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## Intellectual Property Rights As A Barrier For Developing Countries To Access A COVID-19 Vaccine

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# INTELLECTUAL PROPERTY RIGHTS AS A BARRIER FOR DEVELOPING COUNTRIES TO ACCESS A COVID-19 VACCINE

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I. INTRODUCTION .....	47
II. ATTEMPTED SOLUTIONS.....	49
III. THE RIGHT TO HEALTH .....	52
IV. WHY DO DEVELOPING COUNTRIES LACK ACCESS TO A COVID-19 VACCINE?.....	54
V. PROPOSED SOLUTION FROM A TRADE PERSPECTIVE.....	56
VI. PROPOSED SOLUTION FROM A HUMAN RIGHTS PERSPECTIVE .....	59
VII. CONCLUSION.....	60

## I. INTRODUCTION

With the ongoing COVID-19 global pandemic, the question has become how will developing countries acquire the vaccine in light of existing intellectual property barriers, specifically the patent law system? High-income countries (“HICs”), like the United States (“U.S.”), conducted extensive research for months in efforts to create a COVID-19 vaccine, and currently, 25 authorized vaccines exist worldwide.<sup>1</sup> The leading vaccines are from the big pharmaceutical companies Pfizer, Moderna, and Johnson & Johnson, all three of which are the only vaccines authorized for use in the U.S.<sup>2</sup> Pfizer’s vaccine has a multinational origin and is authorized for use in 151 different countries.<sup>3</sup> Moderna’s vaccine originated in the U.S. and is authorized for use in 85

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1. Jeff Craven, *COVID-19 Vaccine Tracker*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Mar. 25, 2021), <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker> [https://perma.cc/R3WM-2335].

2. *Different Covid-19 Vaccines*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 15, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>.

3. Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, THE NEW YORK TIMES (Jan. 13, 2022), <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> [https://perma.cc/9JSB-7NXT].

countries.<sup>4</sup> Johnson & Johnson's vaccine originated in the Netherlands and the U.S., and is authorized for use in 80 countries.<sup>5</sup>

One vaccine that is important to note is the AstraZeneca vaccine, produced by BARDA and OWS.<sup>6</sup> The AstraZeneca vaccine originated in the United Kingdom ("UK") and is authorized for use in 182 countries, not including the U.S.<sup>7</sup> Much debate has surrounded the discussion of this vaccine, as some recipients of the vaccine began to develop an extremely rare form of blood clot occurring in the brain.<sup>8</sup> People questioned if the research and development of the vaccine was robust enough, and fortunately for the developers, UK and European Union ("EU") regulators found that there is no evidence that the AstraZeneca vaccine causes blood clots, and that the benefits of the vaccine outweigh any risks.<sup>9</sup> The 21 other vaccines that currently exist are authorized only in some countries, specifically China, Russia and India, and none of which include the U.S., Canada, or the EU.<sup>10</sup>

Unfortunately, research shows that in low-income countries ("LICs"), fewer than 3% of the population has been vaccinated against COVID-19.<sup>11</sup> As of January 13th, 2022, only eleven percent of all doses administered worldwide have been administered in LICs.<sup>12</sup> This is largely due to the fact that "wealthy nations have reserved more vaccines than they need and developers will not share their intellectual property."<sup>13</sup> In fact, wealthy nations such as Canada, the U.S. and the UK are hoarding so many vaccines that they have enough to vaccinate their population multiple times over.<sup>14</sup>

This Comment seeks to answer the question of how intellectual property rights are acting as a barrier for developing countries to access a COVID-19 vaccine. Section II will first discuss the various attempted solutions to the problem of a lack of COVID-19 vaccine access in developing countries, and

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4. *Id.*

5. *Id.*

6. Craven, *supra* note 1.

7. Holder, *supra* note 3.

8. *South Asian Languages: Is the Oxford-AstraZeneca Vaccine Safe?*, BBC NEWS (Mar. 25, 2021), <https://www.bbc.com/news/uk-56498507>.

9. *Id.*

10. Craven, *supra* note 1.

11. Nurith Aizenman, *Why low income countries are so short on COVID vaccines. Hint: It's not boosters*, NPR (Nov. 10, 2021), <https://www.npr.org/sections/goatsandsoda/2021/11/10/1052078529/why-low-income-countries-are-so-short-on-covid-vaccines-hint-its-not-boosters>.

12. Holder, *supra* note 3.

13. Owen Dyer, *Covid-19: Many Poor Countries Will See Almost No Vaccine Next Year, Aid Groups Warn*, BMJ (Dec. 11, 2020), <https://www.bmj.com/content/371/bmj.m4809>.

14. *Rich countries hoarding Covid vaccines, says People's Vaccine Alliance*, BBC (Dec. 9, 2020), <https://www.bbc.com/news/health-55229894>.

why they are not viable solutions. Section III will address the issue by analyzing the International Bill of Human Rights, specifically, the fundamental right to health,<sup>15</sup> and the obligations of pharmaceutical companies regarding that right. Section IV highlights how intellectual property protection hinders that fundamental right to health, in relation to COVID-19 vaccines. To conclude, Sections V and VI will propose two possible solutions: 1) an international treaty that exempts vaccines from being patented in times of a global health emergency, and 2) constitutional claims brought in national courts.

## II. ATTEMPTED SOLUTIONS

Three main attempts have been made in an effort to solve the problem of the lack of access of a COVID-19 vaccine in developing countries. The first is the COVAX program,<sup>16</sup> the second is an intellectual property waiver for COVID-19 drugs,<sup>17</sup> and the third is a COVID-19 Technology Access Pool.<sup>18</sup> Each attempt has failed to be a viable solution to the problem at hand, for reasons discussed below.

Currently, LICs are reliant on the COVAX program for access to COVID-19 vaccines.<sup>19</sup> COVAX is a collaboration involving the World Health Organization (“WHO”), the United Nations Children’s Fund (“UNICEF”), Gavi (a public-private global health partnership), and the Coalition for Epidemic Preparedness Innovations (“CEPI”), that acts as “a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines.”<sup>20</sup> On February 24<sup>th</sup>, 2021, the first COVAX deliveries of COVID-19 vaccines were made to two West African nations, Ghana and Cote d’Ivoire, a whole 265 days after the inception of the COVAX program.<sup>21</sup> As of February 10, 2022, COVAX has allocated 1.16 billion doses to 144

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15. *Human Rights*, UNITED NATIONS, <https://www.un.org/en/global-issues/human-rights>. (last visited Feb. 10, 2022).

16. *Covax Vaccine Roll-Out: Country Updates*, GAVI: THE VACCINE ALLIANCE (Mar. 25, 2021), <https://www.gavi.org/covax-vaccine-roll-out> [<https://perma.cc/P7YN-RA8M>].

17. Emma Farge, *Backers of IP waiver for COVID-19 drugs make fresh push at WTO*, REUTERS (Jan. 19, 2021), <https://www.reuters.com/article/health-coronavirus-wto/backers-of-ip-waiver-for-covid-19-drugs-make-fresh-push-at-wto-idUSL8N2JU5IQ>.

18. *International community rallies to support open research and science to fight COVID-19*, WHO (May 29, 2020), <https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19>.

19. *Id.*

20. *Covax*, GAVI: THE VACCINE ALLIANCE (Jan. 15, 2022), <https://www.gavi.org/covax-facility>.

21. GAVI, *supra* note 16.

different countries and territories<sup>22</sup>, but unfortunately, there are still large barriers to securing more vaccines, as well as with the COVAX vaccine roll-out.<sup>23</sup>

COVAX still has to compete with other countries to secure vaccines, and HICs are striking “more lucrative deals with manufacturers to secure limited supplies of vaccines.”<sup>24</sup> Further, although most of the first doses available through COVAX will be delivered to LICs, some will be sent to HICs, such as Canada, which poses an additional obstacle for LICs to obtain a vaccine.<sup>25</sup> On top of all of this, there are production obstacles, supply chain obstacles, and community-level confidence obstacles, as there are with any major vaccine roll-out.<sup>26</sup>

Another solution that was proposed in December of 2020, but that has yet to be acted upon, is an intellectual property waiver for COVID-19 drugs.<sup>27</sup> South Africa and India are proponents of the waiver, but several countries including the U.S., and the EU are opponents of the waiver, because they want to protect their pharmaceutical industries.<sup>28</sup> James Bacchus, a former member of the U.S. House of Representatives, and a founding member of the Appellate Body of the World Trade Organization (“WTO”)<sup>29</sup> has stated that the waiver is “an unnecessary proposal” and that it “would eliminate the incentives that are essential to inspire the innovations that make new medicines possible.”<sup>30</sup>

In order for the waiver to move forward, the Council for Trade-Related Aspects of Intellectual Property Rights (“CTRAIPR”) would need to agree on a position and then the WTO’s General Council, made up of 164 members,

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22. *COVID-19 Vaccine Market Dashboard*, UNICEF (Jan. 13, 2022), <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard> [https://perma.cc/YP2L-KV3U] (the numbers depicted in this Article are subject to change as the COVAX program continues to distribute vaccines).

23. WHO, *supra* note 18.

24. *WHO: just 25 Covid vaccine doses administered in low-income countries*, THE GUARDIAN (Jan. 18, 2021), <https://www.theguardian.com/society/2021/jan/18/who-just-25-covid-vaccine-doses-administered-in-low-income-countries>.

25. *Covax: How will Covid vaccines be shared around the world?*, BBC NEWS (Feb. 24, 2021), <https://www.bbc.com/news/world-55795297>.

26. Morgan Winsor, *What is COVAX? How a global initiative is helping get COVID-19 vaccines to poorer countries*, ABC NEWS (Feb. 26, 2021), <https://abcnews.go.com/Health/covax-global-initiative-helping-covid-19-vaccines-poorer/story?id=76106981>.

27. Farge, *supra* note 17.

28. *Id.*

29. *Adjunct Scholars: James Bacchus*, CATO INSTITUTE, <https://www.cato.org/people/james-bacchus> (last visited Mar. 27, 2021).

30. James Bacchus, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, CATO INSTITUTE (Dec. 16, 2020), <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>.

would need to make a decision by consensus.<sup>31</sup> In October of 2020, India and South Africa submitted their request for an IP waiver to the CTRAIPR, but as of January 13, 2022, there is still no agreement within the CTRAIPR, likely due to their consideration of arguments coming from pharmaceutical companies and patent attorneys, which mirror James Bacchus' views.<sup>32</sup> So, although the IP waiver might have potential, progress has yet to be made.<sup>33</sup>

A third solution that was launched by the WHO in May of 2020 was a COVID-19 Technology Access Pool ("C-TAP").<sup>34</sup> Its goal is to make "vaccines, tests, diagnostics, treatments and other key tools in the coronavirus response . . . universally available as global public goods."<sup>35</sup> The five key elements of the initiative are:

[1] Public disclosure of gene sequences and data; [2] Transparency around the publication of all clinical trial results; [3] Governments and other funders are encouraged to include clauses in funding agreements with pharmaceutical companies and other innovators about equitable distribution, affordability, and the publication of trial data; [4] Licensing any potential treatment, diagnostic, vaccine or other health technology to the Medicines Patent Pool – a United Nations-backed public health body that works to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries; and [5] Promotion of open innovation models and technology transfer that increase local manufacturing and supply capacity including through joining the Open Covid Pledge and the Technology Access Partnership (TAP).<sup>36</sup>

Unfortunately, C-TAP is completely voluntary and based on "social solidarity."<sup>37</sup> While 40 countries have joined the so called "Solidarity Call to Action", many countries have not, including the U.S., Canada, the U.K., the EU countries, China, Russia, and India, all of which are the main drivers in COVID-19 vaccine research and development.<sup>38</sup> Therefore, although C-TAP

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31. Farge, *supra* note 17.

32. Allie Nawrat, *Exploring the Covid-19 vaccine IP waiver proposal at the WTO*, PHARMACEUTICAL TECHNOLOGY (Mar. 15, 2021), <https://www.pharmaceutical-technology.com/features/wto-ip-waiver-proposal-covid19-vaccine/>.

33. *Id.*

34. WHO, *supra* note 18.

35. *Id.*

36. *Id.*

37. *Id.*

38. *Endorsements of the Solidarity Call to Action*, WHO, <https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action> (last visited Mar. 27, 2021).

has potential, it has so far proven to be an unworkable solution due to its voluntariness and the resulting lack in number of countries that have joined.

Other proposed solutions that have yet to be acted upon include the need for companies to partner up to maximize their manufacturing capacity as well as stopping export barriers that have been imposed on COVID-19 vaccines.<sup>39</sup>

### III. THE RIGHT TO HEALTH

The United Nations' ("UN") International Bill of Human Rights lays out how governments should act in order to promote and protect human rights and consists of 1) the Universal Declaration of Human Rights (UDHR), 2) the International Covenant on Civil and Political Rights and its two optional protocols, and 3) the International Covenant on Economic, Social and Cultural Rights (ICESCR) and its optional protocol.<sup>40</sup>

The focus of this comment will be on the fundamental right to health, and the specific sections of the aforementioned Bill pertaining to that right are: 1) Article 25 of the UDHR, which states that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family,"<sup>41</sup> and 2) Article 12 of the ICESCR, which states that "the States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and more specifically, that "the steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases."<sup>42</sup>

In 2000, the UN Committee on Economic, Social and Cultural Rights ("CESCR") created General Comment No. 14 "in an attempt to provide further definition for Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)."<sup>43</sup> General Comment No. 14 "enumerates four essential, interrelated components of the right to health: availability, accessibility, acceptability, and quality."<sup>44</sup> It states that essential drugs, defined

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39. Nawrat, *supra* note 32.

40. United Nations, *supra* note 15.

41. *Universal Declaration of Human Rights*, UNITED NATIONS, <https://www.un.org/en/universal-declaration-human-rights/index.html> (last visited Nov. 2, 2020).

42. *International Covenant on Economic, Social and Cultural Rights*, UNITED NATIONS HUMAN RIGHTS OFFICE OF THE HIGH COMMISSIONER, <https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx> (last visited Nov. 2, 2020).

43. Emmanuel Kolawole Oke, *Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes*, HEALTH AND HUMAN RIGHTS JOURNAL (Dec. 6, 2013), <https://www.hhrjournal.org/2013/12/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/>.

44. *Id.*



by the WHO as drugs that “‘satisfy the priority health care needs of the population’ and ‘are intended to be available within the context of functioning health systems at all times in adequate amounts . . . and at a price the individual and the community can afford[,]” must be available in a country.<sup>45</sup> It also states that these essential drugs need to be affordable to all.<sup>46</sup>

The obligations of pharmaceutical companies to promote and protect this fundamental right to health are unclear.<sup>47</sup> However, there are some guidelines set forth in the UN Global Compact.<sup>48</sup> The first two principles of the Global Compact pertain to human rights and the first states that “[b]usinesses should support and respect the protection of internationally proclaimed human rights.”<sup>49</sup> The second principle states that the businesses should “make sure that they are not complicit in human rights abuses.”<sup>50</sup> Such “businesses” include pharmaceutical companies, but commentators have posited that pharmaceutical companies, specifically, have obligations beyond those required in the Global Compact, as indicated in the UN Millennium Development Goal Number 8, Target 8.E.<sup>51</sup>

The UN Millennium Development Goal Number 8 is to “develop a global partnership for development,” and Target 8.E states “[i]n cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.”<sup>52</sup> This furthers pharmaceutical companies’ duty to not only comply with the UN’s Global Compact, but to actively work to provide access to essential drugs in developing countries. Commentators state that this follows the “you must, if you can” social contract between the pharmaceutical industry and society.<sup>53</sup>

Additional impetus of this heightened duty that pharmaceutical companies should undertake comes from nongovernmental organizations (NGOs).<sup>54</sup> For example, Oxford Committee for Famine Relief (“Oxfam”) has stated that:

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45. *Id.*

46. *Id.*

47. Doris Schroeder, *Does the Pharmaceutical Sector Have a Coresponsibility for the Human Right to Health?*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 298, 299 (2011).

48. *Human Rights*, UNITED NATIONS GLOBAL COMPACT, <https://www.unglobalcompact.org/what-is-gc/our-work/social/human-rights> (last visited Nov. 2, 2020).

49. Schroeder, *supra* note 47, at 300.

50. *Id.*

51. *Id.*

52. *Millennium Development Goals and Beyond 2015*, UNITED NATIONS, <https://www.un.org/millenniumgoals/global.shtml#:~:text=Target%208.,and%202014%2C%20reaching%20%24135.2%20billion> (last visited Mar. 27, 2021).

53. Schroeder, *supra* note 47, at 301.

54. *Id.* at 300



There are major shortcomings in the pharmaceutical industry's current initiatives to ensure that poor people have access to medicines . . . . The time is ripe for a bold new approach. The industry must put access to medicines at the heart of its decision-making and practices . . . . [T]he industry's failure to comprehend access to medicines as a fundamental human right enshrined in international law, and to recognize that pharmaceutical companies have responsibilities in this context, has prevented the adoption of appropriate strategies.<sup>55</sup>

So, although it remains unclear as to what specific duties a pharmaceutical company has in regard to the fundamental right to health, Target 8.E from the UN Millennium Development Goals as well as statements from NGOs demonstrate that there is pressure on pharmaceutical companies to play a larger role in protecting such a fundamental right.

#### IV. WHY DO DEVELOPING COUNTRIES LACK ACCESS TO A COVID-19 VACCINE?

As mentioned in the introduction, the issue here is how developing countries will acquire a COVID-19 vaccine in light of existing intellectual property barriers, specifically the patent law system. The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), enacted in 1995, "mandates countries to grant patents to inventions that are 'new, involve an inventive step and are capable of industrial application.'"<sup>56</sup> Prior to the TRIPS Agreement, some countries, such as India, made cheap copies similar to already patented medication and supplied it to developing countries.<sup>57</sup> Unfortunately, since the TRIPS Agreement, those copies of medications are now required to be patented.<sup>58</sup> This negatively affects developing countries' access to medications in two ways.<sup>59</sup> First, it affects access directly, by decreasing the supply of affordable medicines. Second, it affects access indirectly, by eliminating the generic competition that was reducing the cost of name-brand medicines.<sup>60</sup>

On January 23, 2017, the TRIPS Agreement was amended, and a change was made to its compulsory licensing provision.<sup>61</sup> The Amendment provided

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55. *Id.* at 300–301.

56. Ana Santos Rutschman, *The Covid-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J. LAW AND POLICY (2020).

57. Schroeder, *supra* note 47, at 304.

58. *Id.*

59. *Id.*

60. *Id.*

61. Lauren S. Luna, *Patently Limited: The Conflict Between Public Health and Patent Rights*, 53 U.S.F. L. REV. 343, 366 (2019).

the “legal basis for WTO members to grant special compulsory licenses exclusively for production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients.”<sup>62</sup> Although this sounds like an attractive solution to the issue at hand, there is little to no evidence of the success of this compulsory licensing provision in providing more affordable medications to developing countries.<sup>63</sup>

This provision has only been acted upon once, in 2007, when a Canadian company attempted to export HIV medicines from Canada to Rwanda.<sup>64</sup> The mechanism was shown to be neither expeditious nor workable due to various issues such as the “complexity of [the exporting country’s] generic drug legislation,” and the “developing nations lack [of] infrastructure and distribution capabilities necessary to provide the infected with anti-viral medication.”<sup>65</sup> Richard Elliott, the executive director of the Canadian HIV/AIDS Legal Network, said that “the legislation was essentially flawed on a wide variety of grounds.”<sup>66</sup> These grounds included “the list of pharmaceutical products that were eligible for export was too limited; the period of time that a generic could be exported was too short; the administrative roadblocks immense.”<sup>67</sup> Among the administrative roadblocks included the fact that “a generic manufacturer had to file a license application for every drug, for every amount produced and for every country to which it wanted to export a drug.”<sup>68</sup> So, although the 2017 TRIPS Amendment seems to be an attractive solution, it has proven to be very unworkable in the one instance that it was acted upon.

Furthermore, there is an “opt-out” option to the compulsory licensing provision, which allows countries to opt-out of using the system as importers.<sup>69</sup>

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62. *Id.* (quoting *Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)*, WORLD TRADE ORG. (Jan. 23, 2017), [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_01\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm)).

63. Eduardo Urias & Shyama V. Ramani, *Access to Medicines After TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence*, J. INT. BUS. POLICY (2020).

64. See Christina Cotter, *The Implications of Rwanda’s Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT’L L. REV. 177 (2008).

65. *Id.* at 177–178.

66. Goldis Chami & Samuel Wasswa-Kintu, *Compulsory Licensing of Generic Drugs Remains Mired in Quagmires*, 183 CMAJ 705 (2011).

67. *Id.*

68. *Id.*

69. Christopher Garrison, *Never Say Never – Why the High Income Countries that Opted-out From the Art. 31bis WTO TRIPS System Must Urgently Reconsider Their Decision in the Face of the Covid-19 Pandemic*, MEDICINES LAW & POLICY (Apr. 8, 2020), <https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that->

The United States and several other HICs have opted out, which indirectly affects developing countries' access to medications "since the economies of scale that could have been harnessed by exporting to these comparatively wealthy HICs are curtailed, the price of the generic medicines that could be produced for other WTO Members may well be higher than it could have been."<sup>70</sup> Currently, "[compulsory licensing] is the only mechanism available to developing countries without manufacturing capabilities in pharmaceuticals,"<sup>71</sup> and since it has proven to be unworkable in the one instance that it has been exercised, it is not a viable solution to the issue at hand.

#### V. PROPOSED SOLUTION FROM A TRADE PERSPECTIVE

There have been various attempts to provide a solution to this issue, including a COVID-19 technology access pool allowing the voluntary sharing of COVID-19 health technology related knowledge, intellectual property and data (C-TAP),<sup>72</sup> a waiver of intellectual property rights for COVID-19 drugs,<sup>73</sup> and most notably, public-private partnerships, such as COVAX.<sup>74</sup> COVAX, as previously mentioned, "functions as a resource-pooling, risk-sharing and push financing mechanism on a nearly global level," but it differentiates between countries based on economic purchase power.<sup>75</sup> This differentiation hinders the ability of developing countries "to pursue multiple vaccine purchase or pre-purchase pathways, a requirement that is not imposed on self-funded countries."<sup>76</sup> Additionally, as previously mentioned, COVAX also faces production obstacles, supply chain obstacles, and community-level confidence obstacles.<sup>77</sup> So, while COVAX seems to have been made with good intentions, it has not yet proven to be a viable solution to the issue. Moreover, C-TAP is not a viable solution because it is a voluntary program,<sup>78</sup> and a waiver to IP rights for COVID-19 vaccines is also not a viable solution due to a standstill in decision-making at the CTRAIPR level.<sup>79</sup>

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opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/.

70. *Id.*

71. Urias, *supra* note 63.

72. *Covid-19 Technology Access Pool*, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool> (last visited Nov. 2, 2020).

73. Farge, *supra* note 17.

74. Rutschman, *supra* note 56.

75. *Id.*

76. *Id.*

77. Winsor, *supra* note 26.

78. WHO, *supra* note 16.

79. Nawrat, *supra* note 32.

A possible solution to this problem would be to enact an international treaty that exempts vaccines from patenting in times of a global health emergency (epidemic, pandemic, etc.), making them accessible to all countries through a facilitated system. A similar treaty, the Food and Agriculture Organization’s (“FAO”) International Treaty on Plant Genetic Resources for Food and Agriculture (“International Food Treaty”), already exists in the seeds industry to help in combatting world hunger.<sup>80</sup> The International Food Treaty “has established the largest global exchange system for plant genetic material, a global information system with data about that material, a benefit sharing fund that has helped over one million people, and a universal call for protecting traditional knowledge and the rights of smallholder farmers.”<sup>81</sup> It is a “treaty that exempts a number of basic food and seed crops from patenting and makes them accessible to all member states through a facilitated system.”<sup>82</sup> The International Food Treaty is a “multilateral system” that “sets up opportunities for developed countries with technical know-how to use their laboratories to build on what the farmers in developing countries have accomplished in their fields.”<sup>83</sup> With the International Food Treaty, there are mutual benefits among both developed and developing countries. With the proposed international treaty that exempts vaccines from patenting in times of a global health emergency, developing countries would likely unilaterally benefit from the developed countries, but for reasons discussed below, it is still a possible solution.

An international treaty would provide proper weight to the importance of the fundamental right to health, particularly amidst a global pandemic, relative to intellectual property rights and protection for multi-billion-dollar pharmaceutical companies. As Professor Carlos Correa posited, “members [of the TRIPS Agreement] might determine patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from ordinary everyday health and nutrition measures.”<sup>84</sup>

It could be argued that patent rights are of equal weight to human rights, and that therefore, one should not circumvent the other, even in times of global crisis.<sup>85</sup> Currently, there are three different approaches to the relationship

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80. Schroeder, *supra* note 47, at 302.

81. *International Treaty on Plant Genetic Resources for Food and Agriculture*, FAO, <http://www.fao.org/plant-treaty/en/> (last visited Mar. 27, 2021) [https://perma.cc/LW27-AZSP].

82. John Coggon & Swati Gola, *Global Health and International Community: Ethical, Political and Regulatory Challenges* 214 (2013).

83. *Id.*

84. Oke, *supra* note 43.

85. *Id.*

between patent rights and human rights.<sup>86</sup> The first is “the ‘subjugation approach,’ which states that when patent rights and human rights conflict, human rights considerations should trump patent rights.”<sup>87</sup> The second is “the ‘integrated approach,’ which views patents as a human right.”<sup>88</sup> The third is “the ‘coexistence approach,’ which asserts that patent law and human rights law are distinct but share a basic concern in defining the optimal amount of patent protection required to incentivize and practice socially useful innovation.”<sup>89</sup>

It could also be argued that it is clear from the Covenant on Economic, Social and Cultural Rights’ (CESCR) General Comment No. 17 that the subjugation approach is the approach that should be taken worldwide.<sup>90</sup> The CESCR noted that,

[i]n contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights . . . may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.<sup>91</sup>

Professor Peter Drahos and Professor John Braithwaite posited that “in any principled national legal system, a fundamental right such as the right to health should take precedence over utilitarian considerations.”<sup>92</sup> So, it is clear that the drafters of the CESCR, as well as other professionals in the field, find that human rights, such as the right to health, should take precedent over intellectual property rights in certain situations.

Unfortunately, while an international treaty would be an ideal solution, international treaties themselves are difficult to negotiate, as countries generally prefer to enter into voluntary, non-binding agreements.<sup>93</sup> One of the reasons for this is that different countries have different socio-economic contexts.<sup>94</sup> For example, the principle of “Common but Differentiated

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86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Why is a global agreement so difficult to achieve?*, MEI, <https://www.iedm.org/56529-why-is-a-global-agreement-so-difficult-to-achieve/> (last visited Jan. 13, 2022).

94. *Id.*

Responsibilities” (CBDR), which was formulated in the United Nations Framework Convention on Climate Change (UNFCCC), states that while all countries have a role to play in obtaining a solution for a common problem (i.e. climate change), the differing abilities of different countries in working towards such a solution must be taken into account.<sup>95</sup> Translated into the COVID-19 pandemic context, this would mean that the ability of a developing country to contribute to COVID-19 vaccine research and development pales in comparison to that of a developed country, and therefore if the principle of CBDR were to apply, it would enforce greater responsibility on those developed countries. For such countries, this heightened responsibility might not be viewed favorably by their governments, as they might feel that their country is doing all the work while the developing countries are “free-riding” off their successes. Because of this, developed countries would have little incentive to enter into an international agreement. Therefore, I will propose an alternate solution to an international treaty, from a human rights perspective.

#### VI. PROPOSED SOLUTION FROM A HUMAN RIGHTS PERSPECTIVE

Due to the shortcomings of a solution from a trade perspective, a more practical solution from a human rights perspective is to bring constitutional claims in national courts. More than half of the world’s countries (not including the United States) have a right to health and medical care in their constitutions to some degree.<sup>96</sup>

For example, in 1996, in light of the HIV/AIDS pandemic, South Africa enacted the Constitution of the Republic of South Africa which has a section that guarantees the right to have access to health care services and emergency medical treatment.<sup>97</sup> Section 27 provides that, “everyone has the right to have access to health care services and no one may be refused emergency medical treatment; sufficient food, water and social security including, if they are unable to support themselves and their dependents, to appropriate social assistance.”<sup>98</sup> Since so many countries have a similar right in their constitutions, the best solution to intellectual property rights as a barrier for developing countries to

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95. *Common but Differentiated Responsibilities and Respective Capabilities (CBDR-RC)*, CLIMATE NEXUS, <https://climatenexus.org/climate-change-news/common-but-differentiated-responsibilities-and-respective-capabilities-cbdr-rc/> (last visited Jan 13, 2022).

96. Mark Wheeler, *A constitutional right to health care: Many countries have it, but not the U.S.*, SCIENCE DAILY (July 19, 2013), <https://www.sciencedaily.com/releases/2013/07/130719104927.htm>.

97. *HIV/AIDS and Human Rights*, SOUTH AFRICAN HUMAN RIGHTS COMMISSION, <https://www.sahrc.org.za/home/21/files/FINAL%20HIV%20AIDS%20and%20Human%20Rights%20Educational%20Booklet.pdf> (last visited Jan. 13, 2022).

98. *Id.*

access the COVID-19 vaccine would be to bring a claim in their national court, alleging violation of their constitution. Unfortunately, this would not be a viable solution for countries that lack such a right in their constitution, such as the United States, but it is still the best solution available at this time.

#### VII. CONCLUSION

In light of the current COVID-19 global pandemic, it is of the utmost importance that all countries, not just HICs, obtain access to a vaccine. Under the International Bill of Human Rights, there is a fundamental right to health, and pharmaceutical companies have an obligation to provide access to affordable essential drugs in developing countries in order to protect that right.

Due to the lack of success with attempts to provide a solution, like C-TAP, the idea of an intellectual property waiver, and public-private partnerships such as COVAX, I propose two possible solutions: 1) an international treaty that exempts vaccines from patenting in times of a global health emergency, making them accessible to all countries through a facilitated system, similar to the International Food Treaty, and 2) bringing constitutional claims in national courts. These solutions adopt the subjugation approach for the relationship between patent rights and human rights, meaning that “when patent rights and human rights conflict, human rights considerations should trump patent rights.”<sup>99</sup> They acknowledge the importance of public health amidst a global pandemic relative to intellectual property rights and protection, and prioritize human life over the incomes of multi-billionaire-dollar pharmaceutical companies.

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99. Oke, *supra* note 43.