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Vaccine Apartheid: A Human Rights Analysis of COVID-19 Vaccine Inequity

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VACCINE APARTHEID: A HUMAN RIGHTS ANALYSIS OF COVID-19 VACCINE INEQUITY

SARAH JOSEPH* AND GREGORY DORE**

ABSTRACT

In this paper, we analyse the inequity in current global vaccine distribution through the lens of international human rights law. First, we introduce the currently available COVID-19 vaccines, before discussing causes and consequences of vaccine inequity, as well as efforts to expand global vaccine access. We then turn to explain the relevant obligations of states regarding human rights to health, life, and equitable access to the benefits of technology. In light of those obligations, we assess the human rights compatibility of vaccine procurement and vaccine aid. After a discussion of the possible human rights responsibilities of the pharmaceutical companies that own the vaccines, we focus on whether a proposed waiver of global intellectual property rights in respect of COVID-19 vaccines is demanded under international human rights law. We conclude with a critique of failures in the international legal system, which may have rendered vaccine inequity inevitable.

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I. Introduction

The COVID-19 pandemic has killed millions of people and changed the way life has been lived in almost every corner of the globe for over two years. Yet it has also given rise to an extraordinary triumph in medical science, the production of several highly effective safe vaccines for a novel virus within a year of that virus's appearance. The positive results from clinical trials are now being mirrored in real-world circumstances, with hospitalisations and deaths considerably lower in proportion to cases in countries with high vaccination rates.

However, while some countries were able to achieve mass vaccination of those willing and able to receive vaccines in 2021, many states, particularly low-income ones, may need to wait until at least 2023 for such an outcome. The current situation is characterised by extreme global inequality regarding access to a COVID-19 vaccine, which has been repeatedly condemned by the World Health Organisation ('WHO'). We will refer to this situation as one of 'vaccine inequity.'

In this paper, we analyse vaccine inequity through the lens of international human rights law. After this introduction (Part I), we introduce in Part II the currently available COVID-19 vaccines, before discussing causes and consequences of vaccine inequity, as well as current efforts to expand global vaccine access. In Part III, we turn to explain the relevant obligations of states regarding

^{1.} Economist Intelligence Unit, Q4 Global Forecast: One Year on: Vaccination Successes and Failures 1 (Nov. 10, 2021).

^{2.} WHO Chief Warns Against 'Catastrophic Moral Failure' in COVID-19 Vaccine Access, UN News (Jan. 18, 2021), https://news.un.org/en/story/2021/01/1082362.

human rights to health, life, and equitable access to the benefits of technology. In particular, we discuss a state's extraterritorial obligations to the people of other states. In light of those obligations, in Part IV we assess the human rights compatibility of certain state policies, vaccine nationalism and vaccine aid. In Part V, we analyse the human rights obligations of pharmaceutical companies before moving to state duties to regulate such entities. We then analyse proposals to waive global intellectual property rights in respect of COVID-19 vaccines, and whether assent to such a waiver is demanded under international human rights law. Part VI addresses shortcomings in international human rights law and the international system, which have helped to render vaccine inequity predictable if not inevitable, and the swift solution to it unattainable. Part VII concludes this paper.

II. COVID-19 VACCINES, CAUSES AND CONSEQUENCES OF INEQUITY IN ACCESS

A. Different Types of COVID-19 Vaccines

The development of several safe and effective vaccines within a year of recognition of the COVID-19 disease, and identification of SARS-CoV-2 as its causative agent, is remarkable. Most vaccines take years to develop.³ Key factors in this accelerated development include prior work on similar viruses, notably Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) and Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV),⁴ improved technology for vaccine platforms,⁵ massive scientific and monetary investment,⁶ and the high rates of ongoing COVID-19 enabling rapid enrolment and accrual of events for phase 3 clinical trial endpoints.⁷

^{3.} William Petri, COVID-19 Vaccines Were Developed in Record Time – But Are These Game-Changers Safe?, The Conversation (Nov. 21 2020), https://theconversation.com/covid-19-vaccines-were-developed-in-record-time-but-are-these-game-changers-safe-150249.

^{4.} Philip Ball, The Lightning-Fast Quest for COVID Vaccines – and What it Means for Other Diseases, NATURE (Dec. 18, 2020), https://www.nature.com/articles/d41586-020-03626-1.

^{5.} Petri, supra note 3.

^{6.} This issue is discussed below, infra notes 129–133.

^{7.} Phase 3 efficacy trials are explained in Umair Irfan, COVID-19 Vaccine Efficacy Results Are Not Enough, Vox (Nov. 24, 2020), https://www.vox.com/21575420/oxford-moderna-pfizer-covid-19-vaccine-trial-biontech-astrazeneca-results. "Events" are incidents of people within the trial contracting COVID-19 (whether the infection arises amongst someone who received the vaccine or someone in a comparator group who received a placebo). The high general incidence of COVID-19 at the time of the trials inevitably sped up the accrual of events.

COVID-19 vaccines are largely based on the pivotal S (Spike) protein that enables binding and cell entry, with four broad classes among those currently licensed:⁸

- 1. Protein sub-unit vaccines: With these vaccines, the S protein is delivered as a recombinant protein subunit that incorporates a cell-based system to enable expression of the protein (e.g. Novavax, Abdala).
- 2. Viral vector vaccines: These vaccines use adenoviruses, themselves unable to replicate, to deliver and express the S protein (e.g. AstraZeneca/Oxford; Johnson & Johnson, Sputnik V, Cansino). Several other adenovirus vaccines have been trialled against infectious diseases (HIV, Tuberculosis, malaria, ebola) with variable success.
- 3. *mRNA vaccines:* With these vaccines, S protein-encoding mRNA is protected within lipid nanoparticles that has instructions for making S protein, thus stimulating protective neutralizing antibodies and other elements of the immune response against SARS-CoV-2 (e.g. Pfizer, Moderna). These types of vaccines are clearly the "new kid on the block" as this technology has not previously been approved for use in humans.
- 4. Whole attenuated virus vaccines: These vaccines contain inactivated SARS-CoV-2 that can present the key antigens to simulate an effective immune response, but without producing infection (e.g. Sinovac, Simopharm).

Efficacy against severe COVID-19 or hospitalization and death was close to 100% in clinical trials and above 90% in "real-world" studies.⁹ Furthermore, evidence from real-world evaluation indicates considerable effectiveness against infections.¹⁰ There is also evidence people who develop "breakthrough" infections post-

^{8.} There Are Four Types of COVID-19 Vaccines: Here's How They Work, GAVI, https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-theywork#:~:text=There%20are%20four%20categories%20of,to%20make%20the%20viral%20antigen

^{9.} See Vaccines Highly Effective Against Hospitalisation from Delta Variant, PUB. HEALTH ENG. (Jun. 14, 2021), https://www.gov.uk/government/news/vaccines-highly-effective-against-hospitalisation-from-delta-variant.

^{10.} Emma Pritchard et al., Impact on Vaccination on SARS-CoV-2 Cases in the Community: A Population-Based Study Using the UK's COVID-19 Infection Survey (June 9, 2021) (unpublished manuscript) (on file with MedRxiv).

vaccination have lower viral levels and are thus likely less infectious, further enhancing their potential impact on population-level transmission.¹¹

Increasing data indicates that protection from the initial vaccine schedule (generally two-dose) wanes somewhat, initially against infection from around three months, then against severe COVID-19 disease from around six months. Both a randomised controlled trial and observational studies have demonstrated the benefit of a third or "booster" dose in terms of both reduction of infection and severe disease risk. The impact of the third dose is particularly pronounced against the Omicron variant, compared to the second dose. Large amounts of COVID-19 vaccine have already been purchased by many high-income countries for their booster programs. The number and timing of further boosters, beyond the third dose, remains unclear.

B. Causes of Inequitable Access

By February 2022, 10.38 billion vaccine doses had been administered. Yet the vast majority of vaccines manufactured have been administered in richer states. The New York Times reported on February 14, 2022, that while 78% of people in high and upper-middle-income countries had received at least one dose, only 11% of those in low-income countries had done so, with vaccination rates being particularly dire in Africa.

^{11.} See Ross J. Harris et al., Impact of Vaccination on Household Transmission of SARS-COV-2 in England (Aug. 19, 2021) (unpublished manuscript) (on file with Knowledge Hub)

^{12.} See Noam Barda et al., Effectiveness of a Third Dose of the BNT162b2 mRNA COVID-19 Vaccine for Preventing Severe Outcomes in Israel: An Observational Study, LANCET, (Oct. 29, 2021), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736 (21)02249-2/fulltext; Press Release, Pfizer, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine, (Oct. 21, 2021), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing.

^{13.} Nathan Bartlett, What's the Difference in Protection Against Omicron Between 2 Doses and 3 Doses of Vaccine?, The Conversation (Feb. 8, 2022, 2:09 PM), https://theconversation.com/whats-the-difference-in-protection-against-omicron-between-2-doses-and-3-doses-of-vaccine-176447.

^{14.} Coronavirus (COVID-19) Vaccinations, OUR WORLD IN DATA, https://ourworldindata.org/covid-vaccinations (last visited Feb. 15, 2022).

^{15.} See Director-General's Opening Remarks at the World Health Assembly, WHO, (May 24, 2021), https://www.who.int/director-general/speeches/detail/director-general-sopening-remarks-at-the-world-health-assembly---24-may-2021.

^{16.} Josh Holder, Tracking Coronavirus Vaccinations Around the World, New York Times (Feb. 14, 2022), https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html.

In early 2022, the main reason for vaccine inequity is that demand outstrips supply. Access is currently a zero-sum game where one state's increased access inevitably reduces the availability of vaccines for other states. Amidst such scarcity, developed states have bought the vast majority of available vaccines directly from manufacturers, and advance purchased most of the vaccines that were scheduled to be manufactured in 2021.¹⁷

Logistical limitations also affect access. Access is easier in those states with the capacity to manufacture the vaccines compared to those who must import it. This is especially so, given export restrictions have arisen to prioritise local access in emergency situations (discussed below). Other logistical issues concern the safe and effective rollout of vaccines, such as keeping vaccines at appropriate refrigerated temperatures while they are transported and stored.

Finally, vaccine manufacturers have monopoly rights over their products, which allows them to control manufacture and distribution networks. The monopoly rights of vaccine manufacturers are discussed in detail in Part V.

C. Initiatives to Improve Accessibility

There are several major global and regional initiatives directed towards addressing vaccine inequity, including the following.

COVAX facility: The COVID-19 Vaccines Global Access (COVAX) is an international initiative led by the WHO, Gavi (The Global Vaccine Alliance, an international public-private partnership established in 2000 to increase vaccine access in poor countries), and CEPI (Coalition for Epidemic Preparedness, a Gates Foundation initiative established in 2016 to enhance vaccine development), with UNICEF as a key delivery partner. COVAX is a vaccine procurement and distribution mechanism to enable global COVID-19 vaccine access, with an initial goal of 20% population coverage for around 200 participating countries by the end of 2021, after which vaccines will be allocated according to need determined by COVID-19 threat and vulnerability. 19

^{17.} See Mark Eccleston-Turner & Harry Upton, International Collaboration to Ensure Equitable Access to Vaccines for COVID-19: The ACT-Accelerator and the COVAX Facility, MILBANK QUARTERLY 1, 11 (Mar. 2, 2021), https://onlinelibrary.wiley.com/doi/full/10.1111/1468-0009.12503 (on the effect of bilateral advance purchase orders on COVAX vaccine numbers); see also Alexandra L. Phelan et al., Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access, 396 The Lancet 800 (Sept. 7, 2020).

^{18.} COVAX, GAVI, https://www.gavi.org/covax-facility (last visited Jun. 7, 2021).

^{19.} Allocation Mechanism for COVAX Facility Explainer, WHO, (Nov. 12, 2020), https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer.

COVAX delivered 910 million doses of vaccine in 2021, which was under half of the 2 billion plus doses it aspired to deliver.²⁰

QUAD: This four-member partnership between United States ('US'), India, Australia, and Japan has previously focussed on strategic relationships including military co-operation, and is seen as a grouping to balance the increasing role of China within the Asia-Pacific Region.²¹ In March 2021, political leaders of the four states announced an initiative to enhance Asia-Pacific regional COVID-19 vaccine access with a goal to provide one billion doses by 2022.²² The delivery of vaccines under this scheme was due to commence in the first half of 2022, over a year after the announcement.²³

Bilateral agreements: China and Russia have been very active in support for global vaccine access.²⁴ China estimated that it could produce 2.6 billion doses in 2021, and pledged half a billion vaccine doses to more than eighty countries, providing free doses for fifty-three of those, including states across South East Asia and Africa.²⁵ Russia has concentrated its efforts on bilateral agreements for supply of its Sputnik V vaccine in Latin America and Eastern Europe.²⁶ Although criticisms of Chinese and Russian 'vaccine diplomacy' have been made in relation to these initiatives, other international initiatives such as that of the QUAD clearly also encompass strategic considerations. Other bilateral agreements also exist, such as an agreement for Australia to provide vaccines to Papua New Guinea and Melanesian islands.²⁷

^{20.} Adam Taylor, Covax Vaccine Deliveries Surge in Final Stretch of 2021, with a Record 300 Million Doses Sent out in December, The Washington Post (Jan. 1, 2022, 6:00 AM), https://www.washingtonpost.com/world/2022/01/01/covid-covax-doses-delivered/.

^{21.} Sumitha N. Kutty & Rajesh Basrur, *The Quad: What It Is – and What It Is Not*, THE DIPLOMAT (Mar. 24, 2021), https://thediplomat.com/2021/03/the-quad-what-it-is-and-what-it-is-not/.

^{22.} Fact Sheet: Quad Summit, The White House, (Mar. 12, 2021). https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/12/fact-sheet-quad-summit/.

^{23.} Quad-Supported Vaccine Roll-Out to Begin in First Half, REUTERS (Feb. 12, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/quad-supported-vaccine-roll-out-begin-first-half-2022-02-11/.

^{24.} ECONOMIST INTELLIGENCE UNIT, supra note 1, at 3.

^{25.} Suisheng Zhao, Why China's Vaccine Diplomacy is Winning, EAST ASIA FORUM (Apr. 29, 2021), https://www.eastasiaforum.org/2021/04/29/why-chinas-vaccine-diplomacy-is-winning/.

^{26.} Daria Litvinova, Russia Scores Points with Vaccine Diplomacy, but Snags Arise, AP NEWS (Mar. 7, 2021), https://apnews.com/article/europe-global-trade-middle-east-diplomacy-moscow-e61ebd3c8fe746c60f5ecc1ec323c99a.

^{27.} Stephen Dziedzic, Australia to Supply Doses of Domestically Manufactured COVID-19 Vaccines to Melanesian Countries, including PNG and Timor-Leste, ABC NEWS (Apr. 9, 2021, 6:49 AM), https://www.abc.net.au/news/2021-04-09/australia-png-covid-vaccine-supply-melanesian-countries/100060206.

All of these initiatives are welcome. However, they do not go far enough in delivering vaccines quickly to most of the world.

D. Consequences of Vaccine Inequity

Specific people, particularly the elderly, are more likely to die from or suffer severe COVID-19 if they contract the disease.²⁸ Others, such as frontline health workers²⁹ or people who are incarcerated,³⁰ are much more likely to develop COVID-19 due, respectively, to their frequent contact with the virus or the likelihood of rapid spread if infection breaches their environment. Yet many of the less vulnerable people in rich countries, those much less likely to die from COVID-19, may be vaccinated, and may even have had a booster shot, before many of the most vulnerable in most poor countries.³¹ Hence, the most obvious consequence of vaccine inequity is that more people will die.³²

Even without a global humanistic argument for enhanced vaccine equity, there are global health and economic reasons why pursuit of equity makes sense. First, the emergence of SARS-CoV-2 "variants of concern", such as the Delta and Omicron variants which dominated global infections in 2021 and into 2022, is related to the degree of virus circulating in a population; more infections means greater opportunities for variants to arise. 33 Some variants can have increased transmission potential, higher fatality rates, and/or reduce vaccine efficacy. 34 Hence, continued high-level global infections fosters ongoing potential for new variants of concern,

^{28.} WHO Delivers Advice and Support for Older People During COVID-19, WHO (Apr. 20, 2020), https://www.who.int/news-room/feature-stories/detail/who-delivers-advice-and-support-for-older-people-during-covid-19#:~:text=The%20COVID%2D19%20pandemic, potential%20underlying%20health%20conditions.

^{29.} Long H. Nguyen et al., Risk of COVID-19 Among Frontline Healthcare Workers and the General Community: a Prospective Cohort Study, The Lancet Public Health (May 25, 2020), https://www.medrxiv.org/content/10.1101/2020.04.29.20084111v6.

^{30.} Prevent and Control of COVID-19 in Prisons and Other Places of Detention, WHO, https://www.euro.who.int/en/health-topics/health-determinants/prisons-and-health/focus-areas/prevention-and-control-of-covid-19-in-prisons-and-other-places-of-detention.

^{31.} See the WHO chief lamenting this likely outcome from inequitable vaccine distribution in WHO Chief: "It's Not Right" that Younger Adults in Rich Countries Get Vaccine Before Older People in Poorer Countries, CBS NEWS (Jan. 18, 2021), https://www.cbsnews.com/news/world-health-organization-covid 19-vaccine-inequalities/.

^{32.} Nancy S. Jecker, Aaron G. Whiteman & Douglas K. Diekema, *Vaccine Ethics: an Ethical Framework for Global Distribution*, 47 J. MEDICAL ETHICS 308, 310–11 (2021).

^{33.} Vaughn Cooper and Lee Harrison, Massive Numbers of New COVID-19 Infections, Not Vaccines, Are the Main Driver of New Coronavirus Variants, The Conversation (Sept. 9, 2021), https://theconversation.com/massive-numbers-of-new-covid-19-infections-not-vaccines-are-the-main-driver-of-new-coronavirus-variants-166882.

^{34.} See Tracking SARS-CoV-2 Variants, WHO, https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/ (live site) (last visited Mar. 18, 2022).

which can compromise the protection offered by vaccines. Vaccines tend to lessen transmission and therefore they should reduce the opportunities for the generation of such variants.³⁵

Second, the pandemic has wreaked havoc on local and regional economies, and therefore the global economy.³⁶ Global economic activity will be enhanced through greater COVID-19 control in all states, not just rich countries.³⁷ Thus, global vaccine equity makes public health and economic sense for all states, rich and poor.

III. INTERNATIONAL HUMAN RIGHTS LAW AND VACCINE INEQUITY

In parsing relevant human rights duties regarding vaccine inequity, we will focus on the two United Nations ('UN') human rights covenants, which have global coverage, and cover the greatest range of rights compared to other global human rights treaties.

A. Obligations to a State's Own People

Under international human rights law, states have duties to respect, protect, and fulfil the human rights of their populations.³⁸ The duty to respect is a negative duty to refrain from directly or indirectly interfering with the enjoyment of human rights. The duty to protect is a positive duty for states to take appropriate steps to prevent, investigate, and punish harmful interferences with rights by third parties. The duty to fulfil is a positive duty which requires states to adopt measures to facilitate, promote, and provide for the enjoyment of the relevant right.³⁹

Under Article 12(2)(c) of the International Covenant on Economic, Social and Cultural Rights (TCESCR'), States Parties must "take steps . . . for . . . prevention, treatment and control of

^{35.} Two doses of vaccine have been less successful at containing transmission of the Omicron variant compared to other variants, though three doses do have a significant impact for at least a few months. *See* Bartlett, *supra* note 13.

^{36.} Lora Jones, Daniele Palumbo & David Brown, Coronavirus: How the Pandemic has Changed the World Economy, BBC NEWS (Jan. 24, 2021), https://www.bbc.com/news/business-51706225.

^{37.} Vaccine Inequity Undermining Global Economic Recovery, WHO (July 22, 2021), https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery; The Need for Speed: Faster Vaccine Rollout Critical to Stronger Recovery, OECD (Sept. 3, 2021), https://www.oecd.org/newsroom/the-need-for-speed-faster-vaccine-rollout-critical-to-stronger-recovery.htm.

^{38.} International Human Rights Law, Office of the UN High Commissioner, https://www.ohchr.org/en/professionalinterest/pages/internationallaw.aspx#:~:text=By%20b ecoming%20parties%20to%20international,the%20enjoyment%20of%20human%20rights (live site) (last visited Mar. 18, 2022).

^{39.} SARAH JOSEPH, BLAME IT ON THE WTO? A HUMAN RIGHTS CRITIQUE 22 (2011).

epidemic . . . and other diseases." Hence, states must utilise their "maximum available resources" (under the obligation provision, Article 2(1)) to gain access to and administer safe and effective vaccines. Given the deadly nature of COVID-19, the need to combat it is also required under the right to life in Article 6 of the International Covenant on Civil and Political Rights ('ICCPR'). 40 These are obligations of conduct rather than obligations of result. 41 That is, states are required to exercise due diligence and do what can reasonably be expected to prevent COVID-19 infections and mitigate their impact, including by acquiring vaccines, but it is recognised that resource or other legitimate constraints may hinder and even prevent a state from succeeding in gaining access to vaccines. 42

Once acquired, states have an obligation to roll out vaccines in a safe, effective, and equitable manner.⁴³ Duties of equitable distribution of vaccines also arise under Article 15(1)(b) of the ICESCR,⁴⁴ which recognises the rights of "everyone . . . to enjoy the benefits of scientific progress and its applications". The equitable distribution of vaccines in-country indicates that the vaccine should be rolled out to the most vulnerable populations first, especially while supply outstrips demand.⁴⁵

^{40.} See U.N. Human Rights. Comm., Gen. Comt. No. 36: Art. 6 (Right to Life), U.N. Doc. CCPR/C/GC/35, (Sept. 3, 2019), ¶ 26, where the Human Rights Committee says that States parties 'should take appropriate measures to address the general conditions in society that give rise to direct threats to life', including 'the prevalence of life-threatening diseases', which must now include COVID-19. In the same paragraph, the Committee states that such measures include those 'designed to ensure access without delay by individuals to essential goods and services such as ... health-care'.

^{41.} Antonio Coco & Talita de Souza Dias, *Prevent, Respond, Cooperate: States' Due Diligence Duties Vis-á-Vis the COVID-19 Pandemic*, 11 INT'L HUMANITARIAN LEGAL STUD. 218 (2020).

^{42.} Resource constraints are explicitly acknowledged in Article 2(1) of the ICESCR. On positive obligations in the ICCPR, see U.N. Hum. Rts. Comm., General Comment No. 31: The Nature of the General Legal Obligation Imposed on States Parties to the Covenant, \P 8, U.N. Doc. CCPR/C/21/Rev.1/Add.13 (May 26, 2004).

^{43.} Safety and efficacy are implied within the rights to health and life themselves, as lack thereof jeopardises both rights. A duty of equitable distribution is garnered from these rights in conjunction with rights of non-discrimination, found in Articles 2(1) of the ICESCR and Articles 2(1) and 26 of the ICCPR. See, for example, Under Occupation: Israel's Denial of Equitable Access to COVID-19 Vaccines in the Occupied Palestinian Territories, International Commission of Jurists (Oct. 2021), 8–10.

^{44.} Statement on Universal Affordable Vaccination Against Coronavirus Disease (COVID-19), International Cooperation and Intellectual Property, Comm. on Eco., Soc. & Cultural Rts. (Apr. 23, 2021), UN doc. E/C.12/2021/1, \P 3.

^{45.} WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, WHO (Sept. 14, 2020), https://apps.who.int/iris/handle/10665/334299.

B. Extraterritorial Obligations

Having discussed the human rights obligations of states inside their territories, we turn to extraterritorial obligations.⁴⁶ A joint statement by several UN Special Rapporteurs, experts appointed by the UN Human Rights Council to investigate and report on particular human rights issues, was released on November 9, 2020. It recommended that states should:

Comply with their international obligations of ensuring access to medicines, including COVID-19 vaccines and treatment to all and of international assistance and cooperation. This [sic] by combatting the COVID-19 pandemic in a globally coordinated manner, including by joining the COVAX Global Vaccines Facility and putting aside misplaced individual initiatives to monopolize vaccine or supplies.⁴⁷

The Special Rapporteurs clearly believe there is a duty under international human rights law to equitably share vaccines. In this section, we will parse the potential sources of that duty, first by focusing on the ICCPR (due to the relevance of the right to life in Article 6) and then the ICESCR (due to the relevance of Articles 12 and 15(1)(b)).

The UN Human Rights Committee, the monitoring body which supervises implementation of the ICCPR, addressed the extraterritorial scope of the right to life in 2018 in General Comment 36.⁴⁸ It says that a state is responsible for the rights to life of individuals "located in places that are under their effective control, such as occupied territories".⁴⁹ The notion of territorial control is relevant in cases of occupation, such as Israel regarding the Palestinian territories,⁵⁰ and Russia regarding Crimea, or in cases of effective control of extraterritorial lands, as in the cases of the US

^{46.} See generally Sarah Joseph & Sam Dipnall, Scope of Application, in INTERNATIONAL HUMAN RIGHTS LAW 120–30 (Daniel Moeckli et al. eds., 3rd ed. 2017).

^{47.} Off. of the U.N. High Comm'r for Hum. Rts., Statement by U.N. Human Rights Experts Universal Access to Vaccine is Essential for Prevention and Containment of COVID-19 Around the World (Nov. 9, 2020), https://www.ohchr.org/EN/NewsEvents/Pages/Display News.aspx?NewsID=26484&LangID=E.

^{48.} U.N. Human Rights. Comm., Gen. Comt. No. 36: Art. 6 (Right to Life), U.N. Doc. CCPR/C/GC/35, (Sept. 3, 2019).

^{49.} Id. at ¶ 63.

^{50.} See Eyal Benvenisti, Israel is Legally Obliged to Ensure the Population of the West Bank and Gaza Strip are Vaccinated, JUST SECURITY BLOG (Jan. 7, 2021), https://www.justsecurity.org/74091/israel-is-legally-obligated-to-ensure-the-population-in-the-west-bank-and-gaza-strip-are-vaccinated/ (while Israel has run an excellent vaccination program within Israel, it has failed in its international duties to provide vaccines to the Palestinian populations of the West Bank and Gaza.).

regarding Guantanamo Bay and Guam. All of those states have obligations to the people of those territories to provide them with vaccines and vaccination, just as they do to people within their own territories.

In General Comment 36, a state's extraterritorial human rights obligations also extend to "all persons over whose enjoyment of the right to life it exercises power or effective control" including those "whose right to life is nonetheless impacted by its military or other activities in a direct and reasonably foreseeable manner. This aspect of the formulation of extraterritorial obligations is more expansive than earlier enunciations, with the addition of responsibility based on direct and reasonably foreseeable human rights "impacts." The state of the formulation of extraterritorial obligations is more expansive than earlier enunciations, with the addition of responsibility based on direct and reasonably foreseeable human rights "impacts."

The twin cases of A.S. v. Malta and A.S. v. Italy⁵⁴ concerned the extraterritorial responsibility of states for the lives of people who drowned after the respective states failed to save them when their vessel sank. While the case against Malta, in whose territorial waters the migrants' boat sank, was inadmissible for procedural reasons,⁵⁵ the complaint against Italy was upheld. Italy was found to have breached the right to life by failing to exercise due diligence by promptly sending its navy ship, which was in close proximity to the sinking vessel, to rescue the migrants.⁵⁶ Of relevance was that "a special relationship of dependency had been established between the individuals on the vessel in distress and Italy";⁵⁷ Italy was accordingly held responsible because "the individuals on the vessel in distress were directly affected by the decisions taken by the Italian authorities in a manner that was reasonably foreseeable." ⁵⁸

Italy was held liable for the impacts of its omissions rather than actions, so the case manifested a broad approach to extraterritorial

^{51.} U.N. Hum. Rts. Comm., General Comment No. 36: Art. 6 (Right to Life), U.N. Doc. CCPR/C/GC/35, at \P 63 (Sept. 3, 2019).

Id.

^{53.} See Marko Milanovic, Drowning Migrants, the Human Rights Committee, and Extraterritorial Human Rights Obligations, European J. of Int'l L., EJIL: Talk!, (Mar. 16, 2021) (noting the extension of the right to life in General Comment 36 by this "novel, functional conception of jurisdiction").

^{54.} U.N. Hum. Rts. Comm., Communication on A.S. et al. v. Italy, U.N. Doc. CCPR/C/130/D/3042/2017 (Jan. 27, 2021); U.N. Hum. Rts. Comm., Communication on A.S. et al. v. Malta, U.N. Doc. CCPR/C/130/D/3043/2017 (Jan. 27, 2021).

^{55.} U.N. Hum. Rts. Comm., Communication on A.S. et al. v. Malta, U.N. Doc. CCPR/C/130/D/3043/2017 (Jan. 27, 2021), $\P\P$ 6.8-7.

^{56.} U.N. Hum. Rts. Comm., Communication on A.S. et al. v. Italy, U.N. Doc. CCPR/C/130/D/3042/2017 (Jan. 27, 2021), $\P\P$ 8.1-9.

^{57.} Id. at ¶ 7.8.

^{58.} Id.

ICCPR obligations. Extraterritorial jurisdiction under the ICCPR expanded with these cases, and its outer perimeter is not currently clear.⁵⁹

Extraterritorial obligations under the ICESCR seem broader than those under the ICCPR. Such obligations are alluded to explicitly in Article 2(1) thereof, which requires states parties to progressively realize ICESCR rights through steps taken individually 'and through international assistance and cooperation.' The International Court of Justice ('ICJ') has confirmed that extraterritorial obligations exist under the ICESCR in *Democratic Republic of Congo v. Uganda*, ⁶⁰ though it did not clarify their scope.

The Maastricht Principles on the Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights (Principles) were adopted in 2011 by a group of legal experts under the auspices of Maastricht University and the International Commission of Jurists. They say that states have obligations to respect, protect and fulfil economic, social and cultural rights in particular situations, including those "over which State acts or omissions bring about foreseeable effects on the enjoyment of economic, social and cultural rights, whether within or outside its territory," and "situations in which the State, acting separately or jointly . . . is in a position to exercise decisive influence or to take measures to realize economic, social and cultural rights extraterritorially."61 The Principles purport to explain existing international law. However, they are not of themselves binding, so they do not end debate over the extraterritorial scope of the ICESCR.

Given that the ICJ has confirmed that extraterritorial jurisdiction under the ICESCR exists, the least controversial aspect of such a duty is for states to be required to respect ICESCR rights outside their borders, as negative human rights duties (obligation to respect) tend to be perceived as less onerous than positive duties (obligations to protect and fulfil).⁶² This is reflected, in the context of COVID-19 vaccines, in the following comment from the WHO: "at a minimum, nation-states have an obligation in

 $^{59. \}quad See \ {\bf Milanovic}, supra\ {\bf note}\ 53\ ({\bf criticizing}\ {\bf the}\ {\bf reasoning}\ {\bf in}\ {\bf the}\ {\bf Malta}\ {\bf and}\ {\bf Italy}\ {\bf cases}).$

^{60.} Armed Activities on the Territory of the Congo (Dem. Rep. Congo v. Uganda), Judgment, 2005, I.C.J. 168, ¶ 216. (Dec. 19).

 $^{61. \}begin{tabular}{ll} Maastricht\ Principles\ on\ the\ Extraterritorial\ Obligations\ of\ States\ in\ the\ Area\ of\ Economic,\ Social\ and\ Cultural\ Rights\ 9b-9c,\ ETO\ CONSORTIUM\ (Jan.\ 2013),\ https://www.etoconsortium.org/nc/en/main-navigation/library/maastricht-principles/?tx_drblob_pi1%5BdownloadUid%5D=23\ [hereinafter\ Maastricht\ Principles].$

^{62.} See, e.g., Hugh Breakey, Positive Duties and Human Rights: Challenges, Opportunities and Conceptual Necessities, 63 POLITICAL STUDIES 1198, 1200–01, (2015) (defending the concept of positive rights whilst noting 'uncontroversial' negative duties).

global equity not to undermine the ability of other countries to meet their obligations to their own people to secure vaccines."63

The Committee on Economic, Social, and Cultural Rights (CESCR Committee), the body which monitors and supervises implementation of the ICESCR, has confirmed on numerous occasions its belief that states parties have duties to protect ICESCR rights in other states. ⁶⁴ As such duties are relevant in the context of human rights harms caused by non-state actors, they are discussed in Part V in relation to the human rights obligations of and regarding pharmaceutical companies.

The obligation to fulfil ICESCR rights is a positive obligation to take action rather than the simpler negative obligation to refrain from action. It can be split into obligations to facilitate, promote and provide for such rights. Facilitation of a right is to help to provide an enabling environment for its exercise. Promotion is to raise awareness of a right. Providing is to directly provide for the enjoyment of rights by a person who is unable to otherwise enjoy them.⁶⁵

The CESCR Committee has indicated that states have a duty to assist other states with regard to the enjoyment of ICESCR rights when they are in a position to do so.⁶⁶ An extraterritorial duty to fulfil rights implies that rich states are obliged to provide aid to assist poorer countries. Rich states predictably resist such a characterization of their ICESCR duties. Yet such a duty is evident in the words of the Declaration on the Right to Development,⁶⁷ as well as the 2030 Agenda for Sustainable Development.⁶⁸

A duty to more equitably share global wealth and resources is more easily justified if one accepts that poverty is in large part exacerbated, and even caused, by a global economic order created by

^{63.} WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, supra note 45.

^{64.} See, e.g., CESCR, General Comment 15, HRI/GEN/1/Rev.9 (Vol 1) 97, \P 33. See also CESCR, General Comment 19, HRI/GEN/1/Rev.9 (Vol 1) 152, \P 54; Comm. on Econ., Soc. & Cultural Rts., General Comment No. 24 on State Obligations Under the International Covenant on Civil and Political Rights in the Context of Business Activities, U.N. Doc. E/C. 12/GC/24, Part C (Aug. 10, 2017).

^{65.} Joseph, supra note 39, 22.

^{66.} See, e.g., Comm. on Econ., Soc. & Cultural Rts., General Comment 3: The Nature of States Parties Obligations (Dec. 14, 1990), U.N. Doc. HRI/GEN/1/Rev.9 (Vol 1) 7, ¶14; Comm. on Econ., Soc. & Cultural Rts., General Comment 12: The Right to Adequate Food, U.N. doc. E/C.12/1999/5 (1999); Comm. on Econ., Soc. & Cultural Rts., General Comment 15: The Right to Water, U.N. doc E/C.12/2002/11 (2003).

^{67.} U.N. Off. of the High Comm'r, Declaration on the Right to Development: Adopted by General Assembly Resolution 41/128 (Dec. 4, 1986). https://www.ohchr.org/en/professionalinterest/pages/righttodevelopment.aspx.

 $^{68.\;}$ U.N. G.A. Res. 70/1, Transforming Our World: The 2030 Agenda for Sustainable Development (Oct. 21, 2015).

developed states in favour of developed states; that is that poverty might be 'done' by the rich to the poor. ⁶⁹ Philosopher Thomas Pogge has cogently argued that the long-term tolerance of an inequitable system, which has led to gross global inequality and mass poverty, is a failure in negative duties to respect rather than positive duties to fulfil. ⁷⁰ Arguments regarding an unfair global economic order, which has itself contributed to the present situation of vaccine inequity, are explored below in Part VI.

Aspects of extraterritorial duties remain debateable, particularly positive duties to protect (discussed below) and fulfil. The legal position is muddied because statements by treaty bodies like the CESCR Committee, and by Special Rapporteurs, are not binding at international law. Some relevant instruments such as the Declaration on the Right to Development are not treaties. Nevertheless, we contend that on balance, and in concordance with the CESCR Committee and the Maastricht Principles, that such duties exist, though we acknowledge the ongoing controversy again in Part VI.

The existence of negative extraterritorial duties is less controversial than the existence of positive extraterritorial duties. Yet the contrast between negative duties and positive duties is occasionally blurred. As noted several times below, and in the arguments of Pogge referenced above, it is sometimes possible to classify a state's action as a failure to take appropriate positive action to enhance human rights and, simultaneously, as an action which negatively interferes with another state's ability to fulfil its own human rights obligations.

Furthermore, the dichotomy between intra-territorial and extraterritorial obligations is not as stark as might be thought. As noted above, it is in the interests of a state's own population for the pandemic to be extinguished, both inside and outside territory. As the WHO has stated:

Infectious threats to health know no borders; as long as there is active SARS-CoV-2 transmission anywhere there will be a risk of transmission everywhere. Moreover, protecting the public health of one's residents is not the only national interest countries have in containing the pandemic globally. The recovery of national economies also depends on securing stable global supply chains and global markets and regularizing international travel, which will not be possible

 $^{69.\;}$ Susan Marks, $Human\ Rights\ and\ the\ Bottom\ Billion,\ 1\ Eur.\ Hum.\ Rts.\ L.\ Rev.\ 37,\ 48\ (2009).$

^{70.} Thomas Pogge, Severe Poverty as a Violation of Negative Duties, 19 Ethics and Int'l Affairs 55, 68 (2005).

until the pandemic is contained globally. Hence the equitable allocation of vaccines globally is in all countries' enlightened self-interest.⁷¹

Thus, there is a strong argument that a state has obligations to its own people to do what it can reasonably do to facilitate and provide for increased vaccinations all over the world, so as to help end the pandemic and all associated detrimental rights impacts.

C. Customary Extraterritorial Duties

While both Covenants have over 170 states parties, not all states are party to both of them. Notable absentees include the United States ('US') from the ICESCR and China from the ICCPR. The relevant rights in both Covenants are included in the Universal Declaration on Human Rights ('UDHR'). There are strong arguments that the UDHR, or at least some of its norms, have evolved into binding customary law.⁷² For example, states are required to report on their implementation of the UDHR as part of the Universal Periodic Review process before the UN Human Rights Council, which is arguably indicative of customary status.⁷³ The extraterritorial scope of customary duties with regard to the relevant rights is probably less extensive than the scope of extraterritorial duties under the respective Covenants.⁷⁴ However, as noted directly above, there are also relevant intra-territorial duties, which are more likely to be part of customary international law.

IV. HUMAN RIGHTS COMPATIBILITY OF VACCINE-RELATED STATE ACTIONS

Let us now turn to look at the human rights compatibility of specific actions with regard to COVID-19 vaccines.

^{71.} WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, supra note 45, at 7.

^{72.} See, e.g., Mary Ann Glendon, The Rule of Law in the Universal Declaration of Human Rights, 2 NW. J. OF INT'L HUM. RTS. 1 (2004) (noting that the UDHR is not binding of itself, but there are strong arguments that it represents custom binding on all States).

^{73.} Ionel Zamfir, The Universal Declaration of Human Rights and Its Relevance for the European Union, European Parliamentary Research Service (Nov. 2018), PE 628.295.

^{74.} MARKO MILANOVIC, EXTRATERRITORIAL APPLICATION OF HUMAN RIGHTS TREATIES: LAW, PRINCIPLES, AND POLICY 3 (2011).

A. Vaccine Nationalism

Developed states scooped up most available vaccines in 2021 pursuant to Advance Purchase Agreements with vaccine manufacturers. The procurement of vaccines for national use by states, which we will refer to as 'vaccine nationalism', interferes with vaccine access by the people of other countries while demand outstrips supply, so perhaps it could be viewed as a breach of the duty to respect human rights extraterritorially. The CESCR Committee thinks so, in a statement issued on April 23, 2021:

Given the global nature of the pandemic, States have the obligation to support, to the maximum of their available resources, efforts to make vaccines available globally. Vaccine nationalism breaches the extraterritorial obligations of States to avoid taking decisions that limit the ability of other States to make vaccines available to their populations and thus to implement their human rights obligations relating to the right to health, as it results in a shortage of vaccines for those who are most in need in the least developed countries.⁷⁶

However, while national procurement reduces the pool of available vaccines (while scarcity prevails), it also manifests a state's fulfilment of human rights obligations to its own people. There are as yet no coherent principles for how a state is meant to balance its internal and external human rights duties, when those duties conflict.⁷⁷

According to the CESCR Committee: "Prioritization in the global . . . distribution of vaccines should be based on medical needs and public health considerations." ⁷⁸

Thus, the CESCR Committee seems to believe that vaccine accessibility for vulnerable populations abroad must be prioritised over less vulnerable populations at home.⁷⁹ Given the mandated distribution strategy matches that of the COVAX facility, the

^{75.} Phelan et al., supra note 17.

^{76.} Comm. on Eco., Soc. & Cultural Rts., supra note 44 ¶ 4.

^{77.} See also Ralph Wilde, Dilemmas in Promoting Global Economic Justice through Human Rights Law, in The Frontiers of Human Rights 127, 162, 165–67 (Nehal Bhuta ed., 2016); Benoit Mayer, Climate Change Mitigation as an Obligation under Human Rights Treaties, 115 Am. J. Int'l L. 409, 428 (2021) (". . . states do not generally take the same measures to protect. . . the right to health beyond their territory as they do within it").

^{78.} Comm. on Eco., Soc. & Cultural Rts., supra note 44, ¶ 5.

^{79.} See also Ezekiel J. Emanuel et al., How Many Vaccine Doses Can Nations Ethically Hoard?: The Case for Sharing Supplies Prior to Reaching Herd Immunity, FOREIGN AFF'S (Mar. 9, 2021), https://protectau.mimecast.com/s/HovXCoVzpvfrxNWZ0H1DsK9?domain=foreignaffairs.com; Phelan et al., supra note 17.

CESCR Committee may be inferring that distribution should take place largely if not exclusively through that facility.⁸⁰

Such a strategy would have delayed vaccines for most young people until at least 2022. Yet while younger people are at lesser risk of severe outcomes from COVID-19 than older people, they can still die or suffer grave health issues such as "long COVID". They are also the main spreaders of COVID-19 due to their great mobility. Additionally, the terms of the COVAX facility do not ban separate bilateral deals with vaccine manufacturers: their existence is conceded by Gavi in its COVAX explainer. It is difficult to claim that COVAX must govern vaccine allocations to the exclusion of bilateral deals when that is not what was actually agreed.

The UN Special Rapporteurs, in their November 2020 statement, argue that vaccine nationalism prejudices the interests of a state's own people:

In addition, epidemiologists and others fear that, because of the limited capacity of production of the vaccine, countries that are striking deals to secure vaccines for their own population—instead of engaging in a coordinated global effort to share them across borders—will not achieve their intended purpose. The pandemic will continue and will come back to impact those countries sooner or later, including through further economic disruption. A message, often repeated in 2020, remains essential: No one is secure until all of us are secure.⁸³

This instrumentalist argument provides a human rights justification for states to prioritise the sharing of vaccines with other countries over vaccines for their own, less vulnerable, people. Such a trade-off would not breach a state's intra-territorial human rights duties to its own people. However, that does not translate into a duty for states to prioritise extraterritorial access over internal access to vaccines. At most it means that states have discretion as to which people to prioritise, which will normally mean that they prioritise the rights of their own populations.

Any duty to prioritise extraterritorial obligations regarding vaccine access over parallel internal obligations likely crystallises

^{80.} Comm. on Eco., Soc. & Cultural Rts., supra note 44 \P 6.

^{81.} William Wan & Moriah Balingit, WHO Warns Young People Are Emerging as Main Spreaders of Coronavirus, The WASHINGTON POST (Aug. 18, 2020), https://www.washingtonpost.com/health/who-warns-young-people-are-emerging-as-main-spreaders-of-the-coronavirus/2020/08/18/1822ee92-e18f-11ea-b69b-64f7b0477ed4_story.html.

^{82.} Seth Berkley, $COVAX\ Explained$, GAVI (Sept. 3, 2020), https://www.gavi.org/vaccineswork/covax-explained.

^{83.} Off. of the U.N. High Comm'r for Hum. Rts., supra note 47.

only after a significant part of a state's own population has been vaccinated. Despite the comments of the CESCR Committee in April 2021, current state practice indicates that that point does not arise until all adults within a state have been offered an opportunity to be vaccinated.

After that point, perhaps a relevant extraterritorial obligation arises. Dame Sarah Gilbert, one of the Oxford-based creators of the AstraZeneca vaccine, has suggested, in relation to the UK's vaccination strategy, that vaccination for vulnerable people in developing states be prioritised ahead of vaccines for children in the UK under 16, because children rarely suffer severe disease.⁸⁴ Nevertheless, it seems difficult to maintain that a state has a human rights duty to refrain, for quite some time, from taking measures to protect the health of its children.

It is probably more arguable that the administration of booster shots, prior to significant vaccination in many other states, breaches human rights obligations, except in the case of the very vulnerable such as immunocompromised people. In mid-2021, the Director General of the WHO, Dr. Tedros Adhanom Ghebreyesus, condemned proposals to administer boosters in high-income countries prior to the administration of first shots in many developing states. Yet by November 2021, more booster shots had been administered in high-income countries in three months than had been administered in developing countries all year. 86

However, any assessment of the human rights compatibility of boosters in the midst of global vaccine shortage was muddied by December with the emergence of the highly infectious Omicron variant: two doses seem to confer little protection against infection with Omicron, while third shots confer significant protection against infection as well as greater protection against severe disease.⁸⁷ By January 2022, the WHO itself was recommending boosters four to six months after primary vaccination shots.⁸⁸ In that

^{84.} Hugo Gye, Dame Sarah Gilbert: Jab Poorer Nations Before UK Children, Oxford Vaccine Creator Says, I News, (July 15, 2021, 6:08 PM), https://inews.co.uk/news/politics/oxford-jab-chief-sarah-gilbert-says-uk-should-not-vaccinate-children-while-poorer-countries-are-unprotected-1106354.

^{85.} WHO Says Vaccinated Countries Must Stop Ordering Booster Shots Until Others Are Fully Vaccinated, ABC NEWS (July 12, 2021, 1:58 PM), https://www.abc.net.au/news/2021-07-13/who-tedros-covid-19-boosters-vaccine-inequality/100287792.

^{86.} Donato Paolo Mancini & John Burn-Murdoch, Global COVID-19 Death Toll Tops 5m but Underestimates True Figure, Say Experts, FINANCIAL TIMES (Nov. 1 2021), https://www.ft.com/content/35a3d40a-f71f-4fca-893d-884fec5633d8.

^{87.} Nathan Bartlett, supra note 13.

^{88.} WHO Strategic Advisory Group of Experts on Immunization Updates Recommendations on Boosters, COVID-19 Vaccines for Children, PAN AMERICAN HEALTH ORGANIZATION (Jan. 21, 2022), https://www.paho.org/en/news/21-1-2022-who-strategic-advisory-group-experts-immunization-updates-recommendations-boosters.

light, it is difficult to condemn a booster programme as a breach of extraterritorial human rights obligations, even though boosters push people in other states further down the vaccine queue. Booster programs should, however, not be premature, and questions may remain over the prioritisation of boosters for those who are at low risk of severe disease in situations of global vaccine scarcity.

The hoarding or stockpiling of scarce vaccines after the vaccination of one's population would constitute a breach of a duty to respect the rights of people in other states to access a scarce resource that enhances their enjoyment of rights to health and life. Furthermore, the rights of a state's own people are also harmed if a state hoards vaccines, as such actions help to delay the end of the global pandemic while vaccine scarcity prevails. Thus, hoarding and stockpiling may breach a State's intra-territorial human rights duties too.⁸⁹

However, while the hoarding of, or, possibly, the premature mass delivery of booster shots, might be termed a breach of a state's human rights obligations at a general level, it is difficult to ascertain whose rights are being breached. The jurisdictional link between a state's "vaccine greed", and the lack of vaccines for a particular person or people, is more remote, for example, than that between Italy and the migrants who drowned in A.S. v Italy. After all, it cannot be known where vaccines will go if a particular state refrains from acquiring them: they could go to a high-income state that already has ample vaccines. Hence, while hoarding or stockpiling can be classified as human rights breaching activity, and could legitimately attract criticism from international human rights bodies, it is difficult to see how they could be the subject matter of a human rights claim by particular individuals or groups due to difficulties in establishing causation. We return to this point below in Part VI.

There have been instances of states blocking access to vaccines by other states. An export block on vaccines, directly interfering in a commercial arrangement between the exporter and the intended importing state, probably constitutes a prima facie breach of extraterritorial duties to respect human rights.⁹⁰ Furthermore, the causal link between the actions of the

^{89.} See also Aubrey Allegretti, UK to Set to 'Hoard' up to 210m Doses of Covid Vaccine, Research Suggests, The Guardian (Aug. 9, 2021, 1:00AM), https://www.theguardian.com/society/2021/aug/09/uk-set-to-hoard-up-to-210m-doses-of-covid-vaccine-research-suggests.

^{90.} See also Comm. on Econ., Soc. & Cultural Rts., General Comment No. 8: The Relationship Between Economic Sanctions and Respect for Economic, Social and Cultural Rights, $\P = 3-4$, U.N. Doc. E/C. 12/1997/8 (Dec. 12, 1997). See also Maastricht Principles, supra note 61 art. 22 (regarding the human rights non-compliance of embargoes affecting the right to health).

blocking state and the people of the thwarted importing state is clearer than in the above scenario of vaccine procurement.

In March 2021, Italy blocked a shipment of the AstraZeneca vaccine to Australia, entailing a direct interference in access by Australians to that vaccine. Italy's stated reason for blocking export to Australia was that AstraZeneca had failed to fulfil its contractual obligations to deliver vaccines to the EU, and that the bloc's need for the vaccines was plainly greater than that of Australia at the time. As another example, COVAX suffered a major blow in April 2021 when a large allocation of the AstraZeneca vaccine to it was delayed: the allocation was coming from the Serum Institute of India, which was forced to switch its focus to supply India in the midst of a devastating domestic COVID-19 wave. AstraZeneca vaccine to it was

Thus, Italy and India prioritised fulfilment of their national human rights obligations over any extraterritorial ones. However, it is difficult to label such actions as human rights abuses if there is a genuine need for vaccines inside the blocking state, especially if it is clearly greater than that of the intended recipient state, as was the case when Italy blocked a delivery to Australia in March 2021.

B. Vaccine Aid

Vaccine aid is a means by which to comply with the extraterritorial duty to fulfil ICESCR rights in its most onerous form: providing for rights. Vaccine aid is being delivered, including by funding commitments to COVAX and through bilateral arrangements. Of even more use than money are actual donations of vaccines. As stated by Dr Tedros: "if there are no vaccines to buy, money is irrelevant".⁹³ In June 2021, the US announced that it would donate 500 million Pfizer doses to COVAX.⁹⁴ The G7 pledged one billion doses in June 2021, some to be distributed directly and

^{91.} Italy, EU Refuse AstraZeneca Request to Ship 250,000 Doses of Vaccine to Australia, ABC News (Mar. 4, 2021,12:03 PM), https://www.abc.net.au/news/2021-03-05/italy-eu-block-250000-astrazeneca-doses-to-australia/13218348.

^{92.} Amy Kapczynski, *How to Vaccinate the World, Part 1*, LPE PROJECT BLOG (Apr. 30, 2021), https://lpeproject.org/blog/how-to-vaccinate-the-world-part-1/; Achal Prabhala & Leena Menghaney, *The World's Poorest Countries Are at India's Mercy for Vaccines. It's Unsustainable*, THE GUARDIAN (Apr. 2, 2021, 4:00 AM), https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable.

^{93.} WHO (@WHO), TWITTER (Feb. 23, 2021, 1:16 AM), https://twitter.com/WHO/status/1363870364657475586?s=20.

^{94.} Nancy Cordes, Alexander Tin & Kathryn Watson, *Biden Administration Buys 500 Million Pfizer COVID-19 Vaccine Doses for Global Use*, CBS NEWS, (June 10, 2021, 7:49 AM), https://www.cbsnews.com/news/covid-vaccine-pfizer-global-distribution-biden-administration/.

others through COVAX. These pledges are welcome but not enough, according to the WHO and the International Monetary Fund. 95

Vaccine aid is not mere beneficence on the part of donors, if one accepts (as we do) that extraterritorial duties to fulfil rights exist. A state that is in a position to donate vaccines or money towards vaccines is breaching such duties if it fails to do so. However, as with the duties discussed above with regard to vaccine nationalism, such violations are more readily identifiable as being at large, rather than violating the rights of particular people. It is difficult to draw a causal connection between a particular state's vaccine niggardliness and the absence of vaccines for particular people in another state. We return to this point in Part VI below.

V. INTELLECTUAL PROPERTY, COVID-19 VACCINES AND HUMAN RIGHTS

The biggest problem regarding vaccines in the world today is that there are not enough of them. Therefore, the most crucial aspect of any relevant human rights duties is for states to do what they can to increase the number of vaccines in the world so that supply can more swiftly match demand. Just as importantly, states must do what they reasonably can to remove barriers to such an increase. Finally, states must not themselves erect or keep barriers to such an increase in place. This issue is taken up in this Part.

A. Human Rights Duties of Pharmaceutical Companies, and Duties to Protect

We now turn our discussion from state obligations under international human rights law to those of the entities that own the vaccines and therefore must play a critical role in increasing their availability, that is pharmaceutical companies. The orthodox view is that non-state actors do not have direct obligations under international human rights law, except, perhaps, with regard to the most extreme abuses which constitute international crimes.⁹⁶

Concern over business-related human rights abuses, generated by the great power and multi-jurisdictional nature of multinational corporations, led in 2011 to the adoption by the UN of the UN

^{95.} Euronews & AP, $G7\ COVID-19\ Vaccine\ Pledge\ Ts\ Not\ Enough',\ Says\ WHO,\ IMF,$ EURONEWS, (June 13, 2021), https://www.euronews.com/2021/06/12/g7-covid-19-vaccine-pledge-is-not-enough-says-who-chief.

^{96.} See e.g., Joanna Kyriakakis, Corporations, Accountability and International Criminal Law: Industry and Atrocity (Edward Elgar Publ'g 2021), Chapter 6.

Guiding Principles on Business and Human Rights ('UNGPs'). ⁹⁷ One 'pillar' of these Principles is the enunciation of a corporate responsibility to respect human rights. This is not a legally binding duty but is instead sourced in societal expectations, which demand that businesses identify and address their adverse impacts on human rights. ⁹⁸ Many businesses have accepted the existence of this 'responsibility', at least rhetorically.

This responsibility has been highlighted with regard to COVID-19 vaccines. The UN Special Rapporteurs stated that pharmaceutical companies should:

Discharge their responsibilities, including by exercising human rights due diligence to identify and address adverse impacts on the rights to life and health as set out in the Guiding Principles on Business and Human Rights. In particular, they should refrain from causing or contributing to adverse impacts on the rights to life and health by invoking their intellectual property rights and prioritizing economic gains.⁹⁹

Some pharmaceutical companies have arguably abided by these responsibilities. AstraZeneca has said it will work to license the manufacture of its vaccine across the world at no profit. 100 Moderna has promised not to enforce its patent during the pandemic. 101

^{97.} John Ruggie, (Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises), *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework*, UN Doc A/HRC/17/31 (Mar. 21, 2011) https://www.ohchr.org/Documents/Issues/Business/A-HRC-17-31_AEV.pdf.

^{98.} John Ruggie, (Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises), *Protect, Respect and Remedy: A Framework for Business and Human Rights*, U.N. Doc. A/HRC/8/5, ¶ 54. (Apr. 7, 2008).

^{99.} Off. of the U.N. High Comm'r for Hum. Rts., *supra* note 47. See also Report, Paul Hunt (Special Rapporteur), The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. Doc. A/63/263, annex (Aug. 11, 2008). See also Michael Santoro & Robert Shanklin, *Human Rights Obligations of Drug Companies*, 19 J. OF HUM. RTS. 557 (2020).

^{100.} AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University's Potential COVID-19 Vaccine, ASTRAZENECA: MEDIA (June 4, 2020), https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html (note, however, that AstraZeneca reserved a right to declare an end to the pandemic, and thus charge higher costs, as early as July 2021).

^{101.} Moderna Will Not Enforce COVID-19 Vaccine Patents During Pandemic, REUTERS (Oct. 8, 2020, 9:46 PM), https://www.reuters.com/article/health-coronavirus-moderna-idUSL4N2GZ2D6 (however, one may note that Moderna's patent is enforceable, while its statement is not. Furthermore, there are multiple patents in that vaccine that are not owned by Moderna); Rebecca Robbins & Peter S. Goodman, Pfizer Reaps Hundreds of Millions in Profits from COVID Vaccine, THE NEW YORK TIMES (May 4, 2021), https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html).

Pfizer, on the other hand, seems to be taking full commercial advantage of its monopoly control of its vaccines. ¹⁰² An April 2021 deal with the European Union involved a 50% price rise from a previous deal, according to the Prime Minister of Bulgaria. ¹⁰³ Israel's early access to Pfizer was facilitated by its willingness to pay a high price, ¹⁰⁴ and to share the disaggregated anonymised data of its vaccinated people with the company. ¹⁰⁵ Pfizer has been criticised by Latin American countries for allegedly making unreasonable demands regarding collateral guarantees for any future legal cases, ¹⁰⁶ as well as extensive unusual indemnities. ¹⁰⁷

Despite international (and national) developments regarding business and human rights, the primary duty-bearers under international human rights law remain states. States are required to exercise due diligence to protect their people from rights abuses by third parties so that duty entails appropriate regulation of the private sector. Hence, states are required to exercise due diligence to protect people from rights abuses by pharmaceutical companies. 108

The existence of an extraterritorial duty to protect is contentious and indeed was denied in the commentary to the UNGPs. However, it has been repeatedly confirmed by the CESCR

^{102.} Robbins & Goodman, supra note 101.

^{103.} Bulgarian PM Reveals Price for EU's New Vaccine Contract with Pfizer, REUTERS (Apr. 12, 2021, 11:10 PM), https://www.reuters.com/world/europe/bulgarian-pm-reveals-price-eus-new-vaccine-contract-with-pfizer-2021-04-12/.

^{104.} Ari Rabinovitch et al., *Pizza-Sized Boxes and Paying a Premium: Israel's COVID-19 Vaccine Rollout*, REUTERS (Jan. 6, 2021, 4:08 PM), https://www.reuters.com/article/us-health-coronavirus-israel-vaccination-idUKKBN29B0KJ.

^{105.} Aditya Goenka, Israel's Vaccine Rollout has been Fast So Why Is It Controversial and What Can Other Countries Learn?, The Conversation (Jan. 28, 2021, 1:40 AM), https://theconversation.com/israels-vaccine-rollout-has-been-fast-so-why-is-it-controversial-and-what-can-other-countries-learn-153687.

^{106.} Madlen Davies et al., 'Held to Ransom': Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal, The Bureau of Investigative Journalism (Feb. 23, 2021), https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal.

^{107.} See Madlen Davies & Rosa Furneaux, Vaccine Contract Forces Government to Pay if Pfizer Makes Mistakes, The Bureau of Investigative Journalism (Mar. 10, 2021), https://www.thebureauinvestigates.com/stories/2021-03-10/vaccine-contract-forces-dominican-republic-government-to-pay-if-pfizer-makes-mistakes (similar demands were apparently also made of South Africa before Pfizer "backed down": Madlen Davies & Rosa Furneaux, Pfizer Backs Down Over 'Unreasonable' Terms in South Africa Vaccine Deal, The Bureau of Investigative Journalism (Apr. 19, 2021), https://www.thebureauinvestigates.com/stories/2021-04-19/pfizer-backs-down-over-asset-seizing-clause-in-south-africa-vaccine-deal).

^{108.} Ruggie, *supra* note 97, Pillar One.

^{109.} Id. (see Commentary to Principle 2).

Committee ¹¹⁰ and the Maastricht Principles. The Human Rights Committee has also recently stated that "there are situations where a State party has an obligation to ensure that rights under the Covenant are not impaired by extraterritorial activities conducted by enterprises under its jurisdiction," ¹¹¹ indicating that such duties are emerging under the ICCPR.

The main way that a state could 'protect' people from pharmaceutical companies with regard to vaccine access, both inside and outside territory, is by removing any barriers that the companies have created in relation to access. That duty can be conceptualised as part of the contentious extraterritorial duty to protect, but it might also be conceptualised as a duty to protect people inside a state's territory, a duty that definitely exists under international human rights law.

At the international level, one apparent blockage to greater access has attracted particular attention: the intellectual property (IP) rights afforded to pharmaceutical companies by the Agreement on Trade Related Aspects of Intellectual Property ('TRIPS') under the auspices of the World Trade Organisation ('WTO'). It is to that issue which we now turn.

B. TRIPS and the Proposed Waiver

Under the Agreement on Trade Related Aspects of Intellectual Property ('TRIPS'), WTO Members are required to protect IP rights, such as copyright, patents and trademarks. Of most relevance here is Article 33, which demands patent protection of twenty years. ¹¹² The rationale for IP rights, as discussed below, is that they provide appropriate rewards to innovators and thus encourage and foster research and development.

Compulsory patent protection for pharmaceutical products provides monopoly rights to patent-holders, which can restrict access thereto. In this way, TRIPS and IP rights may prejudice

^{110.} See Comm. on Econ., Soc. & Cultural Rts., General Comment No. 24 on State Obligations Under the International Covenant on Civil and Political Rights in the Context of Business Activities, U.N. Doc. E/C. 12/GC/24, ¶ 20–35 (Aug. 10, 2017); Comm. on Econ., Soc. & Cultural Rts., General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights, U.N. Doc. E/C. 12/GC/25, ¶ 83–84 (Apr. 30, 2020); Comm. on Econ., Soc. & Cultural Rts., General Comment No. 23 (2016) on the Right to Just and Favourable Conditions of Work, U.N. Doc. E/C. 12/GC/23, ¶ 69–70 (Apr. 27, 2016); Comm. on Econ., Soc. & Cultural Rts.

^{111.} Basem Ahmed Issa Yassin et al. v. Canada, U.N. Hum. Rts. Comm., U.N. doc. CCPR/C/120/D/2285/2013 ¶6.5. (Dec. 7, 2017).

^{112.} The Least Developed Countries do not have to fully comply with TRIPS until July $1,\,2034.$

rights in Articles 12 and 15(1)(b) of the ICESCR. As stated by the CESCR Committee in General Comment 25 on Article 15:

Patents give patent holders a temporary exclusive right to exploit the product or service they have invented. Thus, they can determine a price for these products and services. If prices are set very high, access to these products and services becomes impossible for low-income persons or developing countries as has happened with new medicines that are essential for the health and life of persons with certain diseases. 113

Hence, the patent protection mandated by TRIPS might pose a barrier to access to medicines, including COVID-19 vaccines. In this regard, the Office of the UN High Commissioner for Human Rights ('OHCHR') stated in a guidance note on "Human Rights and COVID-19 Vaccines":

Intellectual property rights should not be applied in a manner which undermines the rights to health, food, science and other human rights. Obligations under [TRIPS], for example, should be interpreted consistently with the protection of public health ¹¹⁴

TRIPS is binding on the 164 members of the WTO. Relevantly, the Maastricht Principles states at Principle 15:

As a member of an international organisation, the State remains responsible for its own conduct in relation to its human rights obligations within its territory and extraterritorially. A State that transfers competences to, or participates in, an international organisation must take all reasonable steps to ensure that the relevant organisation acts consistently with the international human rights obligations of that State.

Similar sentiments are expressed by the CESCR Committee in General Comments 14 (on Article 12)¹¹⁵ and 25 (on Article 15).¹¹⁶ Duties regarding a state's own behaviour within an international organisation may be classified as duties to fulfil extraterritorial

^{113.} Comm. on Econ., Soc. & Cultural Rts. Gen. Cmt. No. 25 on science and economic, social and cultural rights, articles 15(1)(b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights, U.N. Doc. E/C. 12/GC/25, ¶ 61 (2020).

^{114.} Human Rights and Access to COVID-19 Vaccines, U.N. Hum. RTS., OFF. OF THE HIGH COMM'R (Dec. 17, 2020), https://www.ohchr.org/Documents/Events/COVID-19_AccessVaccines_Guidance.pdf.

^{115.} Comm. on Econ., Soc. & Cultural Rts., Gen. Comt. No. 14: the right to the highest attainable standard of health (Art. 12), U.N. Doc. E/C. 12/2000/4, ¶ 39 (Aug. 11, 2000).

^{116.} Comm. on Econ., Soc. & Cultural Rts., General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights, U.N. Doc. E/C. 12/GC/25, ¶ 83 (Apr. 30, 2020).

rights by facilitating appropriate actions by that international organisation. However, they might also on occasion entail duties to respect if a state's behaviour within an international organisation impairs, or contributes to the impairment of, the ability of another state to comply with its human rights obligations.

On October 2, 2020, South Africa and India sent a communication to the TRIPS Council of the WTO arguing for a waiver of certain parts of the TRIPS agreement with regard to COVID-19 vaccines, "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity." That initiative has been supported by most developing states but was initially resisted by developed states in the WTO.

On May 5, 2021, the Biden administration in the US announced that it would support a waiver of IP protections for COVID-19 vaccines, in light of the 'extraordinary' COVID-19 pandemic. There may be devil yet in the detail, with the US Trade Representative stating that: "We will actively participate in text-based negotiations at the [WTO] needed to make [the waiver] happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved." ¹¹⁸

Indeed, negotiations have taken time, despite the need for speed in manufacturing and distributing COVID-19 vaccines. WTO decisions are normally made by consensus, though a waiver may be approved by 75% of the membership. 119 Other states, particularly from the EU, may continue to block waiver negotiations, 120 which remain unresolved as of February 2022. Finally, the announcement indicates that the US supports a waiver, but not necessarily the waiver as outlined in the South Africa/India proposal. For example, it is limited only to vaccines, rather than broader medical developments such as therapeutics to combat COVID-19.

^{117.} Council for Trade-Related Aspects of Intellectual Property Rights, Communication from India and South Africa: Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669 (Oct. 2, 2020). A slightly revised text was submitted to the TRIPS on May 25, 2021: WTO Doc. IP/C/W/669/Rev. 1 (May 25, 2021).

^{118.} Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver, OFF. OF THE U.S. TRADE REP. (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

^{119.} Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

 $^{120.\} Communication\ from\ the\ European\ Union\ to\ the\ Council\ for\ TRIPS,\ Urgent\ Trade\ Policy\ Responses\ to\ the\ COVID-19\ Crisis:\ Intellectual\ Property,\ (June\ 4,\ 2021),\ https://trade.ec.europa.eu/doclib/docs/2021/june/tradoc_159606.pdf.$

The waiver is strongly supported by the CESCR Committee¹²¹ and the UN Special Rapporteurs.¹²² Does blockage of the waiver constitute the maintenance of a barrier to faster and greater vaccine distribution? If so, that would indicate that blockage or delaying tactics breach extraterritorial human rights obligations to respect rights.

In this respect, four issues are investigated below. First, might a waiver of IP be a breach of the legitimate rights of pharmaceutical companies which have, quite magnificently, created safe and effective vaccines in record time? Second, might a waiver discourage pharmaceutical companies from developing new vaccines in a future pandemic? Third, do existing TRIPS flexibilities with regard to patent rights render a waiver unnecessary? Fourth, would a waiver of IP rights actually assist in the desired goal, the swifter manufacture of more vaccines?

1. Intellectual Property as a Human Right

Article 15(1)(c) of the ICESCR recognises 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 is the author". Would a TRIPS waiver breach the rights of the pharmaceutical companies that own the relevant patents?

In General Comment 17, the CESCR Committee distinguished Article 15(1)(c) rights from IP rights. Article 15(1)(c) protects "the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their material interests which are necessary to enable authors to enjoy an adequate standard of living." In contrast, IP rights are temporary and transferrable, and "primarily protect business and corporate interests and investments." ¹²³ In that respect, the CESCR Committee underlined that Article 15(1)(c) rights vest only in human beings rather than corporations. ¹²⁴ The CESCR Committee also anticipated that a variety of regimes, including but not limited to IP-like regimes, could satisfy Article 15(1)(c). ¹²⁵

^{121.} Comm. on Eco., Soc. & Cultural Rts., supra note 44, ¶ 12–13.

^{122.} Off. of the U.N. High Comm'r for Hum. Rts., supra note 47.

^{123.} Comm. on Econ., Soc. & Cultural Rights. Gen. Comt. No. 17 on 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 (art. 15, \P 1(c) of the Covenant), U.N. Doc. E/C.12/GC/17 \P 2 (Jan. 12, 2006).

^{124.} Id. at ¶ 7.

^{125.} Id. at ¶¶ 16, 47.

Regarding COVID-19 and IP, the UN Special Rapporteurs said: "Industry and private benefit cannot be prioritized over the rights to life and health of billions with so far-reaching consequences." ¹²⁶

Given the grave impact of COVID-19 on lives, health, livelihoods, and national and global economies, it seems clear that the rights to health and life must override any claim that pharmaceutical companies would have to countervailing 'human rights' in the form of IP rights.

2. IP as a Facilitator of Pharmaceutical Research and Development

IP rights are justified by the rewards and consequent incentives they deliver to creators, innovators, inventors and authors. IP protection of life-saving drugs is said to be needed in order to incentivise the research and development ('R&D') which leads to the creation of those drugs. Hence, perhaps one can argue that the rights to health and life are ultimately prejudiced by a waiver of IP rights. While a waiver might help in the short term, it might disincentivise the creation of new vaccines, which will probably be needed on an ongoing basis to address variants, as well as medicines needed for the next pandemic.¹²⁷

In response, one may note that it is the developing world that is most desirous of the waiver. A waiver would not prevent any state, most obviously high-income states, from applying national patent protections to COVID-19 vaccines. In 2013, the UN Special Rapporteur on the Right to Health reported that 95% of the sales of new medicines launched from 2004-2008 took place in North America, Europe and Japan, while Africa and the rest of Asia accounted for only 5% of sales. While that percentage has likely grown, the developing world component of the patented pharmaceutical market remains small, so it makes little difference to the resources available for pharmaceutical R&D. 129

^{126.} Off. of the U.N. High Comm'r for Hum. Rts., supra note 47.

^{127.} See Reto M. Hilty et al., COVID-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021, MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION (May 25, 2021), https://www.ip.mpg.de/en/research/research-news/covid-19-and-the-role-of-intellectual-property-list-of-supporters.html; see also Sarah Joseph, Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny, 25 Hum. Rts. Q. 425, 431–32 (2003).

^{128.} Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health), *The Right to Health*, ¶ 13, U.N. Doc. A/63/263 (Aug. 11, 2008).

^{129.} Amy Kapczynski & Jishian Ravinthiran, *How to Vaccinate the World: Part 2*, LAW AND POL. ECON. PROJECT BLOG, https://lpeproject.org/blog/how-to-vaccinate-the-world-part-2.

In any case, much of the R&D into the creation of new drugs is undertaken at public expense in government and university laboratories. The prevalence of public R&D funding for pharmaceutical products again indicates that R&D budgets could remain robust if patent rights were decreased.

The development of COVID-19 vaccines was facilitated by massive investments from governments and philanthropic organisations. The AstraZeneca vaccine was developed by Oxford University and was reportedly 97% publicly funded. The Moderna vaccine was funded by US government money, while Pfizer benefited from financial assistance from Germany as well as guaranteed pre-purchase contracts. The Pfizer and Moderna mRNA vaccines benefit from licensing agreements with the US's public National Institute of Health, which owns patented technology that makes mRNA vaccines possible. Even COVAX invested in manufacturing capacities prior to the end of vaccine clinical trials. As noted by Eccleston-Turner and Upton, such arrangements privatised the profits but socialised the risks in vaccine development.

Serious questions may be raised, generally, regarding the actual pharmaceutical innovations incentivised by IP rights. As stated by the CESCR Committee in General Comment 25:

[I]ntellectual property can sometimes create distortions in the funding of scientific research as private financial support might go only to research projects that are profitable, while funding to address issues that are crucial for economic, social and cultural rights might not be adequate, as these issues do not seem financially attractive for business. This has been the case with the so-called neglected diseases. ¹³⁶

IP incentivises R&D into drugs which treat chronic, ongoing conditions, like heart disease or high cholesterol, as opposed to cures

^{130.} Hunt, supra note 128, at ¶ 13.

^{131.} Siva Thambisetty et al., The TRIPS Intellectual Property Waiver Protocol: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic (May 24, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737, (citing the figure of €85.6 billion into the development of vaccines).

^{132.} Michael Safi, Oxford/AstraZeneca COVID Vaccine Research 'Was 97% Publicly Funded', The Guardian (Apr. 15, 2021, 2:00 PM), https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded.

^{133.} Kapczynski, supra note 92.

^{134.} Rebecca Robbins & Peter S. Goodman, Pfizer Reaps Hundreds of Millions in Profits from COVID Vaccine, The New York Times (May 4, 2021), https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html.

^{135.} Eccleston-Turner & Upton, supra note 17.

^{136.} Comm. on Econ., Soc. & Cultural Rts., General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights, U.N. Doc. E/C. 12/GC/25, ¶ 61 (Apr. 30, 2020).

and, ironically, vaccines, which rarely have the same ongoing market potential.¹³⁷ Only four companies were reportedly making vaccines for the US at the beginning of 2020, compared to over twenty in the 1970s.¹³⁸ Dr. Paul Stoffels, chief scientific officer at Johnson & Johnson, admitted in June 2020 that: "there is no real incentive to [make vaccines], no financial incentive," reflecting on the failure of the industry to create vaccines for previous novel coronaviruses such as SARS and MERS.¹³⁹ Furthermore, IP rights may now be incentivising the marketing of boosters for rich countries instead of first doses for poorer countries.¹⁴⁰

IP protection also restricts R&D by preventing non-IP holders from building on patented R&D. Patentees may for example refuse to license competitors so as to diminish the chances of an R&D breakthrough by a rival. Useful knowledge, which might likely lead to more useful knowledge, is 'locked up.' 142

Regardless of the rationale for IP, IP law has facilitated major market failure in the current COVID-19 crisis. As explained by Thambisetty et al.:

[P]atent law is fundamental to the way the pharmaceutical market is constructed; and as such patent law must be considered a key factor when the market produces dysfunctional and inequitable results, as it is doing now during the COVID-19 crisis.¹⁴³

Overall, we conclude that the human rights arguments in favour of patent protection are outweighed by the arguments in favour of relaxation of patents to facilitate access to life-saving vaccines in a global pandemic.

^{137.} Anna-Marie Tabor, Recent Developments: AIDS Crisis, 38 HARV. J. ON LEGIS. 514, 524 (2001); Thambisetty et al. supra note 131, at 41–42.

^{138.} Jay Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, Then Sold Them to Pharma*, KAISER HEALTH NEWS (Aug. 25, 2020), https://khn.org/news/rather-thangive-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/.

^{139.} Knvul Sheikh & Katie Thomas, Researchers Are Racing to Make a Coronavirus Vaccine. Will It Help?, The New York Times (Jan. 28, 2020), https://www.nytimes.com/2020/01/28/health/coronavirus-vaccine.html.

^{140.} See also Thambisetty et al., supra note 131, at 13.

^{141.} Mark Eccleston-Turner, Beyond Patents: Scientific Knowledge, and Access to Vaccine, 3 Ethics, Medicine and Public Health 64, 69 (2017).

^{142.} Thambisetty et al., *supra* note 131, 38–40; *see also* Peter Drahos & John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy?, 3 (2002) (on Myriad's IP rights over BRCA1 and BRCA2 genes which may deter further research into the genes' connection to breast and ovarian cancer).

^{143.} Thambisetty et al., supra note 131, at 12.

3. TRIPS Flexibilities

Does a waiver-less TRIPS treaty mandate breaches of human rights?¹⁴⁴ The CESCR Committee stated in its General Comment 25: "A balance must be reached between intellectual property and the open access and sharing of scientific knowledge and its applications, especially those linked to the realization of other economic, social and cultural rights, such as the rights to health, education and food."¹⁴⁵

TRIPS allows for exceptions which support countervailing public health rights, and may perhaps achieve the 'balance' sought by the CESCR Committee. ¹⁴⁶ In particular, Article 31 permits states to issue compulsory licences for the generic manufacture of patented goods without the consent of the patent holder. Under Article 31(b), the license may be issued without preceding negotiations with the patent-holder in times of "national emergency or other circumstances of extreme urgency." ¹⁴⁷

The Declaration on the TRIPS Agreement and Public Health in December 2001 ("the Doha Declaration")¹⁴⁸ clarified that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to public health and, in particular, promote access to medicines for all." Furthermore, "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics" were recognised as national emergencies for the purposes of issuing a TRIPS-compliant compulsory licence. ¹⁴⁹ COVID-19 constitutes a comparable or even larger public health emergency.

Compulsory licensing could be of some use in addressing COVID-19 vaccine shortages. In early May 2021, Bolivia announced that it would be seeking a supply of generic versions of Johnson & Johnson's COVID-19 vaccines from a Canadian company, Biolyse,

^{144.} See JOSEPH, *supra* note 39, Chapter 2.B (2011) for further discussion on this issue, but note that the question of the resolution of any such normative conflict is beyond the scope of this article.

^{145.} Comm. on Econ., Soc. & Cultural Rts., General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights, U.N. Doc. E/C. 12/GC/25, ¶ 62 (Apr. 30, 2020).

^{146.} See also Human Rights Council, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover', UN doc. A/HRC/11/12 (March 31, 2009), ¶ 94.

^{147.} Agreement on Trade-Related Aspects of Intellectual Property Rights as Amended by the 2005 Protocol Amending the TRIPS Agreement, art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299 (amended Dec. 5, 2005, entered into force Jan. 23, 2017). The patent-holder must be notified as soon as possible in such circumstances.

^{148.} Ministerial Declaration of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 ILM 755 (2002).

under Article 31bis, a TRIPS amendment which facilitates the export of compulsorily licensed medicines to countries that lack appropriate manufacturing capacity.¹⁵⁰ At the time of writing, Canada had not granted a compulsory license to the company.

However, compulsory licensing seems unlikely to be of great use in boosting COVID-19 vaccine production. Generic production often relies on reverse engineering of patented chemical compounds. It is very difficult to reverse engineer biologic products, and to prove bioequivalence between a generic and a patented vaccine, due to their "complex structure and manufacturing processes." ¹⁵¹ Consequently, generic products cannot simply rely on the clinical trial data of the patented vaccines; further procedures to prove safety and efficacy will likely be necessary, which is costly and time-consuming. ¹⁵²

Moreover, the complexity of vaccines means that they are often the subject of multiple overlapping patents registered by different entities. These "patent thickets" tall compulsory licensing initiatives significantly, as a license is needed for each patent. Yet speed is essential to vaccinate the world against COVID-19.

It is submitted that TRIPS flexibilities are less likely than a waiver to facilitate the swifter production of more vaccines.

4. Would a TRIPS Waiver Help?

The strongest argument against a TRIPS waiver regarding COVID-19 vaccines is that it would not achieve its goal of increasing vaccine manufacture and access across the world. In an open letter to US President Biden on 5 March 2021, which urged the US

^{150.} Biolyse Pharma, *Bolivia and Biolyse Sign Landmark Agreement for Export of COVID-19 Vaccines*, CISION (May 12, 2021, 6:32 PM), https://www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmark-agreement-for-export-of-covid-19-vaccines-832670191.html; Thambisetty et al., *supra* note 131, at 28.

^{151.} Eccleston-Turner, supra note 141, 67 (2017). See also Nicholas G. Vincent, Trip-ing Up: The Failure of TRIPS Article 31bis, 24 GONZAGA J. OF INT'L L. 1, 24–27 (2020). However, see infra, notes 161 to 163, regarding attempts to reverse engineer the Moderna vaccine in Africa.

^{152.} Eccleston-Turner, supra note 141, at 67.

^{153.} Jocelyn Bosse et al., TRIPS Waiver: There's More to the Story than Vaccine Patents, THE CONVERSATION (May 8, 2021, 12:37 PM), https://theconversation.com/trips-waiver-theres-more-to-the-story-than-vaccine-patents-160502. See also Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths, Public Citizen (Mar. 29, 2021), https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/(talking of the dozens of patents applicable to mRNA vaccines).

^{154.} Eccleston-Turner, supra note 141, at 69-70 (2017).

^{155.} See Hilty et al., supra note 127.

government to resist the waiver, ¹⁵⁶ a group of pharmaceutical companies claimed: "COVID-19 vaccines are complex biologic products. The manufacturing requires specialized experience, expertise and equipment. For example, only a few facilities in the world perform some of the critical steps needed to manufacture mRNA vaccines."

As suggested above, compulsory licensing may be ineffective as a remedy for the scarcity of COVID-19 vaccines. Is the same true of a TRIPS waiver, generally?

As an initial argument in favour of a waiver, one might wonder why pharmaceutical companies are lobbying so vehemently against it if it would make no difference. At present, pharmaceutical companies control access to the vaccine, as well as licenses for manufacturing the vaccine. Monopoly rights are a filter which must logically be limiting supply. Furthermore, history demonstrates that we must be wary of arguments which might underestimate global pharmaceutical manufacturing capacities, including the ability to learn and retool, especially in the Global South. Such arguments were wrong and self-serving twenty years ago in regard to anti-retroviral HIV drugs;¹⁵⁷ they could be wrong now and deserve no benefit of the doubt.¹⁵⁸

States must make a comprehensive effort to identify underutilised manufacturing capacity, ¹⁵⁹ and bring it online as soon as possible. In their open letter to President Biden, pharmaceutical companies claimed that global manufacturing capacity for mRNA vaccines was exhausted. ¹⁶⁰ However, mRNA manufacturing capacity will not remain static. ¹⁶¹ Indeed, the WHO has launched an initiative in South Africa to try to reverse engineer and manufacture the Moderna vaccine, to "lay the foundation for more globally

 $^{156.\} Letter\ to\ President\ Biden\ from\ 31\ PhRMA\ Board\ Members,\ PhRMA\ (Mar.\ 5,\ 2021), https://phrma.org/Public-Communication/Letter-to-President-Biden-from-31-PhRMA-Board-Members.$

^{157.} Kapczynski, *supra* note 92; *see also* Nathan Ford et al., *The First Decade of Antiretroviral Therapy in Africa*, 7 GLOBALIZATION & HEALTH 1, 1 (2011), https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-7-33.

^{158.} See also Thambisetty et al., supra note 131, at 38-39.

^{159. &}quot;Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, Human Rights Watch (Oct. 29, 2020). https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency. See also The Independent Panel, COVID-19: Make IT the Last Pandemic 42 (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

^{160.} Derek Rowe, *Myths of Vaccine Manufacturing*, SCIENCE (Feb. 2, 2021), https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing.

^{161.} Matthew M. Kavanagh et al., To Democratize Vaccine Access, Democratize Production, FOREIGN POLICY (Mar. 1, 2021), https://foreignpolicy.com/2021/03/01/to-democratize-vaccine-access-democratize-production/.

distributed mRNA-vaccine industry." 162 A waiver would derail any attempt by Moderna to enforce a patent in South Africa to disrupt this initiative. 163

In any case, arguments regarding mRNA manufacturing capacity do not apply to non-mRNA vaccines. Significant pharmaceutical manufacturing capacities exist in India, South Africa, Senegal, Egypt, ¹⁶⁴ Bangladesh, Mexico, ¹⁶⁵ Brazil, Argentina, China, South Korea, and Singapore. ¹⁶⁶ Companies in Canada, India, Israel, Denmark and Bangladesh have all claimed that they have offered to produce COVID-19 vaccines but have been unable thus far to obtain a license. ¹⁶⁷ A TRIPS waiver could help to maximise these factories' capacities for vaccine production.

A waiver has an advantage over compulsory licensing in that it would enable a state to slice through the patent thickets described above, ¹⁶⁸ and to avoid onerous procedural requirements regarding the manufacture and export of compulsorily licensed vaccines. ¹⁶⁹

The TRIPS waiver would also represent an important normative rebuff of the standard market approach to product distribution. It would reduce the spectre of political retaliation for states that depart from IP orthodoxy in the context of COVID-19 vaccines.¹⁷⁰

Finally, a waiver would help to rebalance power between pharmaceutical companies and governments.¹⁷¹ For example, in

^{162.} Amy Maxmen, South African Scientists Copy Moderna's COVID Vaccine, NATURE (Feb. 3, 2022), https://www.nature.com/articles/d41586-022-00293-2?utm_medium=Social&utm_campaign=nature&utm_source=Twitter#Echobox=1644234128.

^{163.} Moderna has filed patents in regard to its vaccine in South Africa. It has pledged not to enforce its patent until the pandemic is over, but no law prevents it from changing its mind, nor is it clear how Moderna will determine when the pandemic is in fact over: *Moderna's African Patents Pledge to be Tested by Interpretation of 'During Pandemic'*, THEPHARMALETTER (Feb. 14, 2022), https://www.thepharmaletter.com/article/moderna-safrican-patents-pledge-to-be-tested-by-interpretation-of-during-pandemic.

^{164.} Kavanagh, supra note 161.

^{165.} Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths, supra note 153.

^{166.} Sharon Lerner & Lee Fang, Factory Owners Around the World Stand Ready to Manufacture COVID-19 Vaccines, The Intercept (Apr. 29, 2021, 7:00 AM), https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/; "Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, supra note 159.

^{167.} Ashleigh Furlong, *Big Vaccine Makers Reject Offers to Help Produce More Jabs*, POLITICO (May 14, 2021), https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/; Thambisetty et al., *supra* note 131, at 38.

^{168.} Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths, supra note 153. See also Thambisetty et al., supra note 131, at 35–36.

^{169.} Kapczynski & Ravinthiran, supra note 129.

^{170.} *Id.* at 3; see also Joseph, *supra* note 127, 442–45, on historical examples of pressure being placed on states to attempt to dissuade them from utilising legitimate TRIPS flexibilities.

^{171.} See also Thambisetty et al., supra note 131, at 5–7.

commercial vaccine negotiations, there is great information asymmetry between governments, which represent millions of people at risk of COVID-19, and pharmaceutical companies representing their shareholders. Pricing and other conditions should be transparent, and differences justified, given the high stakes. Confidentiality means that the companies cannot be held accountable for behaviour which unreasonably blocks manufacturing and further supply, 174 or which gouges profits. Even COVAX negotiations are secret, so it is uncertain whether the facility is prioritising vaccine affordability, which would maximise the amount of vaccines it can disperse. 175

In light of the above, we submit that a waiver would help to speed up the swifter vaccination of the world. Alternatively, the threat of the TRIPS waiver might prompt pharmaceutical companies to offer concessions to increase vaccine accessibility, including voluntary technology transfer, to which we now turn. ¹⁷⁶

A TRIPS waiver alone would not be a silver bullet that creates more vaccines quickly. In their October communique, India and South Africa state at paragraph 11: "Internationally, there is an urgent call for global solidarity, and the unhindered global sharing of technology and know-how in order that rapid responses for the handling of COVID-19 can be put in place on a real time basis."

As noted above regarding compulsory licensing, it is difficult to reverse engineer a vaccine. It is much easier and immensely faster if manufacturers have access to the technological know-how, including manufacturing processes, of the original manufacturer.¹⁷⁷

The need for technological transfer was foreseen in May 2020, when Costa Rica headed a WHO initiative to create the COVID-19 Technological Access Pool ('C-TAP'), a depository to share innovations and expertise regarding the medicines needed to combat COVID-19 including vaccines. Yet the initiative has been

^{172.} Oliver Pieper, *Coronavirus Vaccine: Did Pfizer Put Profit First?*, DW (Feb. 21, 2021), https://www.dw.com/en/coronavirus-vaccine-did-pfizer-put-profit-first/a-56622056 (see the statements of a former Peruvian Health Minister).

^{173.} U.N. Secretary-General, Rep. of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Annex, U.N. Doc. A/63/26 (Aug. 11, 2008); "Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, supra note 159.

^{174. &}quot;Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, supra note 159.

^{175.} *Id.*; see also Phelan et al., supra note 17, at 801; Eccleston-Turner & Upton, supra note 17, at 433–34.

^{176.} Thambisetty et al., supra note 131, at 25–26.

^{177.} Eccleston-Turner & Upton, supra note 17, at 434.

^{178. &}quot;Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, supra note 159.

ignored by pharmaceutical companies and developed states.¹⁷⁹ Instead, states should be using their considerable clout to encourage and enable technology transfer and data sharing amongst companies.¹⁸⁰

It is arguably a failure in extraterritorial human rights obligations to protect for states to have failed to attach technological transfer conditions to their extensive vaccine funding. 181 As noted above, the existence of such an extraterritorial duty is contentious. However, an attenuated extraterritorial duty to protect will crystallise, according to the Maastricht Principles, "where there is a reasonable link between the [s]tate concerned and the conduct it seeks to regulate." 182 There is a 'reasonable link' between certain governments and the vaccines that they have largely funded. While that investment must be applauded, sponsoring states can be criticised for their failure to prevent monopoly control over vaccine outcomes. This failure might also be characterised as a failure in a state's intra-territorial duties to its own people, whose rights are enhanced by an earlier cessation of the global pandemic.

States have extraterritorial obligations, encompassed within duties to respect, protect and fulfil, to do what they reasonably can do to increase the number of COVID-19 vaccines in the world as quickly as possible. Parallel obligations are owed to their own people too. In that regard, the TRIPS waiver should be negotiated quickly and in good faith to remove or at least ameliorate IP obstacles to global vaccine equity, and/or prompt important concessions from the pharmaceutical companies that own the vaccines. States must also pull domestic and international policy levers to facilitate the technological transfer of vaccine recipes, and to utilise and scale up manufacturing capacity for vaccines.

VI. INADEQUACY OF INTERNATIONAL REGIMES

Article 28 of the Universal Declaration on Human Rights ('UDHR') states: "Everyone is entitled to a social and international

^{179.} Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths, supra note 153; Emily Baumgaertner, Vaccine Companies and the U.S. Snubbed WHO Initiative to Scale Up Global Manufacturing, Los Angeles Times (Apr. 30, 2021), https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing; Thambisetty et al., supra note 131, at 13

^{180. &}quot;Whoever Finds the Vaccine Must Share It": Strengthening Human Rights and Transparency Around COVID-19 Vaccines, supra note 159.

^{181.} *Id.*; see also The Independent Panel (WHO), COVID-19: Make it the Last Pandemic 55 (2021), https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf; Hilty et. al., supra note 127.

^{182.} Maastricht Principles, supra note 161, at ¶¶ 24 and 25(d).

order in which the rights and freedoms set forth in this Declaration can be fully realized."

As noted above, the UDHR has arguably crystallised into customary international law. In this section, we discuss some problematic aspects of the prevailing international order in relation to vaccine inequity.

A. Failures in International Human Rights

There are relevant extraterritorial and intra-territorial obligations for states, both negative and positive, with regard to vaccine inequity. However, international human rights law provides for an incomplete patchwork quilt of limited assistance to those who currently lack vaccine access.

First, the outer perimeters of this patchwork quilt are frayed: the scope of the relevant obligations is unclear. This indeterminacy is fuelled by controversy over the existence of positive extraterritorial duties to protect and fulfil, and the lack of balancing mechanisms for extraterritorial and intra-territorial obligations. The scope of relevant customary international law, which is very relevant to the two most powerful states, the US and China, is extremely uncertain.

Second, as noted above, it will be difficult on most occasions to identify human victims of a state's iniquitous vaccine policies, as the causal link between the relevant actions and omissions (eg hoarding or stockpiling of scarce vaccines, premature administration of boosters, voting against a TRIPs waiver, inadequate vaccine aid) and a specific population without vaccines will be too tenuous. The advantages of an international human rights framing of an issue are diminished if opportunities for direct claims by rights-holders are unavailable. 183

In this regard, perhaps a glimmer of hope can be found in a recent decision of the UN Committee on the Rights of the Child ('CRC Committee'), which supervises and monitors implementation of the Convention on the Rights of the Child ('CRC'). Sacchi et. al. v. Brazil was one of a series of cases brought by children, including Swedish climate activist Greta Thunberg, ¹⁸⁴ against certain States regarding alleged breaches of the CRC entailed in the foreseeable consequences of their environmental policies, which were said to

^{183.} See Mayer, supra note 77, 423.

^{184.} U.N. Comm. on the Rights of the Child, Decision Adopted by the Committee on the Rights of the Child under the Optional Protocol to the Convention on the Rights of the Child on a communications procedure in respect of Communication No. 105/2019, U.N. Doc. CRC/C/88.D/105/2019 (Nov. 21 2021).

exacerbate the impact of climate change. The cases were ultimately found inadmissible due to failures to exhaust local remedies.

Nevertheless, the CRC Committee found that a State could bear extraterritorial responsibility under the CRC when it fails to take measures to prevent foreseeable human rights harm arising from transboundary environmental damage caused by activities over which the State has effective control. The test adopted of 'effective control' was broad, including control over private and public sector emissions, which could be reduced by greater regulatory control. ¹⁸⁵ This test of extraterritorial jurisdiction is of limited relevance here as it was explicitly adopted to address the "novel jurisdictional issues of transboundary harm related to climate change." ¹⁸⁶

Of more relevance, perhaps, is the CRC Committee's finding that the applicant children could potentially be deemed to be identifiable victims of the respondent State's climate change policies:

[T]he Committee concludes that the authors have sufficiently justified, for the purposes of establishing jurisdiction, that the impairment of their Convention rights as a result of the State party's acts or omissions regarding the carbon emissions originating within its territory was reasonably foreseeable. It further concludes that the authors have prima facie established that they have personally experienced a real and significant harm in order to justify their victim status. 187

The children were deemed to be victims for the purposes of admissibility even though it would be impossible to establish an actual causal connection between a particular State's emissions and any human rights harm suffered by the children due to climate change, given the multitudinous causes of climate change. Similar reasoning might result in a finding that particular people, who are deprived of vaccines due to their State being unable to secure them, are victims of another State's action in over-purchasing vaccines. Having said that, there are limits to the extrapolations that can be made from Sacchi when it never moved beyond the admissibility phase to actual application of the facts on the merits.

Human rights principles can still be applied at a general level in the absence of a claimant. A state's 'vaccine greed' may be legitimately condemned by other states, and international human rights bodies such as UN Special Rapporteurs, the Human Rights

^{185.} Id. at ¶ 10.5–10.7; see also The Environment and Human Rights, Advisory Opinion OC-23/17, Inter-Am Ct. H.R. (ser. A) No. 23 (Nov. 15, 2017).

^{186.} U.N. Comm. on the Rights of the Child, supra note 184, at ¶ 10.4.

^{187.} Id. at ¶ 10.14.

Council and the UN treaty bodies in concluding observations pursuant to state reports. Such bodies, along with the WHO, are already identifying relevant human rights breaches though they have not as yet gone so far as to name offending states. Indeed, despite the WHO's outrage over rich states moving to boosters ahead of first shots for much of the world, it seemed to concede defeat on this matter by calling for a moratorium on boosters of a mere two months in mid-2021. As noted above, booster uptake in high-income countries was enormous by November 2021, even before the emergence of the Omicron variant in December of that year, which at least rendered boosters more justifiable.

Perhaps, most promisingly, a State's actions in exacerbating vaccine inequity could be the subject of an interstate human rights complaint. However, such complaints are very rare, perhaps for political and diplomatic reasons. The first interstate human rights complaint before a UN treaty body was only filed in 2018, after decades of disuse. Human rights cases before the ICJ are also rare and have tended to focus on only a few human rights where states can perhaps be more certain of the legal outcome, namely genocide, self-determination, racial discrimination and procedural rights in the context of the death penalty. 190

John Knox, the (then) Special Rapporteur on human rights and the environment, released a report on human rights and climate change in 2016, five years before the CRC Committee's *Sacchi* decision. He found extraterritorial obligations to be of 'limited usefulness' in the context of climate change: "In the human rights context, climate change is probably not best understood as a set of simultaneously occurring transboundary harms that should be addressed by each State trying to take into account its individual contribution to the effects of climate change in every other State in the world." ¹⁹¹

The same may be true of vaccine inequity. Perhaps the grossly uneven global distribution of scarce necessary resources is not best addressed by targeting individual state procurement decisions or individual state votes within the TRIPS Council.

^{188.} Naomi Thomas, WHO Calls for Moratorium on Booster Shots Until at least the End of September, CNN (Aug. 4, 2021), https://www.cnn.com/2021/08/04/health/who-coronavirus-booster-shots/index.html.

^{189.} U.N. Off. of the High Comm. for Hum. Rts, Committee on the Elimination of Racial Discrimination: Interstate Communications (Aug. 17, 2021), https://www.ohchr.org/EN/HRBodies/CERD/Pages/InterstateCommunications.aspx.

^{190.} Sandesh Sivakumaran, *The International Court of Justice and Human Rights*, INTL HUM. RTS. L. 299, 319–25 (Sarah Joseph & Adam McBeth eds., 2009).

^{191.} Rep. of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clear, Healthy and Sustainable Environment, \P 41, U.N. doc A/HRC/31/52 (Feb. 1, 2016).

In the context of climate change, Knox endorsed a 'duty of international cooperation,' drawn from a number of sources including Article 2(1) of the ICESCR, state practice, and Articles 55 and 56 of the UN Charter. ¹⁹² Such a duty, essentially falling on the international community, might provide an appropriate vehicle for addressing vaccine inequity too. Such a duty could apply, for example, to mandate international cooperation in prioritising vaccine distribution via the COVAX facility or facilitating the sharing of technological knowledge via C-TAP.

However, Mayer mounts a convincing argument against the existence of such 'collective obligations': "No source or authority demonstrates the existence of a "collective obligation" of the international community as a whole or the parties to a treaty, as a single legal person, to protect human rights "193

Even if such a duty exists, there is no mechanism to enforce it against the amorphous entity known as the international community. The symbolic, political and moral power of human rights may diminish to the point of disappearance if the accountable entity is the "international community", behind which every wrongdoing state can hide.

In contrast to Knox's views, the CRC Committee in *Sacchi* found that: "the collective nature of the causation of climate change does not absolve the State party of its individual responsibility that may derive from the harm that the emissions originating from its territory may cause to children, whatever their location." ¹⁹⁴

Again, such reasoning indicates that a State's wrongful hoarding of vaccines might lead to individual human rights culpability, even though vaccine inequity is caused by the policies of multiple State actors as well as private actors like pharmaceutical companies. Having said that, the CRC Committee's finding in this respect was influenced by international environmental law, including specific climate change treaties and agreements, which limits the transference of its reasoning to the situation of vaccine inequity.

The orthodox structure of human rights, based on the accountability of single states for harms caused to identifiable individuals, even if those individuals are located in other states, is not optimal for addressing a global problem like vaccine inequity which requires global burden-sharing, cooperation and coordination. While the CRC Committee's recent *Sacchi* decision may signal an evolving capacity for international human rights law

^{192.} Id. at ¶¶ 42–49.

^{193.} Mayer, *supra* note 77, at 428–30.

^{194.} U.N. Comm. on the Rights of the Child, supra note 184, at \P 10.10.

^{195.} See also Milanovic, supra note 53.

to address such global problems, such a conclusion is premature given the explicit confinement of the decision to the issue of climate change, and the fact that the application of potentially new, arguably radical, principles never moved beyond the admissibility stage of proceedings.

B. Embedded Neo-Liberalism

While the international human rights system provides inadequate protection to the victims of global vaccine inequity, embedded neo-liberalism in other parts of international law exacerbate their plight.

The neo-liberal model for access to medicines is protected by international economic law. That model failed with regard to the needs of victims of the AIDS pandemic in the early 2000s, 196 and is failing now with regard to the victims of the COVID-19 pandemic. As stated by the UN Special Rapporteurs: "Access and availability of a vaccine cannot be left in the hands of traditional market forces, to be defined by rules of supply and demand. Market solutions alone will not efficiently contain this pandemic nor prioritize the protection of millions of people in situations of vulnerability." 197

Despite their avid imposition of neo-liberal orthodoxies on other states, richer states readily depart from those orthodoxies when it is in their own interests. The EU threatened AstraZeneca's patent due to its frustration with the company's lagging delivery plan in early 2021. 198 As noted, Italy blocked exports to Australia in order to preserve resources for their own markets. While UK Prime Minister Boris Johnson boisterously attributed the UK's successful vaccination program in early 2021 to "capitalism" and "greed," the AstraZeneca vaccine created in the UK was almost completely publicly funded. 199 We did not rely on the free market to provide the R&D for vaccine development. It does not make sense to rely on it to provide for equitable vaccine distribution. 200

Yale Professor Amy Kapczynski has labelled the current situation of vaccine inequity a man-made problem of "private power

^{196.} Fernando Pascual, Intellectual Property Rights, Market Competition and Access to Affordable Antiretrovirals, 19 Supp. 3 Antiviral Therapy 57 (2014).

^{197.} Off. of the U.N. High Comm'r for Hum. Rts., *supra* note 47; *see also* U.N. Educ., Sci., & Cultural Org., Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications, ¶ 3(ii), U.N. Doc. SHS/RSP/HRS-GED/2009/PI/H/1 (2009).

^{198.} Ashleigh Furlong & Sarah Anne Aarup, Europe Hints at Patent Grab from Big Pharma, POLITICO (Feb. 3, 2021), https://www.politico.eu/article/europe-patent-grab-big-pharma/.

^{199.} Safi, supra note 132.

^{200.} Thambisetty et al., supra note 131, at 37.

and monopoly."²⁰¹ The IP and trade secrecy rights of pharmaceutical companies limit supplies rather than share knowledge which would enable more global vaccine production. Yet this system of "privatized control," which sits atop "a vast regime of open science and public subsidy,"²⁰² is protected under international economic law. As stated by Kapczynski: "The rules of global markets are not just unequal but extractive. They reproduce colonial dynamics in new forms,"²⁰³

Indeed, while we have thus far emphasised the vaccine divide in the polite language of "developed" and "developing" states, that divide is the same as between coloniser and colonised states, reflecting a stark racial divide too.²⁰⁴

The global IP rights ordained by TRIPS are not yet 30 years old and have always been controversial. The treaty is an odd fit within the WTO, given it mandates trade restrictions amongst a suite of treaties devoted to freer trade.²⁰⁵ Notably, the most ardent lobbyists for TRIPS, in a campaign that built throughout the 1980s, were the US and a group of pharmaceutical companies including Pfizer.²⁰⁶

Part of the TRIPS bargain for the global South at the time of its adoption in 1994 was the promise of greater technology transfer. ²⁰⁷ Instead, TRIPS has reinforced the technical dominance of the global North. ²⁰⁸ While middle income states such as China and India are increasingly competing in regard to IP rights, ²⁰⁹ higher income states still dominate innovation as measured by the World Intellectual Property Organization. ²¹⁰ TRIPS also constrains the developmental capacities of developing states in

^{201.} Kapczynski, supra note 92.

^{202.} Id. One example given by Kapczynski was the free sharing of the viral sequence of SARS-CoV-2 by China in early 2020.

^{203.} Id.

^{204.} Sharifah Sekalala et al., $Decolonising\ Human\ Rights:\ How\ Intellectual\ Property\ Laws\ Result\ in\ Unequal\ Access\ to\ the\ COVID-19\ Vaccine,\ July\ 2021\ BMJ\ GLOBAL\ HEALTH,\ 1.$

^{205.} See, e.g., Jagdish Bhagwati, Afterword: The Question of Linkage, 96 Am. J. OF INT'L L. 126, 128 (2002).

^{206.} Anne Orford, *Broken Bargains*, LONDON REV. OF BOOKS: LRB BLOG (May 5, 2021), https://www.lrb.co.uk/blog/2021/may/broken-bargains.

^{207.} Thambisetty et al., supra note 131, at 2.

^{208.} *Id.* at 42.

^{209.} Peter K. Yu, Intellectual Property., Global Inequality and Subnational Policy Variations, in Intellectual Property, Innovation and Global Inequality (Daniel Benoliel, Francis Gurry, Keun Lee & Peter K. Yu eds., forthcoming 2021); Sekalala et al., supra note 204, at 6.

^{210.} GLOBAL INNOVATION INDEX 2020: WHO WILL FINANCE INNOVATION? pp. xxxii-xxxvii (Soumitra Dutta, Bruno Lanvin, & Sacha Wunsch-Vincent eds., 13th ed. 2020).

ways not experienced by today's developed states, which benefited from their own industrialising periods as IP pirates.²¹¹

IP rights are enhanced by bilateral and regional "TRIPS-plus measures," which are even more protective of IP than TRIPS itself,²¹² as well as rights under bilateral investment treaties,²¹³ which further shrink the policy space of states.²¹⁴ The soft law human rights responsibilities of companies outlined by the UNGPs, explained above, provide no real counterweight.

The result, as noted in the following passage from Anne Orford, was foreseeable:

The current scarcity of vaccines is the predictable effect of a system that allows the use of monopoly rights to control pharmaceutical production globally. The result is a moral catastrophe as well as an ongoing public health and economic crisis. The ability of a handful of powerful companies based in Europe and the US to claim property rights over innovations resulting from the collective processes of modern science, and to use those rights to control the pace of manufacture and thus the price of pharmaceutical products, is not an unfortunate side effect of this system but its goal.²¹⁵

In these circumstances, at this time, Article 28 of the UDHR is not being respected. We do not have a social and international order in which the many rights compromised by the pandemic can be enjoyed on an equitable basis across the world.

VII. CONCLUSION

COVID-19 vaccines have brought a miraculous light to the end of the pandemic tunnel. But that light is too far off for much of the world.

The rush to the front of the vaccine queue by rich states is ethically wrong but is difficult to characterise as a breach per se of human rights, given that vaccines fulfil the genuine human rights of their own populations. However, blatant national oversupply

^{211.} Robert Wade, What Strategies Are Viable for Developing Countries Today?: The World Trade Organization and the Shrinking of 'Development Space', 10 Rev. of Int'l Pol. Econ. 621, 626 (2003); see also Ha-Joon Chang, Kicking Away the Ladder: Development Strategy in Historical Perspective 57, 84–85 (2002), detailing how the United States and European countries in the 19th century failed to give protection to foreign patents.

^{212.} JOSEPH, supra note 39, at 241-43.

²¹³ Id

^{214.} Sarah Joseph, *Trade Law and Investment Law: Intersections with Human Rights Issues*, in The Oxford Handbook of International Human Rights Law 841 (Dinah Shelton ed., 2013).

^{215.} Orford, supra note 206.

changes this assessment from non-breach to breach, which may be the case with any premature administration of populationwide booster shots. Export blockage of vaccines is a breach of extraterritorial obligations, unless there is an urgent need to provide for home supply. Furthermore, vaccine aid is a duty rather than mere charity for higher income states.

The biggest problem with vaccine inequity at the beginning of 2022 remains the scarcity of vaccines. Hence, all States have human rights obligations, both to the people of other states and to their own, to do what they reasonably can to increase global supply, and to not obstruct initiatives that can increase global supply. In that respect, states must swiftly negotiate a waiver of TRIPS over COVID-19 vaccines. But more must be done, including all states mobilising to prompt technology transfers, for example via C-TAP, and to maximise latent manufacturing capacities for the creation of COVID-19 vaccines. Pharmaceutical monopoly rights cannot be permitted to block progress in this regard.

The crisis of vaccine inequity is an indictment on the structure of our international legal, political and economic system. As stated by Dr. Tedros in January 2021, vaccine inequity is "a catastrophic moral failure—and the price of this failure will be paid with lives and livelihoods in the world's poorest countries."²¹⁶ Far from the first time, the international system reveals its enduring colonial dynamics. This time, though, the price may be paid by all of us in the form of a prolonged pandemic. As Dr. Tedros stated in a plaintive tweet, commenting on the need for agreement on the IP waiver, but of relevance to the need for an international system that fixes international problems for the benefit of us all: "if not now, when?"²¹⁷

^{216.} WHO Chief Warns Against 'Catastrophic Moral Failure' in COVID-19 Vaccine Access, supra note 2.

 $^{217.\} Tedros\ Adhanom\ Ghebreyesus\ (@DrTedros),\ TWITTER\ (Feb.\ 27,\ 2021,\ 5:40\ AM),\ https://twitter.com/DrTedros/status/1365386263969284096.$