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ADR PROVISIONS TO INOCULATE THE VACCINE INDUSTRY FROM GOVERNMENTAL IP TAKINGS

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I. INTRODUCTION

It started with a cough.[2] It continued with a fever.[3] After several days of treatment with over-the-counter medications without improvement, it became clear that Victor Villarroel Saavedra, an unvaccinated but otherwise in good health Bolivian physician, had contracted COVID-19 in the summer of 2020.[4] By this point, Victor's options were limited: seek at-home care or go to the hospital.[5] After a few days of in-home care with nasal canal oxygen and nursing/physician oversight, he was eventually transferred to a hospital where he passed within the week.[6] This all could have been avoided with a simple jab in the otherwise healthy man, which would have nearly eliminated his risk of death and significantly reduced his risk of hospitalization.[7] However, Bolivia is without vaccinations originating from most developed countries (MDC) such as the US, UK, CAN, or from the EU, although its government has tried to obtain them.[8] Distribution of the COVID-19 vaccine to least developed countries (LDCs) like Bolivia has been sluggish to non-existent, leading to the needless deaths of many of the world's most medically vulnerable populations.[9]

The lack of vaccination availability to LDC from the US, UK, CAN, or from the EU through existing international patent agreements has not gone unnoticed on the world stage. In response to this, some have argued for governments, in the name of national security, to just take the COVID-19 IP and mass produce the vaccine without paying for it.[10] This article will explore how pandemics generally are a recurring problem, and why this would be a poor long-term solution to them. Further, the article will evaluate the current programs targeting this problem and their shortcomings. As an alternative to the unworkable programs, this

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[2] Victor Villarroel Saavedra et al., *Stories From the Field The Heavy Toll of COVID-19 in Bolivia: A Tale of Distrust, Despair, and Health Inequalities*, 104(5) AM. J. TROP. MED. HYG. 1607 (2021).

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] Kathy Katella, *Comparing the COVID-19 Vaccines: How Are They Different*, YALE MEDICINE (Feb. 18, 2022), https://www.yalemedicine.org/news/covid-19-vaccine-comparison.

[8] *Sputnik V: From vaccine hope to frustration for Latin America*, EURACTIV (Aug. 4, 2021), https://www.euractiv.com/section/global-europe/news/sputnik-v-from-vaccine-hope-to-frustration-for-latin-america/.

[9] EURACTIV, *supra* note 8; *WHO Coronavirus (COVID-19) Dashboard*, WORLD HEALTH ORG., https://covid19.who.int/ (last visited Mar. 15, 2022).

[10] Nancy Jecker & Caeser Atuire, *What's yours is ours: waiving intellectual property protections for COVID-19 vaccines,* 47(9) J. MED. ETHICS 595 (2021).

article explores solutions grounded in the principles of alternative dispute resolution (ADR) rather than using current international patent agreement mechanisms to ensure access to MDC based vaccines for LDCs.[11] Lastly, the article will discuss various ADR-inspired proposals to bridge the vaccine requirement gaps while still respecting the vaccine maker's intellectual property (IP).

This article is divided into four parts. Section II will discuss the problems of the current state of vaccine disruption. Section III will discuss the issues with current solutions to the distribution problem to include free market approach, nongovernmental programs, and finally use of compulsory licensing and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement regarding US and Canada. Section IV will look at alternative dispute resolution inspired solutions via real time aggressive negation of lower prices against the backdrop of TRIPS, the creation of a pandemic like insurance market modeled on the US flood insurance program, and lastly, pre-negotiated purchasing partnerships with most developed countries.

II. THE PROBLEM: LACK OF INITIAL DISTRIPUTION OF COVID-19 TO LDC

As of 2021, nearly eight billion people call the Earth home.[12] That number is increasing at an exponential rate.[13] During a worldwide pandemic, an overwhelming percentage of those eight billion people will need at least one dose, if not multiple doses, of a potential vaccine to ensure protection of all humans on Earth.[14] As we saw during the current pandemic, the COVID-19 appearance started a race with two legs to it. In the first leg, bench scientist raced the clock to develop vaccines as fast and safely as possible. Then in the second leg of race the bench scientists passed the baton to the engineers to create the needed eight billion doses as quickly as possible.[15] The consequences of even a single day's delay meant numerous deaths worldwide.[16]

Given the seriousness of the COVID-19 pandemic, the bench research scientist wasted no time in the first leg of the race creating an approved COVID-19 jab.[17] The World Health Organization (WHO) formally identified COVID-19 in January 2020, beginning the COVID-19 vaccine race.[18] China approved the world's first vaccine in May 2020.[19] Russia

[11] Tedros Adhanom Ghebreyesus, World Health Org. Dir.-Gen., WHO Director-General's opening remarks at 148th session of the Executive Board (Jan. 18, 2021) (transcript available at https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board).

[12] *Current World Population*, WORLDOMETERS, https://www.worldometers.info/world-population/ (last visited Mar. 15, 2022).

[13] *Id.*

[14] Shrikanth Sampath et al., *Pandemics Throughout the History*, 13(9) CUREUS 2 (2021).

[15] Smriti Mallapaty, *China's Coronavac Jab Set to Boosts Global Immunization Campaign*, 594 NATURE 162 (2021).

[16] *Coronavirus (COVID-19) Deaths*, OUR WORLD IN DATA, https://ourworldindata.org/covid-deaths (last visited Mar. 15, 2022).

[17] Joint Report, *WHO-convened Global Study of Origins of SARS-CoV-2*: *China Part*, 9 (Jan. 14 – Feb. 10, 2021).

[18] *Id.*

[19] *See* Mallapaty, *supra* note 15.

approved its first vaccine on August 11, 2020.[20] The US approved England's Pfizer vaccine in December of 2020. [21] The FDA gave initial approval to the United States' Moderna vaccine December 19, 2020.[22] The development of an effective vaccine in record time was a technological marvel and credit to modern science.[23]

However, the second leg of the race, commercial vaccine manufacturing, was not nearly as expedited at the vaccine creation.[24] Indeed, it took another four months after vaccine discovery to produce enough of it in the US market to ensure that half of all US adults received at least one dose of the inoculation.[25] During this period of the vaccine race where supply is unable to keep up with demand, MDCs will generally operate in a self-interested way, leading to reduced access to the vaccine for LDCs until MDCs feel their markets have been saturated.[26] To this point in the current pandemic, the US did not began to send their excess supply of vaccine to LDCs until they felt their market was saturated creating nearly an eight month delay from when the jab was introduced on the market to when LDC began to receive excess US doses. The delay cost innumerable LDC lives who were without access to the vaccine.[27]

It is not a matter of if, but when the next pandemic level event occurs, and the world needs to be ready for it.[28] Pandemics like COVID-19 happen with some regularity, but generally only every 100 or so years.[29] One only needs to take a cursory look at history to see the metronomic recurrence of pandemic level events such as the Plague of Athens, the Antonine Plague, the Plague of Cyprian, the Plague of Justinian, and the Black Plagues.[30] More recently there has been the 1855 "Third Plague Pandemic," which was responsible for 10 million deaths worldwide and brought the Black Plague to the US.[31] In addition, the

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[20] Bianca Nogrady, *Mounting Evidence Suggest Sputnik Covid Vaccine is Safe and Effective*, 595 Nat. 339, 339, (July 15, 2021), https://www.nature.com/articles/d41586-021-01813-2.

[21] *A Timeline of COVID-19 Developments in 2020*, AM. J, MANAGED CARE, (last updated Jan. 1, 2021), https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020 (last visited Mar. 15, 2022); *See also* Press Release, U.S. Food & Drug Administration, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[22] *Moderna COVID-19 Vaccine*, U.S. Food & Drug Administration, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#:~:text=On%20December%2018%2C%202020%2C%20the,SARS%2DCoV%2D2).

[23] Joint Report, *supra* note 17.

[24] *A Timeline of COVID-19 Developments in 2020*, *supra* note 21.

[25] *Id.*

[26] Fact Sheet, The White House, *President Bident Announces Major Milestone in Administration's Global Vaccination Efforts: More than 100 Million U.S. COVID-19 Vaccine Doses Donated and Shipped Abroad*, (Aug. 3, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/03/fact-sheet-president-biden-announces-major-milestone-in-administrations-global-vaccination-efforts-more-than-100-million-u-s-covid-19-vaccine-doses-donated-and-shipped-abroad/#:~:text=Today%2C%20the%20President%20will%20announce,in%20COVID%2D19%20vaccine%20donations.

[27] Adhanom Ghebreyesus T, *WHO Director-General's opening remarks at 148th session of the Executive Board*, World Health Organization (Jan. 18, 2021).

[28] Sampath et al., *supra* note 14.

[29] *Id.*

[30] *Id.*

[31] *Id.*

Spanish Flu was responsible for killing at least 20 million people worldwide in the late 1910s.[32] Pandemic-level infections are a fact of life.[33]

Further, the next pandemic could be as communicable as measles[34], as deadly as smallpox, have the long-term consequences such as paralysis seen in polio, or as perplexing and devastating as the bubonic plague.[35] Given these risks, an internationally coordinated rapid response to the next pandemic with an equitable distribution plan that considers all stakeholders is key. Otherwise, individual nations will do whatever they feel they have to in order to secure vaccines for the good of their populations.[36] MDCs could secure their control over the vaccine by nationalizing the medication, ensuring foreign countries are legally excluded from any hope of purchasing the vaccine in the open market.[37] Or an MDC could prevent export of the vaccine from wide dissemination as means to further its own national security plan.[38] Though the Geneva Convention prevents active biological warfare, it says nothing about maximizing the effect of a naturally occurring biological agents by withholding nationalized treatment in the name of national security.[39] This mentality might lead to war as countries fight to secure their vaccination resources.

Though, war over securing nationalized treatments is a worst case senecio, a much more likely situation is that nationalization of vaccine IP may set a precedent that inoculation developers will lose control of their IP and/or be excluded from various markets. Without market forces providing the necessary economic drive for vaccine development and dissemination, vaccine developers may be dissuaded from doing as much vaccine research as they might have during inevitable next pandemic due to lack of compensation.[40]

In a hundred years or so years when the next pandemic is likely to hit, market forces like supply and demand, the preference to avoid war, and the need for IP protections, will remain concerns for vaccine developers. Given all these issues, the main concern is the inability of LDCs to even attempt procurement of vaccines during the initial sale period.

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[32] *Id.*

[33] Sampath et al., *supra* note 14.

[34] *14 Diseases You Almost Forgot About (Thanks to Vaccines)*, CDC (May 8, 2020), https://www.cdc.gov/vaccines/parents/diseases/forgot-14-diseases.html.

[35] Jenny Howard, *Plague was one of history's deadliest diseases – Then we found a cure*, NATIONAL GEOGRAPHIC (July 6, 2020), https://www.nationalgeographic.com/science/article/the-plague.

[36] Kai Kuperschmidt, *'Vaccine nationalism' threatens global plan to distribute COVID-19 shots fairly*, SCIENCE (July 28, 2020), https://www.science.org/content/article/vaccine-nationalism-threatens-global-plan-distribute-covid-19-shots-fairly.

[37] *Id.*

[38] Jeffrey Gettleman et al., *India Cuts Back on Vaccine Exports as Infections Surge at Home*, N.Y. TIMES (Apr. 22, 2021), https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html.

[39] Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571.

[40] Tanley Plokin et al, *The complexity and cost of vaccine manufacturing – An overview*, 35 VACCINE 4064, 4065 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/pdf/main.pdf; Dimitrios Gouglas et al., *Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimization study*, THE LANCET, 6, 1386, 1386 (2018), https://www.thelancet.com/action/showPdf?pii=S2214-109X%2818%2930346-2; Philip Ball, *The lightning-fast quest for COVID vaccines – what it means for other diseases*, 598 NATURE 16, 16–18, Jan. 7, 2021, https://media.nature.com/original/magazine-assets/d41586-020-03626-1/d41586-020-03626-1.pdf.

III. CURRENT SOLUTIONS UNDER CONSIDERATION AND THEIR SHORTCOMINGS

This article will evaluate four current solutions to the COVID-19 distribution. The first is the free market approach, then class IP theory, followed by a look at the COVAX system. Lastly the article will evaluate the compulsory license approach from the Canada and US perspective. Free market approach, COVAX and classic IP theory mechanisms all create too high an economic hurtle for LDCs, while a compulsory licenses approach create political and industry disincentives for vaccine distribution to LDC. Indeed, each of these current solutions fails to provide LDCs with a reasonable way to gain access to the vaccine during its initial release.

A. Free Market Approach

The traditional free market system operating under classic supply and demand forces has led to the distribution problem of the US, UK, and EU COVID-19 vaccines.[41] Under this system, only countries who can afford to pay the vaccine's price are given access to it.[42] This causes two concerns. First, it is in everyone's best medical interest to get as many of the world's inhabitants vaccinated, as universal vaccination provides the best protection against the disease.[43] Second, and of more concern in this article, there is no effort by the free market to ensure the broadest access to the vaccine for all the world.[44] Instead, access is based on the socio-economic status of the country, allowing for a only 1% of LDC to have received at least one dose of a vaccine as of July 1, 2019.[45]

To this point, before a vaccine had even been completed, numerous MDCs, with the ready cash on hand, had already purchased at least 51% of the US, UK, CAN or EU dose pre-order offerings.[46] Indeed, some of these countries, such as Canada seemed to have purchased more doses than they had population by a four to one margin.[47] On January 18, 2021, a month after the US, UK, CAN or EU doses were approved for use, the Director-General of the WHO, Dr. Tedros Adhanom Ghebreyesus, noted the disparity of the free market's distribution of the vaccine when he stated, "More than 39 million doses of vaccine have now been administered in at least 49 higher-income countries. Just 25 doses have been

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[41] Ghebreyesus, *supra* note 11.

[42] *Id.*

[43] *Frequently Asked Questions about COVID-19 Vaccination*, CDC (Feb. 4, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Fkeythingstoknow.html

[44] Ghebreyesus, *supra* note 11.

[45] Ghebreyesus, *supra* note 11; T.V. Padma, *COVID vaccines to reach poorest countries in 2022—despite recent pledges*, 598 NATURE 342, 342–43, July 15, 2021, https://media.nature.com/original/magazine-assets/d41586-021-01762-w/d41586-021-01762-w.pdf.

[46] Anthony D. So & Joshua Woo, *Reserving coronavirus disease 2019 vaccines for global access: cross sectional analysis*, 371 BMJ m4750, 4752 (2020).

[47] *Id.*

given in one lowest-income country. Not 25 million; not 25 thousand; just 25."[48] That country was reportedly Guinea.[49]

Lastly, the free-market approach leads to desperate decisions by LDCs unable to enter the US/UK/CAN/EU vaccine market.[50] For example, Bolivia agreed to purchase vaccines from Russia out of necessity due to the effective lockout of the Western vaccine market.[51] Russia sold 5.2 million doses to Bolivia, with the first dose administered on January 28, 2021.[52] Given that Bolivia has 11.2 million people, this was thought to be a good start.[53] However, one has to pay careful attention to the fine print. The Russian vaccine is a two-dose vaccine, and each dose is unique.[54] Indeed, one cannot simply just get the first dose twice, or rely on the first dose for a reasonable level of protection like a US, UK, or EU approved two-dose vaccine series.[55] Russia's vaccine requires a person to receive the unique first dose and then sometime later the unique second dose.[56] The first dose alone is basically ineffective in preventing hospitalization or death on its own.[57] Proper immunization requires both doses for efficacy.[58] Unfortunately, Bolivia only contracted for the first dose, giving Bolivia 5.2 million first doses and zero second doses; Bolivia had no money left over to contract for the second doses.[59] The lack of second dose severely compromised the country's goal to provide effective vaccination of its citizens.[60]

A pure free market approach leads to countries procuring more vaccinees than they require, predatory practices have effectively locked out least developed countries from access to the vaccine.[61]

B. Classic IP Approach

Under classical IP theory applied to the medical field, IP protections via patents incentivize the development of new medical treatments.[62] Patents do this by trading disclosure

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[48] Ghebreyesus, *supra* note 11.

[49] *Opinion: Rich countries' 'me first' vaccine hoarding is leaving behind low-income nations*, THE WASH. POST (Jan. 24, 2021), https://www.washingtonpost.com/opinions/global-opinions/rich-countries-me-first-vaccine-hoarding-is-leaving-behind-low-income-nations/2021/01/23/3830e7d4-5c23-11eb-a976-bad6431e03e2_story.html.

[50] *Bolivia consults with experts from Spain, Argentina and Russia to combine vaccines,* THE RIO TIMES (July 29, 2021), https://www.riotimesonline.com/brazil-news/covid-19/bolivia-consults-with-experts-from-spain-argentina-and-russia-to-combine-vaccines/; EURACTIV, *supra* note 8.

[51] THE RIO TIMES, *supra* note 50; EURACTIV, *supra* note 8.

[52] THE RIO TIMES, *supra* note 50; EURACTIV, *supra* note 8.

[53] THE RIO TIMES, *supra* note 50; EURACTIV, *supra* note 8.

[54] EURACTIV, *supra* note 8.

[55] THE RIO TIMES, *supra* note 50.

[56] EURACTIV, *supra* note 8.

[57] THE RIO TIMES, *supra* note 50.

[58] EURACTIV, *supra* note 8.

[59] THE RIO TIMES, *supra* note 50.

[60] EURACTIV, *supra* note 8.

[61] So & Woo, *supra* note 46.

[62] Stanley Plotkin, *The Complexity and Cost of Vaccine Manufacturing – An Overview,* 35 VACCINE 4064, 4066 (2017); *See* Dimitrios Gouglas et al., *Estimating the Cost of Vaccine Development Against Epidemic Infectious Diseases: A Cost Minimization Study,* 6 THE LANCET GLOBAL HEALTH e1386 (2018).

of the specific details of a new medication for a limited monopoly on that medication.[63] This monopoly is respected not just by current US patent laws, but also by international agreement among all WTO members via the international agreements.[64] In this way, a medical company may invest heavily in numerous risky medication development with the knowledge that upon governmental approval, it will have a predictable path to recoup its investment and turn a profit.[65] As the monopoly on the medication is for a limited time, the company is encouraged to not rest on its laurels, but instead to reinvest any profits into further research looking for the next breakout medication.[66] Further, public disclosure of the medication via the patent system may allow third parties to take what has been created and improve on it faster than might have otherwise occurred.[67] In these ways, patent protection encourages perpetual development of new vaccines needed during a pandemic in the long run.[68]

However, the policy behind patent protection is not without issues. During the life of a patent, the price of the medication is often super competitive. Though this super competitive price point encourages fast vaccinee discovery, it significantly slows worldwide distribution. Indeed, a patent's monopoly allows for a market price point of the new medication well beyond the means of least developed nations locking them out of the initial distribution system as seen with the Pfizer costing upwards of $19 a dose[69] leading to LDCs only initially receiving 25 jabs.[70]

C. COVAX Approach

COVAX is a vaccine distribution program based on the idea that the only way out of the COVID-19 pandemic is by every country in the world working closely together to ensure everyone has access to a COVID-19 vaccine.[71] The Coalition for Epidemic Preparedness Innovations (CEPI), unicef, Gavi, and the WHO provided the funding to create a program to acquire and distribute, in an equitable fashion, US, UK, or EU, etc. vaccines to countries economically locked out of the those vaccine markets.[72]

Though the program was met with some initial success, it had two major issues. The first issue is that the program was designed to only provide enough vaccines to cover up to 20% of each LDC's population.[73] This is a non-solution for 80% of the population for each participating country. The second and more pressing issue is that it has run into the same

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[63] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[64] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[65] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[66] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[67] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[68] Plotkin, *supra* note 62; Gouglas et al., *supra* note 62.

[69] Owen Dyer, *Covid-19: Countries Are Learning What Others Paid for Vaccines,* 372 BJM n281 (2021).

[70] Editorial Board, *Rich Countries' 'Me First' Vaccine Hoarding is Leaving Behind Low-Income Nations,* THE WASHINGTON POST (Jan. 24, 2021), https://www.washingtonpost.com/opinions/global-opinions/rich-countries-me-first-vaccine-hoarding-is-leaving-behind-low-income-nations/2021/01/23/3830e7d4-5c23-11eb-a976-bad6431e03e2_story.html.

[71] Benjamin Mueller & Rebecca Robbins, *Where a Vast Global Vaccination Program Went Wrong,* THE NEW YORK TIMES (Aug. 2, 2021), https://www.nytimes.com/2021/08/02/world/europe/covax-covid-vaccine-problems-africa.html.

[72] *Id.*

[73] *Id.*

problem the LDCs ran into when they attempted to purchase the vaccine on the free market, they could not pay the high prices the market was calling for.[74] Thus, the COVAX program was just as locked out of the vaccine purchasing market as all the other LDCs since most of the vaccines were already spoken for by the MDCs.[75]

Under this market constraint created by inadequate nongovernmental agency funding and looked at the through the MDC 'me first' lens, COVAX continues to find itself unable to meet its vaccine acquisition goals, meaning countries are not even receiving the 20% they were promised, making a COVAX system a nonviable solution during the initial, vaccine supply limited portion of the next pandemic.[76]

D. Compulsory Licensee Approach

1. WTO TRIPS Agreement

WTO member countries passed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the Uruguay Round in 1990.[77] This agreement was helmed by the US to improve US IP rights, which the United States felt were lacking under previous agreements.[78] In its final form, the agreement codified many US IP protections in the international trade system.[79] In doing so, the agreement defined the minimum standards for WTO member countries to use in protection of each member country's IP without providing a series of carved out exceptions for IP use in LDC.[80] TRIPS began to be regarded as a one-sided agreement that placed least developed nations at a significant disadvantage in matters of healthcare, which created international backlash.[81] In response to this perception, the Doha Declaration was released in 2001.[82]

The Doha Declaration created a mechanism to balance the IP rights of all WTO member countries against the need for healthcare in least developed WTO member countries.[83] The key to achieving this balance was paragraphs four, five and six of the Doha Declarations. Paragraph four states that the entire TRIPS agreement should be viewed through the lens of international support of the public health for all member countries.[84] In support of a member country's public health, paragraph five guarantees a WTO member country the right to determine what may be considered a national emergency or an issue of extreme

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[74] *Id.*

[75] *Id.*

[76] Mueller & Robins, *supra* note 71.

[77] Adrian Otten, *The TRIPS negotiations: an overview*, *in* THE MAKING OF THE TRIPS AGREEMENT 55, 59 (Jayshree Watal & Anthony Taubman eds., 2015).

[78] *Id.* at 59.

[79] *Id.* at 60.

[80] *Id.*

[81] *Id.*

[82] *IP Justice Policy Paper for the WIPO Development Agenda*, WIPO, (June 20, 2005), https://archive.md/20130108183327/http://www.ipjustice.org/WIPO/WIPO_DA_IP_Justice_Policy_Paper.shtml.

[83] *Declaration on the TRIPS agreement and public health,* WTO (Nov. 14, 2021) https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[84] Otten, *supra* note 77, at 108.

urgency.[85] Then, in light of such a national emergency or issue of extreme emergency, each WTO member country has the right to grant compulsory licenses on any healthcare related IP.[86] Lastly, understanding that LDCs, with their inability to produce at large scale lifesaving medicines, may need more than just the ability to grant compulsory licenses in their future healthcare crisis, paragraph six grants member WTO countries the ability to find unique solutions to this large scale production problem.[87] This eventually lead to a series of amendments culminating in the sixth amendment of the TRIPS agreement passed in 2017.[88] This amendment to the TRIP agreement, which is binding on all WTO countries, authorized compulsory licensed medications to be produced by a third party and exported to a least developed or developing country.[89] It is this amendment that has become of increased interest in the last year given the plight of least developed countries and their lack of vaccine manufacturing ability as the COVID-19 pandemic has raged across the world.[90]

2. Canada Law in Support of TRIPS Agreement

Canadians have a worldwide reputation of being friendly, polite, and social justice oriented.[91] It was in this spirit that the Canadians recently developed their "Access to Medicine Regime" legislation.[92] This program seeks to provide LDCs access to life-saving vaccines and medication by compulsory license.[93] Indeed, this Canadian program leverages the WTO TRIPS sixth amendment authorization to award a compulsory license to a Canadian manufacturer.[94] In this way, the Canadian manufacture under the compulsory license, may produce the vaccine and distribute it in an LDC that lacks the means to buy or create the vaccine themselves.[95] Canada was one of the first WTO member countries to pass legislation to take advantage of the WTO TRIPS sixth amendment program.[96] Although Canada was the first country to implement legislation that took advantage of the TRIPs sixth amendment agreement, Canada has yet to create an efficient mechanism for LDCs to take advantage of this process.[97] The Access to Medicine Regime requires Canadian congressional body

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[85] *Id.* at 109.

[86] WTO, *supra* note 83.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Introduction to the Canada's Access to Medicines Regime*, Government of Canada, https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/introduction.html (last visited Mar. 15, 2022).

[91] *Overview of Canada,* US News and World Reports, *Overview of Canada,* US News and World Reports, https://www.usnews.com/news/best-countries/overall-rankings (last visited Mar. 15, 2022).

[92] *Introduction to the Canada's Access to Medicines Regime*, Government of Canada, https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/introduction.html (last visited Mar. 15, 2022).

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] Helen Lock, *Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines – But Needs Canada to Grant a License*, Global Citizen, (Aug. 2, 2021) at https://www.globalcitizen.org/en/content/bolivia-canada-patents-covid-19-vaccines-trips/; Benjamin Blanco, *With one simple decision, the Canadian government can*

approval to add any vaccine to its list of approved list. In doing so, Canada has necessitated an expensive and lengthy political debate for each vaccine added.[98]

This congressional approval requirement has neutered the effectiveness of Canada's Access to Medicine Regime during COVID-19.[99] As Bolivia was unable to procure a vaccine via the free market, it decided to give the Canadian compulsory licensee approach a try.[100] To this end, Bolivia has contracted with a Canadian manufacturer to produce 15 million doses of the Johnson & Johnson (J&J) vaccine.[101] However, Canada's government has yet to authorize the J&J vaccine to be produced under this legislation.[102] This means Bolivia, who applied May 11, 2021, continues to be in bureaucratic limbo.[103]

Given the highly bureaucratic nature of the Canadian Access to Medicine Regime program, the fickle nature of the Canadian government to place various items on the approved list, and the lack of transparency in the process, Canadian Access to Medicine Regime has proven not to be a viable way forward for Bolivia or any other LDC.[104]

3. U.S. Law in Support of TRIPS Agreement

In contrast to the Canadian legislative solution, which has been made ineffective via a whitelist system, US law, is much more effective at accomplishing compulsory licensing. Under US law, the government has the power to take the patent of a vaccine and use it as the government sees fit. In line with the international TRIPS agreement, "The US government has authorized the 'taking' of a non-exclusive and compulsory license to any United States patent based on the theory of eminent domain," per 28 U.S.C § 1498.[105] Further, the taking of a compulsory license occurs at the instant the invention is first manufactured by the government.[106] Thus, the US government may execute a taking by merely creating the patented item with or without notice.[107] Additionally, the government may contract out for the vaccine's production, and the manufacture will not be liable as they are merely an agent of the US government.[108] Therefore, it does not violate US laws to exercise amendment six of the TRIPS agreement to contract out creation of a patented vaccine, which makes the exercise an attractive option for LDCs attempting to get access to a vaccine.[109]

However, all is not lost for the owner of the patent "taken" by the US government. The owner of the patent may seek relief for this non-exclusive compulsory licensing under 28

save lives, ALJAZEERA (Sep. 28, 2021) at https://www.aljazeera.com/opinions/2021/9/28/the-canadian-government-can-save-bolivian-lives.

[98] Lock, *supra* note 97; Blanco, *supra* note 97.

[99] Lock, *supra* note 97; Blanco, *supra* note 97.

[100] Lock, *supra* note 97; Blanco, *supra* note 97.

[101] Lock, *supra* note 97; Blanco, *supra* note 97

[102] Lock, *supra* note 97; Blanco, *supra* note 97.

[103] Lock, *supra* note 97; Blanco, *supra* note 97.

[104] Lock, *supra* note 97; Blanco, *supra* note 97.

[105] Liberty Ammunition, Inc. v. United States, 119 Fed. Cl. 368, 385 (2014), *aff'd in part, vacated in part, rev'd in part*, 835 F.3d 1388 (Fed. Cir. 2016).

[106] *Id.*

[107] *Id.*

[108] *Id.*

[109] *See id.*

U.S.C. §1498(a).[110] This section "is a waiver of sovereign immunity only with respect to direct governmental infringement of a patent."[111] If the owner of the patent can show direct infringement, "relief may be provided for the 'reasonable and entire compensation' for the compulsory non-exclusive patent license."[112] Per §1498, a patent's direct infringement may be demonstrated when the government has among other ways, uses or directly consented to the manufacture of the patented vaccine for its benefit without obtaining a license.[113] Relief is usually determined to be a reasonable royalty which starts from the day of the taking, at an interest rate set at the five-year bond rate on that day.[114]

Though the government has not exercised this option in the medical field, the government has exercised this option numerous times in the name of national defense with regards to ammunition, and other military relevant patents deemed integral to national security.[115] Thus, when worldwide manufacturing and distribution becomes a matter of national defense during the next pandemic, it is probable the US will "take" a nonexclusive compulsory licenses, contract out for its manufacture, and distribute it as far and wide as necessary to ensure the safety of the US, with the royalty to vaccine IP holder be decided later by the courts that will likely be far less than what was needed to justify the cost of investing in vaccine discovery. This uncertainty of royalty payments to the IP holder injects additional risk that the cost of development will not be outweighed by the compensation. As such, a court ordered royalty payment after the country has taken the IP is an untenable long-term solution for the market.

IV. ALTERNATIVE DISPUTE RESOLUTION-INSPIRED SOLUTIONS

A. Alternative Dispute Resolution: A Quick Primer

Alternative Dispute Resolution (ADR) allows parties to settle their disputes without going to court.[116] Though there are many forms ADR may take; arbitration and mediation are the most common.[117] Arbitration and mediation each provide unique tools for out-of-court settlements.[118]

Arbitration is the more formal of the two forms of ADR and provides participants with a binding settlement that is enforceable.[119] Arbitration allows for things like limited discovery with more relaxed rules of evidence that often allow for hearsay evidence.[120] This permits each party to present all the evidence they feel is necessary for a fair decision. Further, the arbitrator may be an individual or a three-person panel chosen directly by

[110] *Liberty Ammunition, Inc.*, 119 Fed. Cl. at 386.
[111] *Id.* at 385.
[112] *Id.* at 386.
[113] *Id.* at 385.
[114] *Id.*
[115] *Liberty Ammunition, Inc.*, 119 Fed. Cl. at 385.
[116] Krystyna Blokhina Gikis, *Alternative Dispute Resolution*, LEGAL INFORMATION INSTITUTE (Jun. 8, 2017), https://www.law.cornell.edu/wex/alternative_dispute_resolution.
[117] *Id.*
[118] *Id.*
[119] *Id.*
[120] *Id.*

participants or via a support organization like American Arbitration Association.[121] This allows parties to choose specific arbitrator(s) for their specialized knowledge of the industry at issue.[122] This industry specific knowledge enables the arbitrator to quickly grasp technical details of the parties' concerns to allow for a more speedy and nuanced settlement.[123] Once an arbitrator has heard all the evidence, the arbitrator will issue a binding judgment that is enforceable domestically[124] and internationally in over 160 countries[125] via the Convention on Recognition and Enforcement of Foreign Arbitral Awards signed in 1958.[126] Additionally, arbitration is done at a fraction of the cost and time of litigation as the parties do not have to wait for a court date or deal with time-consuming full length discovery processes.[127] Thus, arbitration is a speedy, cost-effective way to get an enforceable judgment from a subject matter expert arbitrator.[128]

Mediation is a more informal alternative to litigation that is likely to be adhered to as all parties had a hand in its creation.[129] Mediators are usually chosen specifically for their negotiation background rather than specific knowledge in a particular field.[130] In this way, a mediator leverage their negotiation skills on behalf of all parties to fashion a mutually agreeable solutions.[131] As each party has buy-in to this solution, the parties have a high satisfaction rate of the outcome, which leads to a high level of adherence to the settlement.[132] Just like in arbitration, mediation is a significantly cheaper alternative to litigation.[133] Thus, though mediation settlements lack the force of law, their high adherence rate make them an excellent cost-effective alternative to litigation.[134]

B. Soft Power of Least Developed Nations using ADR in a Pandemic environment.

Mediation is an excellent tool for LDCs to flex their soft power to create access to vaccine markets during the initial phase of the next pandemic. LDCs have three things they may leverage during a pandemic in their efforts to get vaccines. First, it is in MDCs' best

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[121] Gikis, *supra* note 116.

[122] *Id.*

[123] *Id.*

[124] *Id.*

[125] *Contracting States*, NEW YORK ARBITRATION CONVENTION (Last visited Mar. 15, 2022), https://www.newyorkconvention.org/countries.

[126] *Convention on the Recognition and Enforcement of Foreign Arbitration Awards (New York, 1958) (the "New York Convention")*, UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW, (Last visited Mar. 15, 2022), *https://uncitral.un.org/en/texts/arbitration/conventions foreign_arbitral_awards*).

[127] Gikis, *supra* note 116.

[128] *Id.*

[129] *How Courts Work: Mediation – What Are the Advantages to Mediation,* ABA (Sep. 9, 2019), https://www.americanbar.org/groups/public-_education/resources/law_related_education_network/how_courts_work/mediation_advantages/.

[130] *Id.*

[131] *See generally id.*

[132] *Id.*

[133] Gikis, *supra* note 116.

[134] *See generally How Courts Work*, *supra* note 129.

interest to ensure the whole world is vaccinated.[135] Second, vaccine manufacturers will want access to the large markets in LDCs. Lastly, LDCs have the right to leverage TRIPS agreement, Canada laws, and US laws for compulsory licensing.[136] Given these leverage points, LDCs should use ADR venues to create a settlement that is mutually beneficial for all parties before the next pandemic hits.

1. Vaccination of least developed countries protects developed countries

Beyond the humanitarian reasons of preventing loss of life due to lack of vaccination of LDC inhabitants, there is more egocentric reason why MDCs would want to help LDC in this regard. LDC vaccination protects not only the citizens of the LDC, but also inhabitants of MDCs because vaccination limits opportunities for the virus to infect new individuals.[137] The more people the pandemic has an opportunity to infect, especially in countries with limited health care systems, the more likely a new variant will develop that will compromise the effectiveness of current vaccines and medical treatments.[138] As seen with COVID-19 and its Delta and Omicron variants, mutated variants can occur quickly and be more deadly[139] or more communicable than the original strain.[140] Therefore, not only is helping the LDCs appropriate from a humanitarian perspective, it is also in the best interest of the MDCs to ensure the vaccination of LDCs as quickly as possible.

2. Large Market Access of Least Developed Nations

The next leverage point an LDC should use is access to their country's or region's large market. Vaccine creation is an incredibly expensive undertaking, requiring a large market access for the creators to recoup their investment.[141] Nearly 85% of the world's population do not live in a developed nation, so the large markets necessary for vaccine developers to recoup their cost are the rest of the world.[142] Further, given that an effective vaccinee often only requires one dose and numerous people in developed nations with their effective health care system choose not to get the vaccine at all, the developed nation market gets saturate quickly before vaccine development cost may be recouped. However, LDCs with their large populations and ability to ensure higher vaccination rates due to pent up demand are promising markets for vaccination producer to earn back their vaccine investments. To this end, LDC may be able to leverage access to their markets via

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[135] *See generally* Frank T. Wen et al., *The Beneficial Effects of Vaccination on the Evolution of Seasonal Influenza* (Apr. 1, 2020) *reprinted in* BIORXIV, https://www.biorxiv.org/content/10.1101/162545v4 (last visited Mar. 15, 2022) (noting the general benefits of worldwide vaccination).

[136] Otten, *supra* note 77, at 55 (explaining what TRIPS is and how it formed).

[137] Kathy Katella, *5 Things to Know About the Delta Variant*, YALE MEDICINE (Jan. 6, 2022), https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid.

[138] *Id.*

[139] *See id.*

[140] *See id.*

[141] Plotkin, *supra* note 62.

[142] *Developing Countries,* WORLDDATA, https://www.worlddata.info/developing-countries.php (last visited Mar. 15, 2022).

government sanctioned monopoly in exchange for access to the vaccine during the initial distribution phase.

3. International TRIPS Agreement

The next pandemic is merely a matter of time and the issue of initial vaccine access for a LDC will again be raised. However, the next time this arises countries can have a plan in place before hand via ADR negotiations. That is an LDC should work now to create an ADR agreement that leverages their country's ability to take the vaccine IP without adequate compensation granted by the TRIPS agreements to create a vaccine development and distribution settlement in preparation for the next pandemic. An ADR settlement like this, with buy-in from all parties, effectively gets parties to commit to positive actions necessary to enable LDC access to vaccinees in the next pandemic.[143]

C. ADR Settlement Options:

1. Option One: ADR to Codify Current Best practices of Status Quo

It is in the best interests of MDCs and LDCs to create a settlement that provides access to vaccine markets due to LDC's soft power of access to large markets, improved efficacy of the vaccine when universal vaccination occurs in the setting of TRIPS and US law-enabled compulsory licensing.[144] This settlement would trade instant access to vaccines that would cover the highest risk percentage of the country's population for a long-term monopoly of the least developed market once supply catches up to demand. This would provide a legal pathway to protect the most vulnerable of a LDC without having to resort to compulsory licensing taking. [145] Further, the settlement would pre-determine the reasonable royalty rate for use of the non-exclusionary compulsory license without resorting to costly ligation as seen in the *Liberty* case.[146]

In this case, the government was looking for a lead-free bullet, saw that Liberty had created one and took the IP and began producing it themselves. After the governmental taking, the royalty was established by the courts at a price that was likely lower than what Liberty would have gotten had they pre-negotiated a price in an ADR venue. Though this is an ammunition IP case, the principals would apply in a vaccine IP taking. In the setting of a pandemic, vaccine creation and distribution can easily be made into a national security issue, just as the lead-free ammunition was, that would justify governmental taking the vaccine IP. However, if the vaccine IP is taken by the government, as seen in *Liberty*, the royalty rate to be paid to the IP owner, which is set by the court looking at the totality of the facts on a case-by-case basis which would then include the fact the vaccines were given away in the name of national defense may be determined to be set at less than half what the patent owner may

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[143] *How Courts Work*, *supra* note 129.

[144] *See* Frank T. Wen et al., *supra* note 135, at 2.

[145] *How CDC is Making COVID-19 Vaccine Recommendations,* CDC (Nov. 15, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html.

[146] *Liberty Ammunition, Inc.*, 119 Fed. Cl. at 385.

think is appropriate.[147] An ADR settlement that preempts this would reduce uncertainty regarding national defense justified takings during the next pandemic.

2. Option Two: Flood Insurance Model

Knowing that pandemics occur periodically, a US flood insurance type model might be an appropriate way to allow countries like Bolivia to overcome the high initial market cost of a timely vaccine purchase. The US flood insurance model works by allowing and sometimes requiring people who live in flood prone areas to purchase special insurance in case of flooding.[148] These insurance policies are provided directly by the US government but may also be sold through private insurance companies.[149] FEMA reports that for every dollar spent on flood insurance in this way saves the US government six dollars in disaster relief funding.[150]

Like with the flood insurance model, countries could pay an annual premium to an insurance company.[151] This coverage would then obligate the insurance company to purchase a percentage of vaccine doses from approved sellers, up to a certain cost, during the initial rounds of selling during the next pandemic. Given that periodicity of pandemics,[152] the insurance company would likely have roughly 100 years to prepare for its first pay out. This would give insurance companies plenty of time to accrue premiums for participating countries. Further, like all insurance companies they could invest those payments inquiring modest low risk interest rate. Over time the insurance company could learn how to better assess the risk individual LDCs have and adjust their premiums accordingly. Further, like the US flood insurance program, this program could be underwritten by the Unite Nations, World Health Organizations, or even the US.[153]

The flood insurance model might seem like COVAX. After all they would both be third party nongovernmental agencies providing vaccine to LDCs. However, the flood insurance would not rely on donors who might lose interest over time, or become concerned about funding a program that could provide vaccine relief to a non-allied nation. A flood insurance model would mitigate the politics of large donations and allow the program to be self-sustaining.

Thus, an insurance program underwritten by an international organization, or even the US itself, would be an excellent way to create an apolitical self-sustaining mechanism that lowers the barrier to entry for LDCs to the initial vaccine purchasing market as seen in the current COVID-19 pandemic.

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[147] *Id.*

[148] *Who is Required to Have Flood Insurance*, FEMA, https://www.floodsmart.gov/am-i-required-have-flood-insurance (last visited Mar. 15, 2022).

[149] *Flood Insurance*, FEMA, https://www.fema.gov/flood-insurance (last visited Mar. 15, 2022).

[150] Federal Insurance and Mitigation Administration, *Natural Hazard Mitigation Saves Interim Report*, FEMA (Jun. 2018), https://www.fema.gov/sites/default/files/2020-07/fema_mitsaves-factsheet_2018.pdf.

[151] *Numerical Models Meeting the Minimum Requirements of the National Flood Insurance Program*, FEMA, https://www.fema.gov/flood-maps/products-tools/numerical-models (last visited Mar. 15, 2022)

[152] Sampath et al., *supra* note 14, at 1.

[153] *Flood Insurance*, FEMA, https://www.fema.gov/flood-insurance (last visited Mar. 15, 2022).

3. TRIPS enabled Long Term Sustainable Manufacturing Solution

A mediated settlement that enabled LDCs the ability to create a long-term sustainable vaccine manufacturing solution would be best. A multilateral approach with various stakeholders, from MDCs' government officials to the pharmacology industry, with various international organizations like Unite Nations, World Health Organizations, or even the US., to create a vaccine manufacturing infrastructure in numerous countries ensures each country could produce the necessary vaccine in event of a pandemic upon securing a prearranged licensing agreement. When there was not a current pandemic that infrastructure could be used to manufacture other vaccines (for polio, measles, smallpox, etc.) for local and international sale. In this way, countries would enable themselves to be more self-sufficient during the next pandemic, provide the world would have access to additional manufacturing resources that will always be in short supply during a pandemic, and lastly provide an additional source of revenue by producing regular vaccines while providing better preventative health measures.

While continuing to seek a Canadian legislative solution, and further engaging in negotiations with the US government, a LDC like Bolivia should also pursue a settlement to enable their own manufacturing of the vaccine. Vaccine creators are already showing unprecedented cooperation producing each other's vaccines in their own facilities.[154] It would not be hard to go one step further and have those same vaccine creators work with least developed nations to build out vaccine production and the associated logistics tail needed within their nation.[155] With the leverage of the TRIPS sixth amendment, the Canadian Access to Medicine Regime program, and 28 U.S.C. §1498, along with the other previously mentioned soft power of LDCs, it is in the vaccine patent holder's best interest to create a settlement that would allow a LDC to manufacture the vaccine directly in their country without a compulsory license while providing control of the vaccine licensees to recoup their investment at some level while increasing manufacturing capabilities in an interested least developed nation like Bolivia.

V. CONCLUSION

The next pandemic is no more than a hundred years off. Though the COVID-19 pandemic has led to thousands of deaths worldwide, it has not led to billions of deaths as a smallpox-like virus could have caused. Therefore, it is essential to plan now for that contingency. Given these realities, US, UK, and EU vaccine creators must understand that countries will do everything in their power to help the market develop a vaccine in the safest and most timely manner. Possible negotiated plans need to be developed today to ensure the protection of the vaccine developers' IP while the entire world has initial access to the vaccine. In doing so, future vaccinee developers will have a better understanding of the costs and benefits of pandemic laded market and will be able to better use their resources. This will provide the best opportunity for no country to be left behind in the initial dosage procurements.

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[154] Aisling Irwin, *What it Will Take to Vaccinate the World Against COVID-19*, 592 NATURE 176, 179 (Apr. 2021)

[155] *Id.*