Declaration Explained*].

<sup>85</sup> *Id.*

important role in furthering medical R&D, the Declaration is predominantly concerned with the effects that strict IP protections can have on drug prices.<sup>86</sup>

The Declaration sought to resolve the issues that arise with IP protections in times of public health concerns.<sup>87</sup> In the first paragraph, the declaration “recognize[s] the gravity of the public health problems afflicting both developed and least-developed countries, especially problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>88</sup> The Declaration then goes on to reiterate that the TRIPS Agreement should not be read to inhibit member states from “taking measures to protect public health.”<sup>89</sup> Actually, the agreement encourages member states to use to the fullest extent “the provisions in the TRIPS Agreement, which provide flexibility” for this exact purpose.<sup>90</sup> The Declaration provides member states with the authority to grant compulsory licenses and “determine the grounds upon which such licenses are granted.”<sup>91</sup> However, similar to the TRIPS Agreement, the Declaration leaves member states with the authority to determine what constitutes a national emergency.<sup>92</sup> The failure to clearly identify the situations that call for exceptions leaves sovereigns with a substantial amount of leeway that can often hinder less economically developed countries from accessing affordable vaccines even during a health crisis.<sup>93</sup> Access is limited because compulsory licenses are only granted if a State declares a national emergency, and since less economically developed countries are often more reliant on generic importations governments are often hesitant to invoke compulsory licenses under the national emergency exception because of the potential backlash from their trade

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<sup>86</sup> *Id.*

<sup>87</sup> Victoria Hopkins, *Analysis of International Patent Protection and Global Public Health*, 17 J. OF PUB. & INT’L AFF. 83, 86 (2006).

<sup>88</sup> Declaration on the TRIPS Agreement and Public Health, ¶ 1, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter *DOHA Declaration*].

<sup>89</sup> *Id.* at ¶ 4.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at ¶ 5(b).

<sup>92</sup> *Id.* at ¶ 5(c).

<sup>93</sup> Vanessa Bradford Kerry & Kelley Lee, *TRIPS, the DOHA declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?*, GLOBALIZATION & HEALTH 3 (2007), <https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-3>.

partners in other trade areas.<sup>94</sup> Finally, the Declaration encourages members from developed countries to “provide incentives to their enterprises and institutions to promote and encourage technology transfer to least–developed country members.”<sup>95</sup> Although IP rights have substantial protections both nationally and internationally, the right to health is a non–traditional right predominantly found only in international agreements.

### C. *International Right to Health*

An individual’s right to the highest attainable standard of physical and mental health can be found in several international legal agreements.<sup>96</sup> First, the right to health on the international scale is described in ICESCR and affirmed by CESCR’s General Comment 14, the treaty body responsible for monitoring implementation of ICESCR, as the right of everyone to the “enjoyment of the highest attainable standard of physical and mental health.”<sup>97</sup> This idea of a multifaceted right to health is further defined by the World Health Organization (WHO), which defines health as “a state of complete physical, mental, and social well–being and not merely the absence of disease or infirmity.”<sup>98</sup> Inherent in this definition is the fact that the right to health is not a guarantee that everyone will be at the optimum health level or even healthy, as it is impossible for a state actor to prevent every illness or condition.<sup>99</sup> The right to health is more so a guarantee that state actors will take the necessary actions, or forego taking actions, so that individuals have the ability to obtain their personal highest standard of health.<sup>100</sup> The right to health guarantees access to healthcare that is available, accessible, acceptable,

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<sup>94</sup> *Id.*

<sup>95</sup> *DOHA Declaration*, *supra* note 88, at ¶ 7.

<sup>96</sup> *See generally* G.A. Res. 217 (III) A, Universal Declaration of Human Rights, at art. 25(1) (Dec. 10, 1948) [hereinafter *UDHR*]; *see also* ICESCR, *supra* note 64, at art. 12.

<sup>97</sup> ICESCR, *supra* note 64, at art. 12.

<sup>98</sup> World Health Org., *Constitution of the World Health Organization*, pmb1 [https://www.who.int/governance/eb/who\\_constitution\\_en.pdf](https://www.who.int/governance/eb/who_constitution_en.pdf).

<sup>99</sup> Comm. on Econ. Soc., and Cultural Rts., *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 8, U.N. Doc. CESCR/C.12/2000/4 (Nov. 8, 2000) [hereinafter *CESCR General Comment No. 14*].

<sup>100</sup> *Id.* at ¶ 30–33.

and of quality.<sup>101</sup> With that in mind, there are several international agreements and declarations that discuss the right to health and the obligations this right places upon state actors.<sup>102</sup>

Although the most authoritative source on the right to health is ICESCR, the right to health is also referenced in the Universal Declaration of Human Rights (UDHR), the International Convention on the Elimination of all Forms of Racial Discrimination (ICERD), the Convention on the Elimination of all Forms of Discrimination Against Women (CEDAW), and the Convention on the Rights of the Child (CRC).<sup>103</sup> The UDHR is not a legally binding document, so the rights set forth in the document are adopted by states on a voluntary basis.<sup>104</sup> However, it should be noted that the UDHR is a heavily influential document, as it has had a “profound influence on the development of international human rights law.”<sup>105</sup> ICERD, CEDAW, and CRC, however, have differing binding authority on the U.S. and Canada.<sup>106</sup> Therefore, it is necessary to recognize that the U.S.’s obligations under treaties referencing the right to health are distinct from Canada’s obligations.<sup>107</sup>

A country that has signed a treaty, as opposed to having ratified a treaty, imposes differing obligations on the country.<sup>108</sup> A signatory

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<sup>101</sup> *Id.* at ¶ 30.

<sup>102</sup> *Id.* at ¶ 2, 33.

<sup>103</sup> International Covenant on the Elimination of all Forms of Racial Discrimination art. 5(e)(iv), *ratified* Oct. 21, 1994, 660 U.N.T.S. 195, 212 [hereinafter *ICERD*]; Convention on the Elimination of all Forms of Discrimination Against Women art. 11.1(f), *adopted* Dec. 18, 1979, 1249 U.N.T.S. 13 [hereinafter *CEDAW*]; Convention on the Rights of the Child art. 24, *adopted* Nov. 20, 1989, 1577 U.N.T.S. 3 [hereinafter *CRC*].

<sup>104</sup> *What is the Universal Declaration of Human Rights?*, AUSTRALIAN HUM. RIGHTS COMM’N, <https://humanrights.gov.au/our-work/what-universal-declaration-human-rights> (last visited Mar. 1, 2021).

<sup>105</sup> *Id.*

<sup>106</sup> *See generally United States Ratification of International Human Rights Treaties*, HUM. RIGHTS WATCH (July 24, 2009, 12:24 PM), <https://www.hrw.org/news/2009/07/24/united-states-ratification-international-human-rights-treaties>.

<sup>107</sup> *Id.*

<sup>108</sup> *Chapter Four: Becoming a Party to the Convention and the Optional Protocol*, U.N. DEP’T OF ECON. & SOC. AFF., <https://www.un.org/development/desa/disabilities/resources/handbook-for-parliamentarians-on-the-convention-on-the-rights-of-persons-with-disabilities/chapter-four-becoming-a-party-to-the-convention-and-the-optional-protocol.html> (last visited Jan. 21, 2021) [hereinafter *Chapter Four*].

cannot take any actions that would violate the core purpose of the treaty.<sup>109</sup> In the context of the right to health, this could be intentionally denying information about contraception or HIV/AIDS methods of prevention.<sup>110</sup> On the other hand, a state that has ratified a treaty outlining a right to health has three obligations: (1) to respect, (2) to protect, and (3) to fulfill each person's right to the highest attainable standard health.<sup>111</sup> The obligation to respect entails "refrain[ing] from interfering directly or indirectly with the enjoyment of the right to health."<sup>112</sup> The obligation to protect requires state actors to take any necessary measures to "prevent third parties from interfering with individual's right to health."<sup>113</sup> Finally, the obligation to fulfill requires that state actors "adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health."<sup>114</sup>

While the U.S. has only ratified ICERD, they have signed ICESCR.<sup>115</sup> Canada has ratified both ICESCR and ICERD, assuming significantly more obligations than the U.S.<sup>116</sup> Despite only signing ICESCR, the U.S. is still under an obligation to "refrain in good faith from acts that would defeat the object and purpose of the treaty."<sup>117</sup> However, this limitation does not appear to be substantial, as the right to health is only one part of the treaty.

Canada, by ratifying ICESCR, has agreed to be bound by the treaty and thus must respect, protect, and fulfill the right to health.<sup>118</sup>

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<sup>109</sup> *Id.*

<sup>110</sup> *ICESCR General Comment No. 14*, *supra* note 99, ¶ 33.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

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

<sup>115</sup> *Status of Ratification Interactive Dashboard*, UNITED NATIONS OFF. OF THE HIGH COMM'R, <https://indicators.ohchr.org> (last visited Mar. 1, 2021) [hereinafter *Status of Ratification*].

<sup>116</sup> Curtis Bradley, *Treaty Signature*, DUKE LAW SCHOLARSHIP REPOSITORY (Oct. 5, 2011), [https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3088&context=faculty\\_scholarship](https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3088&context=faculty_scholarship); *see also Status of Ratification*, *supra* note 115.

<sup>117</sup> *2011 Treaty Event Towards Universal Participation and Implementation: Fact Sheet #1*, UNITED NATIONS, [https://treaties.un.org/doc/source/events/2011/Press\\_kit/fact\\_sheet\\_1\\_english.pdf](https://treaties.un.org/doc/source/events/2011/Press_kit/fact_sheet_1_english.pdf) (last visited Mar. 1, 2021).

<sup>118</sup> *International Human Rights Law*, UNITED NATIONS OFF. OF THE HIGH COMM'R, <https://www.ohchr.org/en/professionalinterest/pages/internationallaw.aspx> (last visited Mar. 1, 2021).

Respect requires that a “State refrain from interfering directly or indirectly with the enjoyment of the right to health.”<sup>119</sup> Protection entails that a state “take measures that prevent third parties from interfering” with the right to health guaranteed in Article 12.<sup>120</sup> Finally, states must fulfill the right to health by adopting “appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.”<sup>121</sup> General Comment 14 also highlights the “essential role” of international cooperation and that sovereigns “comply with their commitment to take joint and separate action to achieve the full realization of the right to health.”<sup>122</sup>

i. ICESCR: Article 12

As evidenced by General Comment 14 by CESCR, the right to health comes with caveats.<sup>123</sup> First, the right to health is not a guarantee that a person will be healthy, as this is an impossibility.<sup>124</sup> The right to health more predominantly focuses on the actions and lack of actions that are required of the State parties.<sup>125</sup> State parties are limited in the actions they can take that would infringe on individuals’ right to health, given their duty to ensure the realization of the right to health through state actions.<sup>126</sup>

The right to health as it pertains to access to medications was explained by Special Rapporteur Anand Grover in her report to the United Nations General Assembly.<sup>127</sup> The Special Rapporteur was careful to note that “access to medicines is an integral component of the right to health.”<sup>128</sup> Based on this, she explained that all medications should be made “available, accessible, acceptable and of good

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<sup>119</sup> *CESCR General Comment No. 14*, supra note 99, at ¶ 33

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

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at ¶ 38.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at ¶ 8.

<sup>125</sup> *CESCR General Comment No. 14*, supra note 99, at ¶ 38.

<sup>126</sup> *Id.*

<sup>127</sup> Hum. Rts. Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, U.N. Doc. A/HRC/23/42 (May 1, 2013) [hereinafter *Special Rapporteur on Highest Attainable Standard of Health*].

<sup>128</sup> *Id.* at ¶ 3.

quality.”<sup>129</sup> Availability refers to the principle that medications must be “available in sufficient quantity within the state party.”<sup>130</sup> Accessibility, both physical and economic accessibility, means that the medicine must be available to every individual without discrimination.<sup>131</sup> Physical accessibility means that the medicine must be “within safe physical reach for all sections of the population.”<sup>132</sup> Economic accessibility requires that the medicines are affordable for all individuals.<sup>133</sup> Acceptability requires that medicine “must be respectful of medical ethics and culturally appropriate.”<sup>134</sup> Finally, good quality requires that the medications are “scientifically and medically appropriate.”<sup>135</sup>

ii. Universal Declaration of Human Rights (UDHR)

Article 25 of the UDHR contains a detailed list of rights that pertain to an individual’s right to health. Article 25(1) states that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and the necessary social services.”<sup>136</sup> Furthermore, this right goes on to provide that everyone also has “the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”<sup>137</sup> Despite not being legally binding on any countries, the “protections of the rights and freedoms set out in the Declaration has been incorporated into many national constitutions and domestic legal frameworks.”<sup>138</sup>

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<sup>129</sup> *Id.* at ¶ 4.

<sup>130</sup> *Id.*

<sup>131</sup> *CESCR General Comment No. 14*, *supra* note 99, at ¶ 12 (b).

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

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

<sup>135</sup> *Id.*

<sup>136</sup> UDHR, *supra* note 96, at art. 25(1).

<sup>137</sup> *Id.*

<sup>138</sup> *Universal Declaration of Human Rights*, AMNESTY INT’L, <https://www.amnesty.org/en/what-we-do/universal-declaration-of-human-rights/> (last visited Mar. 1, 2021).

### iii. ICERD

Article 5 of ICERD provides that without distinction “as to race, colour, or national origin,” everyone has a right to “public health, medical care, social security and social services.”<sup>139</sup> As both Canada and the U.S. have ratified ICERD, they are both bound by this treaty, and thus have a duty to uphold the right to public health.<sup>140</sup>

While both ICESCR and ICERD seem to put varying degrees of obligations on the U.S., the attention afforded documents in the U.S. is minimal and mainly aspirational.<sup>141</sup> While the U.S. has signed ICESCR and ratified ICERD, the process through which the U.S. ratifies treaties “diminishes the treaties’ intended effects.”<sup>142</sup> When engaging in the ratification process, the U.S. will engage in reservations, declarations, or understandings to combat any provisions in the treaty that are more stringent than existing U.S. law.<sup>143</sup> Furthermore the U.S. renders treaties “not self-executing,” and therefore they are only enforceable in courts through the implementation of legislation.<sup>144</sup> Moreover, the U.S. does not seek to enact legislation promoting the right to health as they argue that the right to health is already protected by the laws in the U.S., however, the U.S. has not expounded on how the right is protected by the current legal regime.<sup>145</sup>

## III. EBOLA CRISIS

This history leading up to the creation of a vaccine for the Ebola virus starkly contrasts the efforts in creating the COVID-19 vaccines, as Ebola is a predominantly underfunded disease.<sup>146</sup> This lack of funding stemmed from the fact that the Ebola virus mainly impacted lower-economic countries and rural communities.<sup>147</sup>

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<sup>139</sup> ICERD, *supra* note 103, at art. 5(e)(iv).

<sup>140</sup> Chapter Four, *supra* note 108.

<sup>141</sup> *U.S. Aversion to International Human Rights Treaties*, GLOB. JUST. CENTER BLOG (June 22, 2017), <https://globaljusticecenter.net/blog/773-u-s-aversion-to-international-human-rights-treaties>.

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

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

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

<sup>146</sup> IP Preparedness, *supra* note 51, at 1218.

<sup>147</sup> *Id.* at 1219.

Attention and funding towards the vaccine did not arise until economically advanced countries were impacted by the effects of the Ebola virus.<sup>148</sup> Thus, analyzing the timeline of the Ebola vaccine development as compared to the COVID–19 vaccine development will help to highlight the dangers that stem from the use of enforcement of strict IP rights during a global health crisis. It will also help illustrate the impact that first world country patent rights can have on those living in less economically stable countries when it comes to widespread viruses.

A. *Timeline*

Unfortunately, it took roughly 30 years to garner enough national attention to start R&D for a potential vaccine.<sup>149</sup> In 1976, the first strain of the virus appeared in Sudan.<sup>150</sup> This initial strain of the virus manifested itself mainly in animals, so response to this initial outbreak was minimal.<sup>151</sup> The next prominent exposure was the third strain of the Ebola virus, which appeared in humans in 1994.<sup>152</sup> At that point, this new strain of the virus began to affect Uganda.<sup>153</sup> A common denominator afflicting all of the areas where outbreaks occurred is the minimal regional economic power that fails to draw interest from private companies.<sup>154</sup> Despite the high outbreak fatality rate between 1996 and 2016 ranging from a low of 25 percent to as high as 90 percent, the lack of funding interest remained.<sup>155</sup>

Despite the reluctance of big pharmaceutical corporations to engage in costly R&D, the Canadian government funded research to create a vaccine for the Ebola virus.<sup>156</sup> After several years of research, a patent for an Ebola virus vaccine, rVSV–ZEBOV, was

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<sup>148</sup> *Id.* at 1224.

<sup>149</sup> See *Outbreaks Chronology: Ebola Virus Disease*, CDC, <http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html> (last updated July 28, 2017).

<sup>150</sup> *Id.*

<sup>151</sup> IP Preparedness, *supra* note 51, at 1208.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 1209.

<sup>155</sup> *Id.* at 1218–19.

<sup>156</sup> William W. Fisher III & Katrina Geddes, *Learning from Ebola: How Drug–Development Policy Could Help Stop Outbreaks of Infectious Diseases*, STANFORD UNIV. PRESS 1, 9 (Oct. 14, 2015), [https://cyber.harvard.edu/people/tfisher/Learning\\_from\\_Ebola.pdf](https://cyber.harvard.edu/people/tfisher/Learning_from_Ebola.pdf).

granted to Canada in 2003.<sup>157</sup> Animal testing was performed on the patented vaccine and these tests confirmed that the vaccine was safe and highly efficient.<sup>158</sup> Moved by these promising results, researchers initially hoped to begin human trials and subsequently licensing the vaccine by 2010.<sup>159</sup> However, this timeline was not met, as private pharmaceutical companies remained reluctant to engage in the costly development process until the 2014–2016 outbreak.<sup>160</sup> The later outbreak, which reached the U.S., opened up funding that would aid in supporting expedited R&D for the virus.<sup>161</sup> After the opening of funding, the rVSV–ZEBOV vaccine was eventually licensed to Merck and received FDA approval for prevention of the Ebola virus in 2019.<sup>162</sup>

### B. *Connections to the COVID–19 Development*

A key theme presented throughout the Ebola vaccine development history was that private pharmaceutical companies were unwilling to engage in the costly R&D associated with vaccine development for a virus that predominantly affected a group of people unable to generate enough revenue to cover the costs of R&D.<sup>163</sup> This notion is central in vaccination processes, as companies engaging in costly R&D have a greater motivation to focus their resources on treatments or preventatives for diseases that will generate large profits, like HIV/AIDS medications.<sup>164</sup> The intermittent nature of the Ebola outbreaks and the fact that these outbreaks occurred in non-affluent areas kept R&D efforts at a minimal level.<sup>165</sup>

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<sup>157</sup> IP Preparedness, *supra* note 51, at 1221; *see also* Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers, Can. Patent No. WO 2004/011–488 A2 (filed July 28, 2003).

<sup>158</sup> IP Preparedness, *supra* note 51, at 1221.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 1222.

<sup>161</sup> *Id.* at 1219.

<sup>162</sup> *First FDA–approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2019), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>.

<sup>163</sup> IP Preparedness, *supra* note 51, at 1218.

<sup>164</sup> *Id.* at 1209.

<sup>165</sup> *Id.* at 1213.

Furthermore, the fact that vaccine development oftentimes entails a reliance on public health organizations, governments, or non-profits renders it challenging to address the spread of viruses.<sup>166</sup> These organizations or entities are often limited in funding, support, and have a lack of experience in developing vaccines at a rapid rate.<sup>167</sup> As seen with the Canadian government during the production of the Ebola vaccine, it took almost a decade to move from patent to human trials.<sup>168</sup> Contrast that process with the less than a year it has taken to place several vaccines on the market for the COVID-19 virus.<sup>169</sup> The main difference between the two historical timelines is that COVID-19 vaccine development was supported by big pharmaceutical companies that have the necessary resources to expedite R&D.<sup>170</sup>

The troubles plaguing the vaccine development for the Ebola virus highlight the potential repercussions that may stem from COVID-19 vaccine patents. While players in big pharmaceuticals were quick to produce these COVID-19 vaccines, these large corporations have failed to address how their granted patents will affect the access to a vaccine in communities that reside in less affluent or rural areas.<sup>171</sup> The main focus on profit fails to consider the widespread impact of this virus, especially as it pertains to the communities that these pharmaceutical companies neglected during the Ebola outbreaks.<sup>172</sup> As seen by the development of the Ebola virus vaccine, private pharmaceutical corporations' main priority is profit.<sup>173</sup> Thus, there must be a system of checks and balances to

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<sup>166</sup> *Id.* at 1244.

<sup>167</sup> *Id.* at 1204.

<sup>168</sup> *Id.* at 1221.

<sup>169</sup> Nikola Davis, *How has a Covid Vaccine been Developed so Quickly?*, THE GUARDIAN (Dec. 8, 2020, 06:58 EST), <https://www.theguardian.com/society/2020/dec/08/how-has-a-covid-vaccine-been-developed-so-quickly>.

<sup>170</sup> Drew Armstrong, *The World's Most Loathed Industry gave us a Vaccine in Record Time*, BLOOMBERG (Dec. 23, 2020, 5:00 AM), <https://www.bloomberg.com/news/features/2020-12-23/covid-vaccine-how-big-pharma-saved-the-world-in-2020>.

<sup>171</sup> Sharon Lerner, *World Faces Covid-19 "Vaccine Apartheid"*, THE INTERCEPT (Dec. 31, 2020, 9:52 AM), <https://theintercept.com/2020/12/31/covid-vaccine-countries-scarcity-access/>.

<sup>172</sup> IP of Vaccines, *supra* note 80, at 170-71.

<sup>173</sup> Richard Anderson, *Pharmaceutical Industry gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <https://www.bbc.com/news/business-28212223>.

ensure that people worldwide have economic and physical access to the vaccines, and this requires a restructuring of the strong IP rights associated with pharmaceutical patents.

#### IV. CURRENT RESPONSES TO COVID-19 VACCINE DEVELOPMENT

##### A. *The Vaccine Race*

As exemplified by the Ebola outbreak in 2014–2016, large scale outbreaks temporarily heighten the incentives for private pharmaceutical companies to engage in costly R&D.<sup>174</sup> These incentives, such as increased funding streams, ignite a race for the development of a vaccine that responds to the outbreak.<sup>175</sup> Moreover, pharmaceutical companies are not often forced to start from scratch on a vaccine.<sup>176</sup> It is likely that any pathogen that has had a modicum of pre-outbreak R&D will be already have technology that is protected by IP rights.<sup>177</sup> However, similar to changing formulations, big pharmaceutical companies can utilize this prior research to develop their own vaccine or drug that they themselves can patent.<sup>178</sup>

While the race for patents primarily wages between private pharmaceutical companies due to their economic power, some governments will often involve themselves in the development process to promote a sense of vaccine nationalism.<sup>179</sup> Countries seeking to be the leader in the vaccine race will open up funding, expedite patent processes, and aid private companies that are within their region.<sup>180</sup>

Currently three major players have hit the U.S. market with a COVID-19 vaccine: (1) Moderna, (2) Pfizer-BioNTech, and (3)

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<sup>174</sup> IP Preparedness, *supra* note 51, at 1222.

<sup>175</sup> *Id.* at 1225–26.

<sup>176</sup> *Id.* at 1244.

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> Jon Smith et al., *Vaccine Production, Distribution, Access and Uptake*, NAT'L CENTER FOR BIOTECHNOLOGY INFO. (July 30, 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3164579/>.

<sup>180</sup> *Id.*

Johnson and Johnson.<sup>181</sup> On December 11, 2020 the first vaccine was approved by the FDA for emergency usage and formulated by Pfizer and BioNTech.<sup>182</sup> The Pfizer vaccine is “based on mRNA technology, which is completely new in a human vaccine.”<sup>183</sup> The vaccine was formulated by introducing “part of the genetic material of the SARS-CoV-2 virus in the form of messenger RNA.”<sup>184</sup> Moderna’s vaccine uses the same mRNA type of formulation in their COVID-19 vaccine.<sup>185</sup>

Ingredients within the two vaccines are similar, however there are some slight differences in formulation and dosages.<sup>186</sup> Pfizer’s ingredients are listed as: mRNA, lipids, potassium chloride, mono-basic potassium phosphate, sodium chloride, dibasic sodium phosphate dehydrate, and sucrose.<sup>187</sup> Moderna’s ingredients are mRNA, lipids, tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.<sup>188</sup> Furthermore, while both vaccines require two shots, Moderna chose a much large dosage per shot than

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<sup>181</sup> Claire Felter, *A Guide to Global COVID-19 Vaccine Efforts*, COUNCIL ON FOREIGN REL, <https://www.cfr.org/backgrounder/guide-global-covid-19-vaccine-efforts> (last updated Mar. 1, 2021, 9:00 AM).

<sup>182</sup> *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Authorization for First COVID-19 Vaccine*, FOOD & DRUG ADMIN. (Dec. 11, 2020), <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>

<sup>183</sup> Nathan Bartlett, *Pfizer Vaccine may not be the Choice for Frail People, but it's too Early to make Firm Conclusions*, THE CONVERSATION (Jan. 18, 2021, 1:43 AM), <https://theconversation.com/the-pfizer-vaccine-may-not-be-the-best-choice-for-frail-people-but-its-too-early-to-make-firm-conclusions-153445>; see also *Understanding and Explaining mRNA COVID-19 Vaccines*, CTR. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html> (last reviewed Nov. 24, 2020).

<sup>184</sup> Bartlett, *supra* note 183.

<sup>185</sup> Alejandra Martinez, *Moderna vs. Pfizer: Is There a “Best” mRNA Vaccine?*, THE SCIENTIST (Sept. 24, 2021), <https://www.the-scientist.com/news-opinion/moderna-vs-pfizer-is-there-a-best-mrna-vaccine-69229>.

<sup>186</sup> Helen Branswell, *A Side-by-Side Comparison of the Pfizer/BioNTech and Moderna Vaccines*, STATNEWS, <https://www.statnews.com/2020/12/19/a-side-by-side-comparison-of-the-pfizer-biontech-and-moderna-vaccines/> (last updated Jan. 31, 2022).

<sup>187</sup> *Fact Check-Anti-COVID-19 vaccine cartoon contains false information*, REUTERS (Aug. 2, 2021 1:22 PM), <https://www.reuters.com/article/factcheck-covid-cartoon/fact-check-anti-covid-19-vaccine-cartoon-contains-false-information-idUSL1N2P91K7>.

<sup>188</sup> *Id.*

Pfizer.<sup>189</sup> The Pfizer vaccine is administered with a first shot of 30 micrograms of the vaccine and a second shot after 21 days of the same dosage.<sup>190</sup> Moderna has a 100 microgram dosage and the second dose is administered after a 28-day waiting period.<sup>191</sup>

Both Moderna and Pfizer–BioNTech claim that several of their preexisting patents protect their vaccine formulations.<sup>192</sup> As listed on Moderna’s website, they have seven patents that protect their COVID–19 mRNA–1273 vaccine.<sup>193</sup> These patents are from the U.S. and foreign jurisdictions.<sup>194</sup> Similarly, the Pfizer–BioNTech COVID–19 vaccine has patent protections both nationally and internationally.<sup>195</sup>

### B. U.S. Response to COVID–19

Similar to the U.S. response during the Ebola outbreak of 2014–2016, the U.S. was quick to get involved in pharmaceutical research for a virus that was and continues to impact people within their borders.<sup>196</sup> The U.S. took swift steps to promote a COVID–19 vaccine development process after the initial outbreak.<sup>197</sup> Through several strategic steps, the U.S. gave U.S.–based pharmaceutical corporations a leg up in creating the world’s first COVID–19 vaccines.<sup>198</sup>

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<sup>189</sup> Branswell, *supra* note 186.

<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> See Daniel Shores, *Breaking Down Moderna’s COVID–19 Patent Pledge: Why Did they do it?*, IP WATCHDOG (Nov. 11, 2020), <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/>; see also Mario Gaviria & Burcu Kilic, *BioNTech and Pfizer’s BNT162 Vaccine Patent Landscape*, PUB. CITIZEN (Nov. 16, 2020), <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>.

<sup>193</sup> *Program Patents*, MODERNA, <https://www.modernatx.com/patents> (last visited Jan. 20, 2021).

<sup>194</sup> *Id.*

<sup>195</sup> Gaviria & Kilic, *supra* note 192.

<sup>196</sup> See generally Karen Weintraub & Elizabeth Weise, *Federal Spending on COVID–19 Vaccine Candidates Tops \$9 Billion, Spread among 7 Companies*, USA TODAY (Aug. 8, 2020, 8:00 AM), <https://www.usatoday.com/story/news/health/2020/08/08/feds-spending-more-than-9-billion-covid-19-vaccine-candidates/5575206002/>.

<sup>197</sup> *Id.*

<sup>198</sup> David E. Sanger et al., *Profits and Pride at Stake, the Race for a Vaccine Intensifies*, NY TIMES (May 2, 2020), <https://www.nytimes.com/2020/05/02/us/politics/vaccines-coronavirus-research.html>.

With respect to funds, the U.S. acted rapidly to ease the financial burden on the companies that were engaging in COVID-19 R&D for a potential vaccine.<sup>199</sup> The U.S. Patent and Trade Office (USPTO) enacted a process called the “COVID-19 Prioritized Examination Pilot Program” on May 8, 2020.<sup>200</sup> This program sought to fast-track the development of COVID-19 related technology and medication by expediting applications for patents relating to this research.<sup>201</sup> At the start of this program, the Patent Office began accepting requests for priority examination of up to 500 qualifying patent applications that pertained to COVID-19 ideas.<sup>202</sup> Furthermore, the Office also waived the payment of certain fees that are usually associated with prioritized examination of patent applications.<sup>203</sup>

The U.S. also limited regulations that were required of new vaccines by allowing the use of vaccines that had not yet been approved to help mitigate the Covid-19 pandemic.<sup>204</sup> Both the Pfizer and Moderna vaccines were given emergency use authorization status, which allowed the vaccines to be given to certain groups of people while safety and effectiveness studies were still underway.<sup>205</sup> Any new vaccine must be reviewed by the FDA, a process which involves a study conducted with thousands of people.<sup>206</sup> The normal process can take up to a decade in some cases.<sup>207</sup> However, as the

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<sup>199</sup> Weintraub & Weise, *supra* note 196.

<sup>200</sup> *COVID-19 Prioritized Examination Pilot Program*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/initiatives/covid-19-prioritized-examination-pilot> (last visited Jan. 22, 2021).

<sup>201</sup> *Id.*

<sup>202</sup> Department of Commerce Patent and Trademark Office; *COVID-19 Prioritized Examination Pilot Program*, 85 Fed. Reg. 94, 28932 (May 14, 2020).

<sup>203</sup> *Id.*

<sup>204</sup> *Emergency Use Authorization for Vaccines Explained*, U.S. FOOD & DRUG ADMIN. (Nov. 11, 2020), <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> [hereinafter *EUA Explained*].

<sup>205</sup> Berkeley Lovelace Jr., *FDA Approves Second Covid Vaccine for Emergency use as it Clears Moderna's for U.S. Distribution*, CNBC (Dec. 18, 2020, 7:59 PM), <https://www.cnbc.com/2020/12/18/moderna-covid-vaccine-approved-fda-for-emergency-use.html>; see generally *EUA Explained*, *supra* note 204.

<sup>206</sup> *EUA Explained*, *supra* note 204.

<sup>207</sup> *What does emergency use of a COVID-19 vaccine mean?*, ASSOCIATED PRESS (Nov. 20, 2020), <https://apnews.com/article/emergency-use-covid-19-vaccine-explained-c8cca451619c1705e06414a32c20facb>.

past years have come to show, the coronavirus is anything but normal. During the coronavirus pandemic, the FDA has minimally loosened their standards to allow “emergency use of experimental drugs, devices, vaccines, and other medical products.”<sup>208</sup> This emergency authorization process was beneficial to pharmaceutical companies who were attempting to be the first into market with their COVID–19 vaccines.<sup>209</sup>

When large pharmaceutical companies started to get close to a potential vaccine, the U.S. government was quick to strike a deal with these corporations.<sup>210</sup> During the early clinical phases of Pfizer and BioNTech’s vaccine research, the U.S. made an agreement for a future order of the vaccine on July 22, 2020.<sup>211</sup> The deal with Pfizer stipulated that the U.S. government would order an initial 100 million doses of the vaccine for \$1.95 billion.<sup>212</sup> This deal also included a provision that the U.S. could acquire an additional 500 million doses.<sup>213</sup> Similarly, the U.S. also made an agreement with Moderna a month later in August of 2020.<sup>214</sup> The Moderna deal stated that Moderna would supply the U.S. government with an initial 100 million doses of their vaccine for \$1.525 billion.<sup>215</sup> The

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<sup>208</sup> *Id.*

<sup>209</sup> See generally Claudia Assis, *Pfizer, BioNTech make it Official: COVID–19 Vaccine EUA Submitted*, MARKET WATCH (Nov. 20, 2020, 5:25 PM), <https://www.marketwatch.com/story/pfizer-biontech-make-it-official-covid-19-vaccine-eua-submitted-2020-11-20>.

<sup>210</sup> See generally Will Feuer, *U.S. Agrees to Pay Pfizer and BioNTech \$2 Billion for 100 Million Doses of Coronavirus Vaccine*, CNBC (July 22, 2020, 7:16 AM), <https://www.cnbc.com/2020/07/22/us-government-taps-pfizer-to-produce-millions-of-doses-of-coronavirus-vaccine.html>.

<sup>211</sup> *Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-Based Vaccine Candidate Against SARS–COV–2*, PFIZER (July 22, 2020, 7:10 AM), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600>.

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> Jeff Mason & Carl O’Donnell, *U.S. Inks \$1.5 Billion Deal with Moderna for 100 Million Doses of COVID–19 Vaccine*, REUTERS (Aug. 11, 2020, 6:08 PM), <https://www.reuters.com/article/us-health-coronavirus-moderna-vaccine/u-s-inks-1-5-billion-deal-with-moderna-for-100-million-doses-of-covid-19-vaccine-idUSKCN2572T5>.

<sup>215</sup> *U.S. Govt Secures Access to 100 Million More Doses of Moderna’s COVID–19 Vaccine*, REUTERS (Dec. 11, 2020, 4:48 PM), <https://www.reuters.com>

Moderna deal also provided the U.S. government an option to purchase an additional 400 million doses.<sup>216</sup>

### C. *Canadian Response*

Canada took a less straight-forward approach by relying on “supply contracts to secure COVID-19 vaccines from drugmakers like Pfizer.”<sup>217</sup> This course of action positioned Canada’s funding to buy doses of the vaccine from abroad.<sup>218</sup> While still economically affluent in many ways, Canada recognized that the process of developing and manufacturing a vaccine would take large pockets which would be tough for them to substantiate.<sup>219</sup> As reported by Michael Mullette, the new managing director of Moderna’s Canadian subsidiary, the U.S. has 10 times the population of that in Canada—a factor in assessing “pandemic vaccine preparedness.”<sup>220</sup> Thus, in addition to Canada’s prior purchase agreements in 2020, the country is still currently procuring more vaccine dosages via more purchase agreements.<sup>221</sup>

Notwithstanding their reliance on supply contracts, Canada has seen “more experimental COVID-19 vaccines in development than any country aside from the U.S. and China.”<sup>222</sup> Medicago, based in Quebec, had been working with minor funding on a plant-based vaccine that includes an efficacy booster, called adjuvant, from GlaxoSmithKline.<sup>223</sup> Medicago is own by the tobacco company Philip Morris and by Japan’s Mitsubishi Tanabe Pharma.<sup>224</sup> The company produced promising data quite early and received a

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m/article/us-health-coronavirus-moderna/u-s-govt-secures-access-to-100-million-more-doses-of-modernas-covid-19-vaccine-idUSKBN28L2SY.

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

<sup>217</sup> Allison Martell, *Canada Bets on Imports as Home-Grown COVID-19 Vaccine Heads to Large-Scale Trials*, REUTERS (Nov. 13, 2020, 8:25 AM), <https://www.reuters.com/article/us-health-coronavirus-canada-vaccines-idUSKBN27T1RS>.

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

<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> *Id.*; See also *Procuring vaccines for COVID-19*, Gov. Can., <https://www.canada.ca/en/public-services-procurement/services/procuring-vaccines-covid19.html> (last updated Feb. 24, 2022).

<sup>222</sup> Martell, *supra* note 217.

<sup>223</sup> *Id.*

<sup>224</sup> *Id.*

purchase offer from the Canadian government in October of 2020.<sup>225</sup> This deal included a Canadian \$173 million purchase agreement.<sup>226</sup> This amount was starkly less than the amount that the U.S. provided to Moderna in their developmental stages.<sup>227</sup> However, Medicago was quite far behind the two power players, as they were only expecting to produce “up to 100 million doses by the end of 2021.”<sup>228</sup> Should Medicago’s development reach this scale, Canada would be the first to receive the Medicago vaccine.<sup>229</sup> As of February 24, 2022, Medicago has received approval for their vaccine from Health Canada and seeks to fulfill the order in the purchase agreement as soon as possible.<sup>230</sup>

## V. TRIPS EXCEPTIONS AND THE RIGHT TO HEALTH

Given the positive effect of IP protections and the right to health on the overall welfare of individuals worldwide,<sup>231</sup> there is a need for both rights to co-exist internationally. Although there are inconsistencies between the two rights at times, utilization of the full scope and language of these international documents allows for a complementary reading where the right to health melds with international IP protections.<sup>232</sup> In fact, with greater flexibility within the international IP regime, these protections can improve individuals’ access to medications and other healthcare technologies.<sup>233</sup>

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<sup>225</sup> *Medicago signs agreements with the government of Canada to supply up to 76 million doses of its recombinant plant-derived COVID-19 vaccine*, MEDICAGO (Oct. 23, 2020), <https://medicago.com/en/press-release/medicago-signs-agreements-with-the-government-of-canada-to-supply-up-to-76-million-doses-of-its-recombinant-plant-derived-covid-19-vaccine/>.

<sup>226</sup> Martell, *supra* note 217.

<sup>227</sup> *Id.*

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

<sup>229</sup> *Id.*

<sup>230</sup> *Medicago and GSK announce the approval by Health Canada of COVIFENZ, an Adjuvanted Plant-Based COVID-19 Vaccine*, MEDICAGO (Feb. 24, 2022), <https://medicago.com/en/press-release/covifenz/>.

<sup>231</sup> Laurence Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 48-49 (2003).

<sup>232</sup> *Id.* at 61.

<sup>233</sup> Diane Nicol & Olasupo Owoeye, *Using TRIPS Flexibilities to Facilitate Access to Medicines*, BULL. OF THE WORLD HEALTH ORG. (Apr. 18, 2013), <https://www.who.int/bulletin/volumes/91/7/12-115865/en/>.

*A. Exceptions to International IP Rights that Account for the Right to Health*

Recognizing the impact that stringent IP protections can have on individuals' access to health, the WTO provided flexibility within the TRIPS Agreement and implemented the DOHA Declaration so that members had the power to impose restrictions on international trade laws in order to protect individuals' health.<sup>234</sup> Explicitly recognized is the right to utilize this flexibility in times of national emergencies, such as those presented during a global pandemic.<sup>235</sup> DOHA simply clarifies the authorization of states to utilize the flexibilities present within the TRIPS Agreement that are enumerated in case of a national emergency.<sup>236</sup> The agreement reiterates the types of actions that states can take regarding patents during a national emergency.<sup>237</sup>

There are two prominent sections of the TRIPS Agreement which limit IP protections. Article 27(2) of the TRIPS Agreement specifically excludes from patentability any invention when exclusion is "necessary to protect ordre public or morality, including to protect human, animal, or plant life or health."<sup>238</sup> This language outlines a relationship between pharmaceutical patents and health within the international trade framework. The next is Article 31(b), which identifies a national emergency exception.<sup>239</sup> Article 31(b) proposes that a member does not need to get prior authorization from the right holder "on reasonable commercial terms and conditions" in order to use a patent in a case of a national emergency.<sup>240</sup> Should a national emergency arise, the right holder must only be "notified as soon as reasonably practicable."<sup>241</sup> Although seemingly applicable during the COVID-19 pandemic, a national emergency is not

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<sup>234</sup> DOHA Declaration Explained, *supra* note 84.

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

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> TRIPS Agreement, *supra* note 78, at art. 27(2).

<sup>239</sup> *Id.* at art. 31(b).

<sup>240</sup> *Id.*

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

defined within the TRIPS Agreement, so the interpretation of which events constitute this high standard are left to each member state.<sup>242</sup>

*B. Current Problems Surrounding the Listed Exclusions and Provisions*

A current problem with the exceptions provided for within the TRIPS Agreement and DOHA is the vagueness of the written terms.<sup>243</sup> Both the TRIPS Agreement and DOHA fail to define clearly what constitutes a national emergency.<sup>244</sup> With such ambiguity, it is often left to the state to determine whether a public health outbreak constitutes a “national emergency,” and would therefore trigger application of the exclusions.<sup>245</sup> This difference in interpretations can lead to a lack of standardized application of the exceptions when a public health issue does arise.<sup>246</sup> Furthermore, both agreements fail to define what constitutes an epidemic.<sup>247</sup> As detailed above, this ambiguity leaves decision-making of what constitutes an epidemic to each country, which leaves less developed countries in a problematic place because if they were to invoke this exclusion they may face repercussions from their trade partners in other areas.<sup>248</sup>

*C. Provisions within the TRIPS Agreement to Promote the Right to Health during a Health Crisis*

*i. Compulsory Licenses*

Compulsory licenses are permitted within the “other use without authorization of the right holder” section of the TRIPS Agreement to balance the promotion of R&D into new drugs and “promoting access to existing drugs.”<sup>249</sup> Compulsory licensing is the process of governments allowing another person to “produce the patented

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<sup>242</sup> Dawn Dziuba, *TRIPS Article 31BIS and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?*, 20 IND. INT’L & COMP. L. REV. 195, 196 (2010).

<sup>243</sup> Wu, *supra* note 29, at 149.

<sup>244</sup> *Id.*

<sup>245</sup> *Id.*

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

<sup>247</sup> *Id.* at 149–50.

<sup>248</sup> Kerry & Lee, *supra* note 93.

<sup>249</sup> DOHA Declaration Explained, *supra* note 84.

product or process without the consent of the patent owner.”<sup>250</sup> This process can be especially beneficial to under-developed countries, as they have the ability to ensure that the good is available to the individuals in their territory for an affordable price.<sup>251</sup> Furthermore, promoting compulsory licensing can help prevent advanced countries from advancing a theory of neocolonialism by upholding strict patent protections which disproportionately “favor advanced countries as developing countries have much fewer patents to protect.”<sup>252</sup> Overall, the largest benefit of compulsory licensing is the ability of this process to save the lives of those in lower-developed countries by ensuring the accessibility of generic drugs at an affordable price.<sup>253</sup>

In order to enact a compulsory licensing process, several requirements must be met beforehand.<sup>254</sup> These requirements are put in place with the intent to protect the legitimate interests of the original patent holder.<sup>255</sup> Typically, absent a national emergency, the individual seeking to license the drug must first attempt “to obtain a voluntary license from the right holder on reasonable commercial terms.”<sup>256</sup> If the license is granted, then the licensee must provide “adequate remuneration” to the original patent holder.<sup>257</sup> While a national or other extreme urgency may provide a bypass for the initial requirement, there are still lingering requirements present.<sup>258</sup> For example, compulsory licenses may not be granted exclusively to licensees.<sup>259</sup> An issued license must also be limited in “scope and duration” for the “purpose for which it was granted.”<sup>260</sup> Finally, an

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<sup>250</sup> Justin Culbertson & Jason J. Jardine, *Compulsory Patent Licensing in the Era of Pandemic*, INT’L BAR ASS’N. (June 30, 2020), <https://www.ibanet.org/Article/NewDetail.aspx?ArticleUid=36a60309-5a33-4891-8624-86a6d89a251e>.

<sup>251</sup> Muhammad Zaheer Abbas, *Compulsory Licensing: An Analysis of Arguments*, 3 INT’L J. OF SOC. SCI. AND HUMAN. 254, 254 (2013).

<sup>252</sup> *Id.* at 255.

<sup>253</sup> *Id.*

<sup>254</sup> *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., [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) (last visited Jan. 22, 2021).

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> *Id.*

<sup>259</sup> *Id.*

<sup>260</sup> *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 254.

issuance of a compulsory license does not diminish the right of the original patent holder.<sup>261</sup> The patent holder is still entitled to compensation for any duplicates of the product that is made under the compulsory license.<sup>262</sup>

ii. Parallel Importation

Parallel importation, along with compulsory licensing, is another method of providing access to a patented good within the TRIPS Agreement that has been described by the WTO in their application of DOHA.<sup>263</sup> Simply put, parallel importation describes the process of a patented good being imported into another country with or without the patent-holder's consent.<sup>264</sup> Therefore, the original patent holder or exclusive licensee of the right in either territory may not be the same.<sup>265</sup> The notion behind this idea is that the patent holder is not able to prohibit subsequent resales of patented goods because the patent holder's control over those goods is "exhausted" after the good has been placed on the market initially by the holder.<sup>266</sup>

The idea of permitting parallel transportation is highlighted in Article 6 of the TRIPS Agreement and the DOHA Declaration.<sup>267</sup> Article 6 of the TRIPS Agreement states that "practices relating to parallel importation cannot be challenged under the WTO dispute settlement system."<sup>268</sup> Moreover, DOHA affirms this right by providing that member states have the right to establish their "own regime for such exhaustion without challenge."<sup>269</sup>

The prices of patented goods sold under the practice of parallel importation can be explained by the discrepancies in the goods

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<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> DOHA Declaration Explained, *supra* note 84.

<sup>264</sup> *Id.*

<sup>265</sup> Frederick M. Abbott, *Parallel Importation: Economic and Social Welfare Dimensions*, INT'L INST. FOR SUSTAINABLE DEV. 4, 4 (2007), <http://law.scu.edu/wp-content/uploads/hightech/Abbott-Parallel-Importation.pdf>.

<sup>266</sup> *Id.*

<sup>267</sup> TRIPS Agreement, *supra* note 78, at art. 6; *see also* DOHA Declaration Explained, *supra* note 84.

<sup>268</sup> TRIPS Agreement, *supra* note 78, at art. 6.

<sup>269</sup> DOHA Declaration, *supra* note 88, at ¶ 5(d).

market.<sup>270</sup> The rationale behind parallel importation is to allow for the importation of lower priced, patented products into less developed countries.<sup>271</sup> In an application of parallel importation, a less developed country has the ability to import and resell a genuine product from a distributor who has legally obtained the product from a manufacturer at a low price instead of the country buying the product directly from the manufacturer.<sup>272</sup> Thus, the product enters a country's market with the express approval of the IP holder. However, the product is then exported to another country without consent.<sup>273</sup>

There is one significant benefit and one significant detriment to the practice of parallel importation that should be noted. First, parallel importation can be a great tool in promoting access to affordable drugs worldwide.<sup>274</sup> Since there are substantial differences in the price between the same drug sold in different markets, parallel importation allows for countries to account for their specific markets.<sup>275</sup> The main consequence of this approach for those in developing countries is the cost of transportation that is associated with importing and packaging medicine.<sup>276</sup> These costs can "decrease a significant portion of any potential price advantages."<sup>277</sup>

Clarification of the U.S.'s treatment of parallel importation is the Supreme Court's decision in *Impression Products, Inc., v. Lexmark Int'l, Inc.*<sup>278</sup> The Court held that a patent holder was not able to bring an infringement suit against a remanufacturer.<sup>279</sup> Here, a toner company, Lexmark, "sells toner cartridges to consumers in the United States and around the Globe" with a cartridge that is

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<sup>270</sup> DOHA Declaration Explained, *supra* note 84.

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

<sup>272</sup> SPA Ajibade & Co., *Parallel Importation and the Exhaustion of Rights Principle under the "TRIPS Agreement" and the "Doha Declaration"*, LEXOLOGY (Dec. 11, 2015), <https://www.lexology.com/library/detail.aspx?g=3056555b-b704-4827-8843-dc7288432fb3>.

<sup>273</sup> *Id.*

<sup>274</sup> Farzad Peiravian, *Parallel Import: Is it Worth?*, 13(4) IRANIAN J. OF PHARM. RSCH. 1111, 1113 (2014).

<sup>275</sup> *Id.*

<sup>276</sup> *Id.*

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

<sup>278</sup> *Impression Products, Inc., v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523 (2017).

<sup>279</sup> *Id.* at 1536.

protected by several patents.<sup>280</sup> In order to keep business for used toner cartridges, the company attempted to provide customers with an incentive to only use the cartridge once instead of having it re-filled by another person or company.<sup>281</sup> However, other companies, like Impression Products, would buy the used cartridges, fill them with toner, and resell them.<sup>282</sup> After being sued by Lexmark, the Supreme Court held that Lexmark had “exhausted its patent rights in these cartridges the moment it sold them.”<sup>283</sup> While the Court explored Lexmark’s potential claim under contract law, it ultimately noted that Lexmark had no authority to retain “patent rights in an item that it has elected to sell.”<sup>284</sup> The rationale behind this holding was the principle that the “exhaustion rule marks the point where patent rights yield to the common law principle against restraints on alienation.”<sup>285</sup> As applied to a vaccine, this case would permit a distributor to purchase vaccines in bulk and then later sell these vaccines to other countries at a discounted rate.

### iii. Least Developed Countries (LDC) Provision

At the forefront of the discussion on access and availability of a COVID–19 vaccine for less developed countries is the LDC Transition Period set forth in the TRIPS Agreement.<sup>286</sup> Due to the special requirements of LDC, such as their “economic, financial and administrative techniques,” LDCs have an “extended transition period to protect IP under the WTO’s” TRIPS Agreement.<sup>287</sup> In the preamble of the TRIPS Agreement, this need is recognized and is set forth to prove a high rate of flexibility for LDCs in implementing “laws and

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<sup>280</sup> *Id.* at 1529.

<sup>281</sup> *Id.* at 1530.

<sup>282</sup> *Id.*

<sup>283</sup> *Id.* at 1531.

<sup>284</sup> *Impression Products, Inc.*, 137 S. Ct. at 1531.

<sup>285</sup> *Id.* at 1537.

<sup>286</sup> *The Need to Extend the WTO TRIPS Pharmaceuticals Transition Period for LDCs in the COVID–19 Era: Evidence from Bangladesh*, UNITED NATIONS DEP’T OF ECON. AND SOC. AFF. (Aug. 27, 2020), <https://www.un.org/development/desa/dpad/publication/the-need-to-extend-the-wto-trips-pharmaceuticals-transition-period-for-ldcs-in-the-covid-19-era-evidence-from-bangladesh/>.

<sup>287</sup> *Responding to Least Developed Countries’ Special Needs in Intellectual Property*, WORLD TRADE ORG. (Oct. 16, 2013), [https://www.wto.org/english/tratop\\_e/trips\\_e/ldc\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm).

regulations domestically.”<sup>288</sup> In Article 66.1 of the agreement, this transition period has been extended on two occasions.<sup>289</sup> The transition period for pharmaceutical patents was initially extended until July 1, 2021.<sup>290</sup> Provoked by the pandemic, another proposal has been entered so as to permit another extension for LDCs as they may face difficulties when attempting to manufacture vaccines in their own countries.<sup>291</sup>

*D. Utilizing the Safeguard Provisions of the TRIPS Agreement to Promote the Right to Health for COVID–19 Vaccines*

On October 2, 2020, both India and South Africa petitioned the WTO to “allow all WTO members to bypass granting or enforcement of patents . . . on COVID–19–related drugs, vaccines, diagnostics and other medical technologies for the duration of the pandemic” under the TRIPS Agreement provisions.<sup>292</sup> Highlighting the devastating health effects of a global pandemic, the petitioning countries sought to waive enforcements for any COVID–19 treatments for the duration of the pandemic.<sup>293</sup> The strongest legal ground for this proposal was the national health crisis section of the TRIPS Agreement. On October 15, 2020, 40 member states of the

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<sup>288</sup> TRIPS Agreement, *supra* note 78, at pmb1.

<sup>289</sup> Nirmalya Syam, *The Trips Council on 15–16 October Should Agree to Extend the Transition Period That Exempts Least Developed Countries From Implementation of the WTO Trips Agreement*, INFOJUSTICE (Oct. 7, 2020), <http://infojustice.org/archives/42666>.

<sup>290</sup> *Extension of the Transition Period Under TRIPS Article 66.1 for Least Developed Country Members*, WORLD TRADE ORG. 1, 2 (Oct. 1, 2020), <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W668.pdf&Open=True>.

<sup>291</sup> *LDCs at the WTO: Proposals for Extension of LDC Support Measures for a Period After Graduation*, UNITED NATIONS (Dec. 11, 2020), <https://www.un.org/ldportal/news/ldcs-wto-proposals-extension-ldc-support-measures-period-after-graduation> [hereinafter *Proposal for Extension of LDC Support*].

<sup>292</sup> Brook Baker, *South Africa and India’s Proposal to Waive Recognition and Enforcement of Intellectual Property Rights for COVID–19 Medical Technologies Deserves Universal Support, but Countries also have to take Domestic Measures*, HEALTH GAP GLOB. ACCESS PROJECT (Oct. 10, 2020), <https://healthgap.org/south-africa-and-indias-proposal-to-waive-recognition-and-enforcement-of-intellectual-property-rights-for-covid-19-medical-technologies-deserves-universal-support-but-countries-also-have-to/>.

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

WTO discussed this proposal and most of the developing countries supported the proposal.<sup>294</sup> Powerful countries, like the U.S., Japan, and Canada, continue to block this proposal despite a global pandemic seeming to be well within this exception.<sup>295</sup> There has still been no action taken on this petition.<sup>296</sup> The WTO upholding coronavirus as a national health crisis would promote acceptance of this proposal, which would uphold the core standards of the TRIPS Agreement while ensuring that individuals residing in less developed countries have the opportunity to receive the vaccine in a reasonable amount of time.<sup>297</sup>

Moderna has already pledged to engage in any licensing deals to help combat the COVID-19 virus, which negates the need for a compulsory license under the TRIPS Agreement because they are voluntarily permitting other countries, upon request, to license their COVID-19 vaccine.<sup>298</sup> This pledge to permit licensing upon request creates an opportunity for lesser developed countries to access the vaccine in a more expedient manner than if their vaccine stockage was dependent upon their ability to afford the vaccine prices set forth by the actual patent holder corporation.<sup>299</sup> Additionally, these licensing deals would “allow other market participants to aggressively pursue mRNA-based therapies for COVID-19 without fear of suit.”<sup>300</sup> While the motives for such a pledge may lie in Moderna’s goal of building an infrastructure for technology based on mRNA, it nonetheless creates an opportunity for countries to

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<sup>294</sup> *Members Discuss Intellectual Property Response to the COVID-19 Pandemic*, WORLD TRADE ORG. (Oct. 20, 2020), [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_20oct20\\_e.htm](https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm).

<sup>295</sup> Shores, *supra* note 192.

<sup>296</sup> See Emma Farge, *A year after COVID vaccine waiver proposal, WTO talks are deadlocked*, REUTERS (Oct. 4, 2021, 12:46 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/year-after-covid-vaccine-waiver-proposal-wto-talks-are-deadlocked-2021-10-04/>.

<sup>297</sup> Baker, *supra* note 292.

<sup>298</sup> Shores, *supra* note 192.

<sup>299</sup> See generally Nasos Koukakis, *Countries Worldwide Look to Acquire the Intellectual Property Rights of Covid-19 Vaccine Makers*, CNBC (Jan. 22, 2021, 8:45 AM), <https://www.cnbc.com/2021/01/22/countries-look-to-acquire-the-ip-of-vaccine-makers-to-fight-pandemic.html>.

<sup>300</sup> Shores, *supra* note 192.

prioritize the right to health within their borders while Moderna retains their IP protections.<sup>301</sup>

A forced compulsory license process could be extremely beneficial in leveraging the vaccine formulation created by Pfizer and BioNTech, as the corporations have failed to give any indication that they will renounce their exclusive right to produce their vaccine.<sup>302</sup> In this situation, countries which have failed to receive authorization to license the Pfizer–BioNTech coronavirus vaccine would receive permission to license the vaccine formulation without consent from the patent holding companies.<sup>303</sup> When granting patents to corporations that are producing COVID–19 vaccines, countries have the authority to put restrictions on exclusive patent rights, which would help balance the health of the public and the creators’ rights over their own creations.<sup>304</sup> The U.S., for example, has implemented “march in” rights under the Bayh–Dole Act, which would permit the U.S. government to “compel the owner of any invention obtained through federal funding to license it to one or more third parties to the extent necessary, among other things, to address health or safety needs, ‘upon terms that are reasonable under the circumstances.’”<sup>305</sup> As long as the government adequately compensates the original IP holders, taking this course of action could significantly benefit those who are unable to attain a licensing deal from the pharmaceutical company themselves.<sup>306</sup>

Utilizing the parallel imports option may prove to be a challenging feat that would not be plausible with the COVID–19 vaccines.<sup>307</sup> Parallel importation is a complex process and even more so with a vaccine that is being provided to countries on a limited quantity

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<sup>301</sup> *Id.*

<sup>302</sup> Culbertson & Jardine, *supra* note 250.

<sup>303</sup> See generally Jerome Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 (2) J LAW MED ETHICS 247 (2009).

<sup>304</sup> Culbertson & Jardine, *supra* note 250.

<sup>305</sup> *Id.*

<sup>306</sup> See generally Wu, *supra* note 29, at 148–51.

<sup>307</sup> Ronald Labonte & Mira Johri, *COVID–19 Drug and Vaccine Patents are Putting Profit before People*, THE CONVERSATION (Nov. 5, 2020, 4:43 PM), <https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270>.

basis.<sup>308</sup> Countries that are hoping to import the vaccine would “need to negotiate formal contracts with an exporting country’s producer” which can be difficult even without the costly devastation imposed by a pandemic.<sup>309</sup> Furthermore, these imports would be required to have their own packaging designs, and approval to import is “only for a specific time and for a specific purpose.”<sup>310</sup> All of these restrictions may be impossible to work around for the vaccine.

Countries like the U.S. and Canada should not continue to halt the LDC extension proposal, so that LDCs are not required to enforce global trade rules that protect pharmaceutical patents during a global pandemic.<sup>311</sup> The pandemic has created a need to reexamine the coexistent nature of trade and health and ensure that any IP laws are in accordance with the international right to health provisions.<sup>312</sup> Research indicates that it is necessary for LDCs to take maximum advantage of the TRIPS extension for LDCs as the COVID–19 virus creates a need for “mass production of low–cost treatments” and vaccines.<sup>313</sup> Permitting an extension of Article 66.1 would allow for LDCs to engage in this imperative task during a national health crisis. Recognizing that the “economic devastation and human cost of the pandemic will require full international support” is a stepping stone in realizing the impact that economically developed countries actions will have on the availability and accessibility of a COVID–19 vaccine in LDCs.<sup>314</sup> While a set date to end the TRIPS extension period may be required eventually, there should nonetheless be an emergency extension set forth that would accommodate for the unnatural circumstances that have been caused by the coronavirus pandemic.

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<sup>308</sup> *Id.*

<sup>309</sup> *Id.*

<sup>310</sup> *Id.*

<sup>311</sup> Baker, *supra* note 292; *see also* Proposal for Extension of LDC Support, *supra* note 291.

<sup>312</sup> Strengthening Human Rights and Transparency Around Covid–19 Vaccines, *supra* note 36.

<sup>313</sup> Daniel Gay & Kevin Gallagher, *The Need to Extend the WTO TRIPS Pharmaceuticals Transition Period for LDCs in the COVID–19 Era: Evidence from Bangladesh*, UNITED NATIONS COMM. FOR DEV. POL’Y 1, 3 (Aug. 2020).

<sup>314</sup> *Id.* at 2.

## VI. CONCLUSION

While compulsory licenses and extensions are viable options to promote widespread distribution of the vaccine, the seemingly more effective way to do so is through the acceptance of the proposed “temporary waiver suspending TRIPs obligation on all medical products needed to control the COVID–19 pandemic.”<sup>315</sup> The actions of the U.S. and Canada in attempting to block the proposal starkly contrast with the international human rights obligations in place.<sup>316</sup> Promotion of this waiver during a time of crisis would allow for LDCs to help combat the spread of coronavirus by attaining herd immunity with a COVID–19 vaccine.<sup>317</sup> The current TRIPS Agreement flexibilities are insufficient to combat this national health emergency and their implementation would “slows down the ability of countries to scale up production of needed COVID–19 products.”<sup>318</sup> Imposition of an obligation, not a voluntary act like that of Moderna, is a necessary step validated under the TRIPS Agreement and would help contain a virus that has already caused so much devastation.

The purpose of this article is not to suggest that patent protections should be rolled back completely during the coronavirus pandemic, but to suggest that there are means of loosening a certain amount of patent protections without disparaging the rights of millions of people across the globe. There can be some coexistence where the rights of public health and the private rights of IP holders can be balanced so as to promote a society where medical inventions can continue to thrive while the entire population accesses these inventions. While the imposition of compulsory licensing deals upon companies like Pfizer may not be looked well upon by the company, it would create an opportunity for millions of people to access vaccines that have been created to combat a worldwide pandemic. Looking at IP rights within a greater human rights framework will highlight the balanced trade–off between IP rights and the limitation of these rights in the process of promoting the right to health. While

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<sup>315</sup> Labonte & Johri, *supra* note 307.

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*; see also *Members Discuss Intellectual Property Response to the COVID–19 Pandemic*, WORLD TRADE ORG. (Oct. 20, 2020), [https://www.wto.org/english/news\\_e/news20\\_e/trip\\_20oct20\\_e.htm](https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm).

<sup>318</sup> Labonte & Johri, *supra* note 307.

there is no perfect system that would please every actor, decisions made internationally during a global pandemic should not be made lightly. Promotion of herd immunity will alleviate global economic strain and human loss—a result that can be obtained via the exclusion provisions already set forth within the TRIPS Agreement.