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.

* Professor of Human Rights Law, Griffith University, Brisbane.

** Professor of Epidemiology, Kirby Institute, University of New South Wales, Sydney.
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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.[1] 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').[2] 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]

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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-they-work#:~: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.[12] The impact of the third dose is particularly pronounced against the Omicron variant, compared to the second dose.[13] 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.[14] Yet the vast majority of vaccines manufactured have been administered in richer states.[15] 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.[16]

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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-s-opening-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.[18] 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]

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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]

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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 workers[29] 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,

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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-covid19-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 ('ICESCR'), 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%20becoming%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]

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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, ¶ 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, ¶ 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

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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/DisplayNews.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'.[51] manner."[52] 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."[53]

The twin cases of *A.S. v. Malta* and *A.S. v. Italy*[54] 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

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

52. *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), ¶¶ 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), ¶¶ 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

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59. *See* Milanovic, *supra* note 53 (criticizing the reasoning in the Malta and Italy 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. *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

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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, ¶ 33. *See also* CESCR, General Comment 19, HRI/GEN/1/Rev.9 (Vol 1) 152, ¶ 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.

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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.[75] 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

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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.[81] 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.[82] 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

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80. Comm. on Eco., Soc. & Cultural Rts., *supra* note 44 ¶ 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.[85] 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

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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, ¶¶ 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.[91] 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.[92]

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

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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 'Is 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]

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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.[109] However, it has been repeatedly confirmed by the CESCR

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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

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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

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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."[117] 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.

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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 Committee[121] 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]

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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, ¶ 1(c) of the Covenant), U.N. Doc. E/C.12/GC/17 ¶ 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.[128] 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]

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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.[130] 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.[131] The AstraZeneca vaccine was developed by Oxford University and was reportedly 97% publicly funded.[132] The Moderna vaccine was funded by US government money, while Pfizer benefited from financial assistance from Germany as well as guaranteed pre-purchase contracts.[133] 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.[134] 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.[135]

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

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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.[141] 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.

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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-than-give-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 BRCA 2 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,

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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).

149. *Id.*

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.[153] These "patent thickets"[154] stall 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.[155] In an open letter to US President Biden on 5 March 2021, which urged the US

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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

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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. *"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

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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-s-african-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.[172] Pricing and other conditions should be transparent, and differences justified, given the high stakes.[173] 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.[178] Yet the initiative has been

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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. *"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. *"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

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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. *"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.[188] 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.[189] 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.

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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*, INT'L 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, ¶ 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 wrong-doing 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.[195] 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 ¶ 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

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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

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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

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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 population-wide 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]

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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.

IN THE DANGER ZONE: THE CALL FOR RESHORING PHARMACEUTICAL MANUFACTURING TO REDUCE THE VULNERABILITY OF THE UNITED STATES' SUPPLY CHAINS TO WAR TACTICS

JESSICA K. ANDREWS*

I. INTRODUCTION

Tactics of war can take many forms, such as a surprise attack through dive bombings on a naval fleet,[1] the dropping of atomic

* B.A., Psychology, 2007, University of West Florida; M.S., Psychology, Specialty in Applied Behavior Analysis, 2009, Florida State University—Panama City; M.P.H, Public Health Practice, 2017, University of South Florida; J.D., 2021, Florida State University College of Law; Board Certified Behavior Analyst®; Certified in Public Health, National Board of Public Health Examiners.

1. In World War II, the United States was not prepared for the bombarding of Pearl Harbor, leading to a significant wound that led to the United States entering the war. *See* RICHARD J. SAMUELS, ENCYCLOPEDIA OF UNITED STATES NATIONAL SECURITY 572–74 (Rolf Janke, 1st ed. 2005); Christopher Klein, *How Japan's Kamikaze Attacks Went from Last*

bombs on cities,[2] or the flying of planes into a financial district.[3] As proven by the United States in World War II, blockading an adversary's access to pharmaceuticals and necessary supplies is also an effective way to damage an enemy.[4] In order to ensure the safety of a country's population, a country must surveil and ensure that such supply chains and vulnerabilities are reduced. When analyzing the vulnerabilities of the United States, the pharmaceutical supply chain is a glaring weakness to national security and public safety.[5] Currently, the United States relies on other countries for essential pharmaceuticals such as antibiotics, heparin, chemotherapy drugs, and medical supplies.[6] Should an adversary choose to injure the

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Resort as Pearl Harbor to WWII Strategy¸ HISTORY STORIES (Dec. 5, 2018), https://www.history.com/news/pearl-harbor-japan-kamikaze-world-war-ii.

2. The United States' entry eventually led to the very shocking but efficacious use of two atomic bombs dropped on Japan, which effectively ended World War II. SAMUELS, *supra* note 1 at 52.

3. Another effective campaign was the attacks of 9/11, which involved hijackers crashing planes into the World Trade Center and the Pentagon. The United States was on lock down. Airplanes could not leave the ground. Millions were afraid to go outside or to go to social events. The New York Stock Exchange dropped 684 points in a day. The campaign was effective at damaging the United States through economic and social upheaval. *Id.* at 50, 652–55; Marc Davis, *How September 11 Affected the U.S. Stock Market*, U.S. MARKETS (Aug. 31, 2021), https://www.investopedia.com/financial-edge/0911/how-september-11-affected-the-u.s.-stock-market.aspx.

4. SUZANNA REISS, WE SELL DRUGS: THE ALCHEMY OF US EMPIRE 15–16 (2014); Richard J. Evans, *Why Hitler's Grand Plan During the Second World War Collapsed*, THE GUARDIAN (Sept. 8, 2009), https://www.theguardian.com/world/2009/sep/08/hitler-germany-campaign-collapsed (discussing the United States' successful blocking of Germany's access to supplies).

5. Although the United States once manufactured almost all its pharmaceuticals, it now relies on other countries for many necessary pharmaceuticals, such as antibiotics and heparin. Ken Dilanian & Brenda Breslauer, *US. Officials Worried about Chinese Control of American Drug Supply*, NBC NEWS (Sept. 12, 2019), https://www.nbcnews.com/health/health-care/u-s-officials-worried-about-chinese-control-american-drug-supply-n1052376; Because United States residents rely on these finished pharmaceuticals (FPPs) and active pharmaceutical ingredients (APIs) to live, a delay or abrupt severing of the supply chain or adulteration of significant batches of pharmaceuticals would result in societal disruption as well as health impairment and potentially death to thousands or millions of Americans. Betsy McCaughey, *The Hidden Peril of Drugs Imported from China*, N.Y. POST, (Sept. 3, 2019), https://nypost.com/2019/09/03/the-hidden-perils-of-drugs-imported-from-china/.

6. Guy Taylor, *'Wake Up Call': Chinese Control of U.S. Pharmaceutical Supplies Sparks Growing Concern*, THE WASHINGTON TIMES (Mar. 17, 2020), https://www.washingtontimes.com/news/2020/mar/17/china-threatens-restrict-critical-drug-exports-us/ (discussing the potential shortage of necessary pharmaceuticals, such as antibiotics, within the United States amid the COVID-19 pandemic because of the United States' reliance on China for manufacturing); Doug Palmer & Finbarr Bermingham, *U.S. Policymakers Worry About China 'Weaponizing' Drug Exports*, POLITICO (last updated Apr. 10, 2020), https://www.politico.com/news/2019/12/20/policymakers-worry-china-drug-exports-088126 (discussing the millions of Americans reliant on pharmaceuticals from China and the vulnerability of the supply chain, such as penicillin and heparin); ROSEMARY GIBSON, CHINA RX 36–56 (2018)).

United States, this reliance could be manipulated and abused to the detriment of the health and lives of the United States' residents.[7]

For example, although China and India did not become major pharmaceutical exporters as a means to damage the United States,[8] their current exportation power could be wielded to the United States' detriment.[9] And when considering the wavering and complex relationship between the United States and China,[10] the pharmaceutical supply chains are suspect for potential manipulation or abuse. As a result, the United States must take

7. Taylor, *supra* note 6; Palmer & Bermingham, *supra* note 6.

8. An official at the China Association of Pharmaceutical Commerce, Zhu Jianyun, suggested that it was pharmaceutical companies searching for cheaper manufacturing that led to China rising to a manufacturing powerhouse, not China seeking out those powers. Palmer & Bermingham, *supra* note 6.

9. For example, China currently manufactures the majority of the United States' penicillin supply as well as supplies for chemotherapy drugs, heparin, blood pressure medications, and doxycycline for anthrax attacks. Rosemary Gibson, *U.S. Dependence on China for Medicine Is a Major Problem*, THE SEATTLE TIMES (July 21, 2019), https://www.seattletimes.com/opinion/u-s-dependence-on-china-for-medicine-is-a-major-problem/. Overall, China is "the world's leading producer and exporter of active pharmaceutical ingredients (APIs) by volume, accounting for 20% of total global API output." WORLD HEALTH ORGANIZATION, CHINA POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 17 (2017) [hereinafter WHO China], https://www.who.int/phi/publications/2081China020517.pdf. As such, many medications reaching the United States often have APIs from China.

10. Aside from other quarrels, the United States indicted it was Chinese hackers who allegedly hacked into United States' governmental systems. The Chinese government responded by refusing continued collaboration in cyber-security workgroups. *U.S. Relations with China, 1949–2020*, COUNCIL ON FOREIGN RELATIONS (2020), https://www.cfr.org/timeline/us-relations-china. In 2020, a Harvard professor and two Chinese nationals were indicted on charges for lying to federal investigators about ties to the Chinese government. It was suggested that the Harvard professor and the nationals were attempting to steal research paid for by the United States government. *See* Veronica Stracqualursi and Sheena Jones, *Harvard Professor Among Three Charged with Lying about Chinese Government Ties*, CNN (Jan. 28, 2020), https://www.cnn.com/2020/01/28/politics/harvard-professor-chinese-nationals-arrest-espionage/index.html. In 2018 and 2019, Chinese nationals were also arrested in the United States for carrying suspected Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) materials. *See* Jerry Dunleavy, *FBI Warned about 'Biosecurity Risk' after Chinese Nationals Snuck Suspicious Vials into US*, WASHINGTON EXAMINER (Apr. 1, 2020), https://www.washingtonexaminer.com/news/fbi-warned-about-biosecurity-risk-after-chinese-nationals-snuck-suspicious-vials-into-us. Further, after United States' government officials referred to the Coronavirus (COVID–19) as the "Wuhan" or "China Virus," a Chinese official claimed that COVID–19 was possibly started by the U.S. and dropped into China to hurt the Chinese reputation. Lee Myers, *China Spins Tale That the U.S. Army Started the Coronavirus Epidemic*, THE N.Y. TIMES (Mar. 13, 2020), https://www.nytimes.com/2020/03/13/world/asia/coronavirus-china-conspiracy-theory.html. Finally, Chinese economists suggested the Chinese pharmaceutical exportation supply chain could be leveraged against the United States during the trade war. *See* Didi Tang, *China Threat to Halt US Antibiotics Supply*, THE TIMES (Mar. 11, 2019), https://www.thetimes.co.uk/article/china-threat-to-halt-us-antibiotics-supply-36tm2v2xp.

steps to reduce such vulnerabilities by reshoring the manufacturing of pharmaceuticals and diversifying supply chains in the interim.[11]

This Note discusses the history of the exportation of the United States pharmaceutical sector as well as the rise of India and China as pharmaceutical manufacturing powerhouses in Part II. Part III discusses the need for increased local production (reshoring) of pharmaceuticals within the United States and the diversification of foreign pharmaceutical supply chains. Further, within Part III, the Note will discuss the barriers to local production and diversification of supply chains. Part IV will follow with a discussion of solutions. Such solutions include incentives to increase reshoring of pharmaceutical manufacturing within the United States through pharmaceutical companies as well as other non-traditional manufacturers. Further, Part V will discuss the need to incentivize local adaption of continuous manufacturing to increase competitiveness with China. Part VI will follow with counterarguments. Part VII concludes with an overview of why reshoring and increasing local production is needed and how to encourage these processes.

II. THE SHIFTING OF THE PHARMACEUTICAL SECTOR OUTSIDE OF THE UNITED STATES TO CHINA AND INDIA

Most of the pharmaceutical powerhouses in the United States, such as Eli Lilly, began in the late 1800s and early 1900s.[12] The United States went on to solidify itself as a global power in the pharmaceutical industry during World War II by using legislative power and trade deals to control global trade of pharmaceuticals and resources.[13] For example, the United States began to shape the supply chain of cocaine, previously considered a useful medication for various injuries.[14] By striking deals with Bolivia and Peru, the United States began to block Germany from supplies and subsequently, started to become the world's supplier of cocaine.[15] The United States did not stop at just manufacturing cocaine,

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11. Such government measures were reinitiated recently through the introduction of Senate Bill 2495, Protecting Our Pharmaceutical Supply Chain from China Act of 2021. S.2495, 117th Cong. (2021). Although this bill would seemingly aid in understanding vulnerabilities, this Note makes other recommendations to improve the pharmaceutical supply chain.

12. *See* Robin Walsh, *A History of the Pharmaceutical Industry*, PHARMAPHORUM (Oct. 1, 2010), https://pharmaphorum.com/articles/a_history_of_the_pharmaceutical_industry/.

13. *See* REISS, *supra* note 4, at 47–52.

14. *See id*. at 22–25.

15. *See id*.

however, and continued to expand into other fields, leading to dominance in various pharmaceuticals' production.

Initially, the United States pharmaceutical companies used vertically integrated models of production as a means to control production.[16] Within this model, companies would do everything from research and development of pharmaceuticals to manufacturing to marketing and commercialization of the products.[17] Having the vertically integrated model, however, became much more expensive as regulations called for more complex processes for the patenting and production of pharmaceuticals.[18]

Such expenses and processes are then coupled with increased competition as others are allowed to enter the market, leading to outsourcing.[19] Pharmaceutical patents generally provide originator companies, companies initially patenting the pharmaceuticals, with several years of patent exclusivity from filing.[20] Although patent exclusivity is generally for twenty years, regulatory exclusivity is much shorter.[21] As regulatory exclusivity periods expire, generic and biosimilar companies can then apply for Abbreviated New Drug

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16. *See* Min Zhang et al., *Evaluating Outsourcing Partners' Capability: A Case Study from the Pharmaceutical Supply Chain*, 24 J. OF MANUFACTURING TECH. MGMT. 2 (2013) (citing to PricewaterhouseCoopers, Pharma 2020: Challenging Business Models- Which Path Will You Take? (2009)). "In this model, success hinges on the firm's internal abilities to identify promising new molecules, test them in large clinical trials, and promote them with an extensive marketing and sales presence."

17. *See id.*

18. *See id.*

19. With the introduction of generics, originator companies see their profits reduced, while generic companies have to cut costs to compete with thinner profit margins. *See id.* (discussing the variety of reasons why outsourcing has become more popular among U.S. pharmaceutical companies). *See also Why Outsource Manufacturing to CMO Pharmaceutical Companies?* ABBVIE CONTRACT MANUFACTURING (2021), https://www.abbviecontractmfg.com/services/expertise/when-to-use-outsourcing-in-drug-development.html; CONG. RESEARCH SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 1 (Feb. 11, 2020) (discussing the billions of dollars spent on research and development to patent pharmaceuticals).

20. *See* U.S. GOV'T ACCOUNTABILITY OFF., DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 7 (2017). Many pharmaceutical companies can retain up to twenty-five years of market exclusivity from filing due to patent extensions of five years with the Hatch–Waxman Act of 1984. Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United Stated*, JAMA INTERNAL MEDICINE ONLINE 2 (Sept. 11, 2017), doi:10.1001/jamainternmed.2017.4329. However, such time is often frustrated due to the FDA's strenuous requirements, with pharmaceutical companies having significantly less than 20 years of exclusivity when their drugs reach market. *Id.* at 2, 4 (suggesting the effective exclusivity period was found to be around 12.5 years in multiple studies).

21. During the patent exclusivity period, other companies are not allowed to "mak[e], us[e], or sell . . . the patented aspects of the drug." These other companies are also excluded from most marketing of the patented aspect or product. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 7; *See* Kesselheim, Sinha & Avorn, *supra* note 20, at 1–3; *See also* 35 U.S.C. § 271. However, as mentioned, the regulatory period is much shorter and generic companies can initiate processes before patent expiration when regulatory exclusivity expires. *See* Kesselheim, Sinha & Avorn, *supra* note 20, at 1–3.

Applications (ANDAs) and eventually begin manufacturing the pharmaceutical once approved.[22] The introduction of such generics leads to reductions in originators' profits.[23] Further, because ANDAs do not require the extensive testing that originator pharmaceuticals require, the generic market is often very competitive[24] and as a result, generic companies operate on thinner profit margins.[25] Thus, companies look for ways to cut costs, such as with manufacturing processes.[26]

Exploration led to the creation and development of contract research and manufacturing organizations (CROs/CRMOs) in emerging economies. By providing a skilled workforce with specialized services, these CROS offered ways to "reduce cost[s], improve speed, quality, and flexibility, and adjust their organizational boundaries in response to external economic pressures."[27] This led to the outsourcing of pharmaceutical manufacturing to countries in Europe and Asia.[28] Process by process was gradually outsourced, until other countries not only manufactured basic chemicals and intermediates, but also active pharmaceutical ingredients (APIs) and finished pharmaceutical products.[29]

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22. Generics are those that are similar to chemically synthesized drugs, while biosimilars are those that are similar to biologic originator drugs. *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 8. To be approved, generic companies must show that their formulary of the generic is similar to the originator "in active ingredient, dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use." *Id*. Biosimilars must be "highly similar" to the approved product and "have no clinically meaningful differences in terms of safety and effectiveness." *Id*.

23. Tom Fezza, Faith Glazier & Jodi Reynolds, *Loss of Exclusivity: Strategies to Maximize Product Value*, PHARMEXEC (Nov. 9, 2016), https://www.pharmexec.com/view/loss-exclusivity-strategies-maximize-product-value.

24. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 20, at 48.

25. *See id*. (discussing the reduction in price as generic companies enter the market).

26. *See* Zhang et al., *supra* note 16, at 2; Alan S. Ryan & Frederick D. Sancilio, *Outsourcing Excellence in China and India*, PHARMA MANUFACTURING (Feb. 12, 2013), https://www.pharmamanufacturing.com/articles/2013/018/ ("The need to reduce time-to-market, boost drug discovery and squeeze costs out of pharmaceutical and nutritional products have forced U.S. companies to look elsewhere for raw materials, active pharmaceutical ingredients (APIs) and manufacturing and packaging services").

27. *See* Zhang et al., *supra* note 16, at 2. See also the statement of Janet Woodcock, Director of the Center for Drug Evaluation and Research in *Safeguarding Pharmaceutical Supply Chains in a Global Economy, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce,* 116th Cong. (Oct. 30, 2019), https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019 (suggesting among costs are "large factory site[s], . . . [and] environmental liabilities" as well as higher workforce costs in the United States).

28. Notably, China and India are countries relied upon for manufacturing through CRMOs. *See* Zhang et al., *supra* note 16, at 2.

29. *See* Sylvia M. Findlay, *Outsourcing in Pharma*, PHARM TECH (May 1, 2007), http://www.pharmtech.com/outsourcing-pharma. The authors suggested that initially basic

A. China's and India's Introduction as Pharmaceutical Powerhouses

Two notable countries that United States pharmaceutical companies turned to for cheaper manufacturing were China and India.[30] China's and India's governments helped propel companies within their boundaries into the global industry through industry design and development processes.[31] As a result, both countries boast substantial market-shares in production of APIs, with China controlling twenty percent of the global market and India controlling just over seven percent.[32]

In the 1950s and 1960s, India's government and pharmaceutical industry developed manufacturing facilities and technology to improve their foundation of pharmaceutical innovation and production.[33] After creating a strong foundation, India turned its views to tackling high income markets, such as the United States in the 1980s.[34] By using its highly integrated industry, local sourcing of low-cost APIs, and efficient production of finished pharmaceutical products (FPPs), India was able to successfully break into these markets, even with the United States' higher standards and regulatory presence.[35] By 2010, India had finished product sales of over "6 billion, increasing at an annual rate of more than 10%" and "account[ing] for nearly 20% of the global generic marketplace."[36]

China's entry into the global pharmaceutical industry came later. In the 1980s, China moved away from a "central government planning economic model to a more market-oriented model" and in 2001, joined the World Trade Organization.[37] China began seeking investors into its companies, especially its manufacturing sector, and quickly became successful in exporting basic chemicals,

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chemical processing was outsourced before moving to manufacturing of the API and now even some finished pharmaceutical products (FPPs). *See also* Ryan & Sancilio, *supra* note 26; Palmer & Bermingham, *supra* note 6.

30. *See* Zhang et al., *supra* note 16, at 2.

31. *See generally* WHO China, *supra* note 9, at 16–20; *See* WORLD HEALTH ORGANIZATION, INDIAN POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH 1–3 (2017) [hereinafter WHO India].

32. *See* WHO China, *supra* note 9, at 17; Julian Issa, India's API Industry: *Exporting to the World*, GLOBAL BUSINESS REPORTS (Mar. 17, 2020), https://www.gbreports.com/article/indias-api-industry-exporting-to-the-world.

33. *See* WHO India, *supra* note 31, at 1.

34. *See id*.

35. *See id*.

36. Ryan & Sancilio, *supra* note 26.

37. WHO China, *supra* note 9, at 5.

intermediates, and APIs.[38] This market was based upon cheaper production of pharmaceutical APIs, leading to more profits for foreign global pharmaceutical companies.[39] Indeed, pharmaceutical companies found a viable industry in China with significantly lower wages, fewer environmental regulations, and lower costs related to electricity, coal, and water when compared to United States equivalents.[40] Additionally, as its industries are "embedded in a network of raw materials and intermediary suppliers," Chinese companies were further able to manufacture and export at significantly lower costs than United States' companies.[41]

As a result of these lower costs for APIs and generic pharmaceutical manufacturing, United States' companies transitioned to India's and China's manufacturing industries to reduce overall costs.[42] Although United States' residents reap the benefit by having more affordable access to generics, it also places them in a vulnerable position. As stated previously, if China (or India) decided to halt the supply to the United States, United States' residents would not have regular access to necessary pharmaceuticals.[43]

III. THE NECESSITY OF LOCAL PRODUCTION AND DIVERSIFICATION OF SUPPLY AS WELL AS BARRIERS

To reduce the vulnerability of the pharmaceutical supply, the United States must shift to local production of needed medications by reshoring pharmaceutical manufacturing.[44]

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38. *See generally id*. at 16. China has now progressed toward finish product pharmaceuticals as well.

39. *See* Ryan & Sancilio, *supra* note 26.

40. *See* Woodcock, *supra* note 27.

41. *Id.*

42. *See* Ryan & Sancilio, *supra* note 26.

43. *See* Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China*, COUNCIL ON FOREIGN RELATIONS: ASIA UNBOUND & GLOBAL HEALTH PROGRAM (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

44. "Reshoring" involves the relocating of pharmaceutical manufacturing and other processes back to the country these processes initially occurred within, such as the United States. *See generally* Jim Miller, *Will Pharma Manufacturing Move Back to the US?*, PHARM TECH: ADVANCING DEVELOPMENT AND MANUFACTURING (Mar. 2, 2017), http://www.pharmtech.com/will-pharma-manufacturing-move-back-us-0. Aside from reducing vulnerabilities due to war tactics, reshoring pharmaceuticals reduces supply issues regarding public health emergencies. Part of the issues with mask shortages and medications during COVID–19 were a result of importing masks and pharmaceuticals from outside of the country. *See* Taylor, *supra* note 6.

However, experts suggest that a shift of many needed generics would take multiple years.[45]

This stems from the barriers that stand in the way of reshoring pharmaceutical manufacturing.[46] First and foremost, costs are high to bring back pharmaceutical manufacturing. Experts suggest that opening a large-scale biologics company would cost upwards of 1 to 2 billion dollars.[47] Although generics manufacturing is substantially cheaper than biologics,[48] reshoring still comes with a significant price. Many directors and corporate boards are hesitant to take hits to quarterly earnings in order to reshore supply chains.[49] As such, one of the first hurdles would be to reduce the price of transitioning back to local production or to incentivize companies to offset losses related to reshoring manufacturing back to the United States.

Beyond the costs, determining where pharmaceutical manufacturing plants will reside is also complicated. Pharmaceutical manufacturing leads to environmental waste that must be disposed of within the Environmental Protection Agency's and state-equivalent regulations and guidelines.[50] Pharmaceutical manufacturing also calls for a good source of

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45. *See* Miller, *supra* note 44, http://www.pharmtech.com/will-pharma-manufacturing-move-back-us-0 (suggesting that to open a manufacturing facility for pharmaceuticals generally takes at least four years, while transferring a drug to another facility can take up to two years. Overall, the process of reshoring pharmaceutical manufacturing back to the United States is expected to take between 7 and 10 years).

46. Although there are barriers, reshoring comes with benefits as well, such as quick delivery of products to customers, better quality control, and more ability to customize products. Customization will play a huge part in patient-centered pharmaceuticals in the future. *See generally* Alessandro Ancarani, Carmela Di Mauro, & Francesco Mascali, *Backshoring Strategy and the Adoption of Industry 4.0: Evidence from Europe*, 54 J. OF WORLD BUS. 360, 360–64 (2019).

47. *See* Miller, *supra* note 44.

48. Avik Roy & The Apothecary, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#2e3994b718b0.

49. Steve Banker, *U.S. Manufacturers Are Not Reshoring*, FORBES (July 11, 2018), https://www.forbes.com/sites/stevebanker/2018/07/11/u-s-manufacturers-are-not-reshoring/#156dd762460 (discussing barriers to reshoring in all industries which includes the reluctance to risk large investments in overseas manufacturing). Afterall, the board's duties are to the corporation and to ensuring the longevity of the corporation. Wolters Kluwer, *Powers & Duties of Corporation Directors & Officers*, ARTICLES (Apr. 24, 2019), https://ct.wolterskluwer.com/resource-center/articles/powers-and-duties-of-corporate-directors-officers.

50. *See generally* Brian Gallagher & Dan Mollohan, *Reshoring Best Practices for Manufacturers*, INDUSTRY WEEK (Feb. 22, 2013), https://www.industryweek.com/expansion-management/article/21959734/reshoring-best-practices-for-manufacturers (discussing the need to consider environmental regulations and impact).

relatively clean water in order to achieve the necessary pristine conditions of developing unadulterated medications.[51]

Beyond these factors, companies must also consider the location due to potential weather-related disasters. For example, Puerto Rico was a significant manufacturer of many pharmaceuticals reaching the United States mainland.[52] When Hurricane Maria devastated the island, Puerto Rico's manufacturing was decimated, leading to the shutdown of manufacturing of intravenous (IV) drip bags.[53] As the United States was already suffering from an IV bag shortage, this severing of the supply chain was substantial.[54] As such, the location of manufacturing will be no small decision and will lead to limitations on potential locations within the United States.

A. Diversification of Pharmaceutical Supply Chains

While waiting on local manufacturing facilities to be arranged, diversifying supply chains would also help to reduce the reliance on a peaceful Chinese-American relationship. Instead of continuing an almost complete reliance on China, the United States should look toward countries it not only has good relationships with but also those with stable economies and those who are less likely to suffer catastrophic weather-related events.[55] Indeed, placing all of the pressure on one supply chain because the country has the lowest price situates any country in a vulnerable spot regardless of the commodity or asset and regardless of the exporting countries.[56] As some suggest, the costs of diversifying to multiple supplies would be expensive and lead to lower quarterly profits, "but it would also guarantee a modicum of stability in case of crises—whatever

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51. *See* Abdul Bake, Zubair Khalid Labu, Khurshid Jahan, *Pharmaceutical Water*, PHARMACEUTICAL GUIDELINES (Sept. 2012), https://www.pharmaguideline.com/2012/09/pharmaceutical-water.html.

52. Walecia Konrad, *Why So Many Medicines Are in Short Supply Months after Hurricane Maria*, CBS NEWS (Feb. 12, 2018), https://www.cbsnews.com/news/why-so-many-medicines-arel-in-short-supply-after-hurricane-maria/.

53. *Id.*

54. *Id.*

55. Elisabeth Braw, *Blindsided on the Supply Side*, FOREIGN POLICY (Mar. 4, 2020), https://foreignpolicy.com/2020/03/04/blindsided-on-the-supply-side/ (referencing the Fukushima earthquake and how it adversely affected pharmaceutical giant Merck by disrupting the supply chain of needed technology. Although weather phenomenon disasters have been rare, they are increasing in frequency. As a result, corporate leaders will have to consider expensive transitions to dual-supply chains to offset disastrous results of relying on a supply chain that can be destroyed by weather).

56. *Id.* (discussing the various supply chains and commodities that have been affected by crises, such as COVID–19 or earthquakes).

those crises might be."[57] Thus, should interactions with China become retaliatory, United States residents would be shielded from punitive actions.

Unfortunately, diversification also comes with complications. Other potential manufacturing sources, such as India, also heavily rely on China for much of the production of active pharmaceutical ingredients.[58] As a result, most of the countries the United States would consider transitioning manufacturing to would also need to increase manufacturing within their countries in order to take on the pharmaceutical needs of the United States.[59] Thus, diversification of pharmaceuticals coming from China will not be an easy task. However, as suggested by the Civica RX company, diversification is possible and manufacturing outside of China can produce necessary pharmaceuticals.[60] Though, to completely secure the pharmaceutical supply chain within the United States, reshoring should be the end goal.

IV. LURING THE PHARMACEUTICAL COMPANIES INTO LOCAL PRODUCTION AND INCENTIVIZING LOCAL ALTERNATIVE COMPETITORS

Transitioning pharmaceutical manufacturing back to local production is a necessary maneuver with many challenges. However, the United States government possesses enough power as well as the responsibility[61] to bring back pharmaceutical

57. Braw, *supra* note 55.

58. Huang, *supra* note 43.

59. *See generally id.* Amid the COVID–19 virus, India is looking to take over more of the API market and limit its reliance on China. Teena Thacker, *As China Stumbles, India Plans Big Exports Push in Bulk Drugs*, THE ECONOMIC TIMES (May 1, 2020), https://economictimes.indiatimes.com/news/economy/foreign-trade/as-china-stumbles-india-plans-big-exports-push-in-bulk-drugs/articleshow/75480532.cms.

60. Civica RX partnered with Xellia out of Denmark to manufacture medications. Ben Hargreaves, *Civica Signs Its First Supplier Agreement for Antibiotics in Short Supply*, OUTSOURCING-PHARMA (May 29, 2019) https://www.outsourcing-pharma.com/Article/2019/05/21/Civica-Rx-signs-manufacturing-agreement-with-Xellia?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright; Civica RX also partnered with ThermoFisher Scientific to manufacture. Ben Hargreaves, *Civica Rx Signs 7-year Deal with Thermo Fisher*, OUTSOURCING-PHARMA (Jan. 20, 2020), https://www.outsourcing-pharma.com/Article/2020/01/20/Civica-Rx-announces-partnership-with-Thermo-Fisher; Among other places, Thermo Fisher has manufacturing sites in Ireland. ThermoFisher Scientific, *Thermo Fisher Scientific to Acquire Manufacturing Site in Cork*, Ireland, from GSK, NEWS RELEASE DETAILS (May 16, 2019), https://thermofisher.mediaroom.com/2019-05-16-Thermo-Fisher-Scientific-to-Acquire-Manufacturing-Site-in-Cork-Ireland-from-GSK; See *infra* note 116 (discussing Civica Rx's partnering with Hikma, a multi-national manufacturer).

61. Although perhaps out of the scope of this paper, the United States government has a responsibility to ensure the health and safety of its populace. The Constitution suggests that the government has the power to tax and spend to "promote the general welfare."

manufacturing to the United States. In order to successfully bring back local production of pharmaceuticals, this Note advocates for the United States to conduct the following steps: 1) use tax incentives targeting reshoring and property taxes instead of corporate tax reductions to incentivize current manufacturers to reshore; 2) use subsidies and tax incentives to incentivize investments in local continuous manufacturing; 3) use grants and prizes to increase universities' and private organizations' research into continuous manufacturing to reduce risks of investment; and 4) incentivize alternative generic manufacturers, such as hospital organizations, to increase local production. Such, incentives for alternative manufacturers includes mandating PBMs contract with local alternative manufacturers over others. These steps will increase access to local generic manufacturing of necessary pharmaceuticals and decrease the vulnerabilities of the United States' supply chain.

A. Using Taxes to Incentivize Current Manufacturers to Reshore

Tax incentives appear to be an obvious choice when incentivizing companies to reshore pharmaceutical manufacturing.[62] Pharmaceutical companies spent millions, if not billions, in developing infrastructure and plants as well as training a workforce in foreign countries to manufacture pharmaceuticals.[63] Furthermore, although the discrepancies in wages and benefits are dwindling,[64] in comparison to salaries of manufacturing workers

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Although this has not been applied to requiring pharmaceutical manufacturing of necessary medications, there is an argument to be had about the General Welfare Clause (supplemented by the Necessary and Proper Clause) or Commerce Clause applying at the federal level to such public health emergencies as COVID–19. Interactive Constitution, *The Constitution and the Corona Virus*, WE THE PEOPLE PODCAST (Mar. 19, 2020), https://constitutioncenter.org/interactive-constitution/podcast/the-constitution-and-the-coronavirus; SEAN M. STIFF, CONG. RESEARCH SERV., LSB10434, COVID-19 RESPONSE: CONSTITUTIONAL PROTECTIONS FOR PRIVATE PROPERTY, 1 (Mar. 27, 2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10434. Former President Trump used the Defense Protection Act to seize medical masks and exporting other medical equipment. However, seizing of manufacturing is a severe response, and incentives would most likely lead to better responses from the pharmaceutical industry and public. Further, it, of course, could also be argued that corporations have a responsibility to the populace, but it is more of a moral argument than a legal argument.

62. Tax incentives are often mentioned when incentivizing reshoring of manufacturing. *See* Harry Moser, *Reshoring Was at Record Levels in 2018. Is It Enough?* THE ECONOMY (July 8, 2019), https://www.industryweek.com/the-economy/article/22027880/reshoring-was-at-record-levels-in-2018-is-it-enough.

63. *See generally* Miller, *supra* note 44.

64. *See* Leigh Buchanan, *Why U.S. Manufacturers Are Turning Their Attention to 'Reshoring'*, INC. (Oct. 26, 2017), https://www.inc.com/leigh-buchanan/how-american-manufacturers-are-reshoring.html (pointing out that Chinese wages have tripled from 2005 to 2016).

in the United States, China still has a significantly lower average for salaries of manufacturer workers.[65] In order to reshore pharmaceuticals, the investments in foreign manufacturing and the costs of reshoring must be financially offset. Indeed, reshoring experts stated, "Reshoring takes place when the trade-offs between cost advantages, market and knowledge seeking, transaction costs and maintaining control are not advantageous for the firm anymore."[66]

It was thought that former President's Trump signing of the Tax Cuts and Jobs Act in 2018 would reduce costs enough to incentivize corporations, including pharmaceuticals, to reshore.[67] The act led to a reduction of the corporate tax from thirty-five percent, one of the highest corporate taxes in the world, to a seemingly competitive twenty-one percent corporate tax.[68] The goal of cutting the corporate tax was the hope that corporations would reinvest the money into the companies, including reshoring manufacturing to the United States.[69] The one-time reparation tax holiday and switch to territorial system for taxation of multinational corporations were also thought to encourage reshoring or reinvestment within the United States.[70] However, data on reshoring based on the Tax Cuts and Jobs Act suggest limited progress in reshoring manufacturing across industries.[71] The effect on reshoring of pharmaceutical manufacturing is even more limited.[72]

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65. *See* Elaine Pofeldt, *Why US Manufacturers Are Nixing the US for China*, CNBC (Sept. 21, 2015), https://www.cnbc.com/2015/09/21/why-us-manufacturers-are-nixing-the-us-for-china.html (stating that the average manufacture worker in China makes approximately $8,060 annually).

66. Steven Kinkel et al., *Measuring Reshoring Trends in the EU and the US*, MAKERS 3 (2017), https://reshoringinstitute.org/wp-content/uploads/2020/11/Measuring-Reshoring-in-the-EU.pdf.

67. *See generally* Jonathan Gardner, *Biopharma Happily Takes the Tax Cuts, But the Jobs Are Harder to Find¸* BIOPHARMA DIVE (May 9, 2019), https://www.biopharmadive.com/news/biopharma-happily-takes-the-tax-cuts-but-the-jobs-are-harder-to-find/553925/.

68. *Id.*

69. Joseph Zeballos-Roig, *These 7 Charts Show Trump's Tax Cuts Still Haven't Been the Economic 'Rocket Fuel' He Promised, 2 Years after the Fact*, MARKETS INSIDER (Dec. 22, 2019), https://markets.businessinsider.com/news/stocks/7-charts-showing-trump-tax-cuts-not-economic-rocket-fuel-2019-12-1028780773.

70. Michael S. Sinha & Aarson S. Kesselheim, *The Tax Cuts and Jobs Act of 2017 and the Pharmaceutical Industry*, 46 J. OF LAW, MED., & ETHICS 806, 806 (2018).

71. Zeballos-Roig, *supra* note 69 (suggesting that there was limited GDP growth and business investments, but both were shortly lived. Further, investments did not offset the loss of tax revenue).

72. Gardner, *supra* note 67 (stating that instead of reshoring or reinvesting in the United States, pharmaceutical companies generally bought back stocks with the corporate tax savings). Interestingly, the Tax Cuts and Jobs Act also potentially breaches World Trade Organization obligations as well as the Ireland-US double tax treaty. Joe Duffy, *The US Tax Reform Impact in Ireland: Game-changer or Business as Usual?*, NEWS & INSIGHTS (2018),

This lack of reshoring based on these tax changes most likely stems from the lack of targeting the costs and burdens of pharmaceutical manufacturing.[73] Although the Tax Cuts and Jobs Acts did put available money back into the coffers of pharmaceutical companies, it did not directly impact the costs of transitioning pharmaceutical manufacturing back to the United States.[74] The law does not reduce the millions of dollars expended on Food and Drug Administration approval of manufacturing sites within the United States nor does it create an expediated process of approving the United States sites.[75] Further, it fails to increase a skilled workforce necessary to manufacture complex pharmaceuticals, and it does not directly incentivize pharmaceutical companies to develop more modern manufacturing processes, such as continuous manufacturing.[76] Instead, the Tax Cuts and Jobs Act repealed 26 U.S. Code § 199, which ironically encouraged multinational companies to manufacture in the United States.[77] By targeting these needed processes and costs, the government would be more likely to incentivize or reinforce reshoring of pharmaceutical manufacturing.

In order to incentivize pharmaceutical companies, tax credits and grants should be directed toward the local manufacturing of essential pharmaceuticals, such as those on the WHO's Essential Medicines List[78] or lists compiled by hospitals. Furthermore, not only should the government incentivize continuous manufacturing, as discussed below, but they should also offer tax write-offs related to property taxes and reshoring. Specifically, the government should re-enact 26 U.S. Code § 199, which would encourage domestic

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https://www.matheson.com/news-and-insights/article/the-us-tax-reform-impact-in-ireland-game-changer-or-business-as-usual.

73. Andrew R. Roberson, Kevin Spencer & Emily A. Mussio, *A Look at Tax Code Section 199's Last Stand*, LAW360 (Nov. 6, 2018), https://www.mwe.com/insights/a-look-at-tax-code-section-199/.

74. Gardner, *supra* note 67.

75. Such incentives as an accelerated FDA assessment which saves money can be effective if targeting specific desired achievements, such as reshoring production. *See generally* FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY 53–56 (2009) (discussing the use of prizes to reinforce achievement in pharmaceutical innovation, such as when used with orphan drugs).

76. These are all barriers suggested by surveys of why reshoring is not occurring and what would be necessary for the U.S. to reshore necessary medicine manufacturing. *See* Gallagher & Mollohan, *supra* note 50 (discussing reshoring amongst all industries). *See also* Narayan Laksham, *Q&A: Barriers to American Re-shoring*, MANUFACTURING (Apr. 10, 2013), https://www.manufacturing.net/labor/article/13057122/qa-barriers-to-american-reshoring.

77. Roberson, Spencer & Mussio, *supra* note 73.

78. *See Executive Summary: The Selection and Use of Essential Medicines, Report of the 22nd WHO Expert Committee on the 2019 Selection and Use of Essential Medicine*, WORLD HEALTH ORGANIZATION [WHO] (2019).

manufacturing.[79] When combining this historical tax write-off of nine percent with Trump's reduction of the corporate tax to twenty-one percent, those reshoring should see the United States' taxing system as more comparable to Ireland's corporate tax of twelve and a half percent.[80] This tax will specifically target reshoring instead of just placing more money into the pharmaceutical companies' coffers. The further addition of property tax reductions will increase potential locations for reshoring and incentivize companies to reshore by reducing local facility costs.[81]

B. Using Tax Incentives and Subsidies to Increase Continuous Manufacturing Development and Adoption

Certain experts suggest for the United States to compete with manufacturing conducted in China and India, the United States must update manufacturing technology.[82] One such manufacturing process that is considered the future of pharmaceutical manufacturing is continuous manufacturing.[83] Continuous manufacturing involves feeding raw materials down an assembly line of fully integrated APIs or finished pharmaceutical products.[84] In contrast, the traditional way of manufacturing pharmaceuticals

79. A domestic manufacturing tax write-off, similar to a reshoring tax write-off, was available prior to the 2017 tax act. As such, bringing back something similar directed at domestic pharmaceutical manufacturing would be similar to a historical tax, while also targeting the behavior we want to change. *See generally* John Bentil, *How Tax Reform Will Affect the Pharmaceutical Industry*, PHARM EXEC (Feb. 15, 2018), http://www.pharmexec.com/how-tax-reform-will-affect-pharmaceutical-industry (discussing the repeal of the domestic manufacturing tax write-off).

80. *See id.* Although the corporate tax does not target manufacturing, it does combine with Research and Development tax credits to make the United States look more favorable as a place for various processes. *See generally id*. President Biden's presented plan would increase the corporate tax from 21 to 28%. *See* Michelle P. Scott, *Biden's Tax Plan: What's Enacted, What's Proposed*, INVESTOPEDIA (Apr. 29, 2021), https://www.investopedia.com/explaining-biden-s-tax-plan-5080766 (also suggesting "American corporations' foreign income generally would be subject to a tax of 21%.").

81. It should be noted that property taxes are generally state taxes and would need to be approved by states. *See generally* Agnes Shanley & Lauren Lavelle, *Lower Taxes, More Flexibility Crucial to Retaining Pharma Employment*, 33 BIOPHARM 52, 52–53 (2020). Stipulations for property tax reductions should be placed on utilization of such properties for pharmaceutical manufacturing, thus reinforcing the desired behavior.

82. Woodcock, *supra* note 27 (discussing the necessity of using advanced manufacturing to regain competitiveness with China).

83. In Jane Woodcock's testimony before Committees, she stated, "Advanced manufacturing offers many advantages over traditional pharmaceutical manufacturing, and if the United States invests in this technology, it can be used to reduce the Nation's dependence on foreign sources of APIs, increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls." Woodcock, *supra* note 27.

84. Babu Padmanabhan, *True Continuous Manufacturing*, AUTOMATION & CONTROL (Feb. 28, 2017), https://www.pharmamanufacturing.com/articles/2017/true-continuous-manufacturing/.

is batch manufacturing, in which pharmaceuticals are manufactured in discrete steps and quality testing is conducted after each step.[85]

As mentioned above, continuous manufacturing is considered the future. This stems from the fact that continuous manufacturing frequently reduces long-term costs and increases efficiency with the changes in manufacturing processes.[86] It reduces costs because of the reduction of steps and travel involved and can be modified more easily based on market fluctuations.[87] Continuous manufacturing requires less space than batch manufacturing, with experts suggesting it takes up seventy percent less space than batch manufacturing.[88] Further, automated monitoring detects errors quickly after they occur instead of after each batch and reduces human error through automation, reducing waste and potential recalls.[89] As a result of the reduction in recalls, errors, and wastes, even the FDA suggests that pharmaceutical manufacturers should invest in continuous manufacturing.[90]

However, continuous manufacturing has upfront challenges. Start-up costs are high as machines must be calibrated to function and workers must be highly skilled.[91] Furthermore, technology is

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85. *See* Sau Lee, *Modernizing the Way Drugs Are Made: A Transition to Continuous Manufacturing*, U.S. FOOD AND DRUG ADMINISTRATION (May 17, 2017), https://www.fda.gov/drugs/news-events-human-drugs/modernizing-way-drugs-are-made-transition-continuous-manufacturing.

86. *See* Clive Badman et al., *Why We Need Continuous Pharmaceutical Manufacturing and How to Make It Happen*, 108 J. OF PHARM. SCIS. 3522, 3522 (2019).

87. *See* Kamna Jhamb, *Continuous Manufacturing – Continuous Manufacturing in Pharmaceuticals: Implications for the Generics Market*, DRUG DEVELOPMENT & DELIVERY (Nov./Dec. 2019), https://drug-dev.com/continuous-manufacturing-continuous-manufacturing-in-pharmaceuticals-implications-for-the-generics-market/; The Brookings Institute, *Promoting Continuous Manufacturing in the Pharmaceutical Sector* (last accessed May 2, 2020), https://www.brookings.edu/wp-content/uploads/2015/10/meetingsummary_101915_continuousmanufacturing.pdf.

88. *See* Jhamb, *supra* note 87.

89. *See id*.; *See also* Stephen McCarthy, *Converting to a "Batch-less" World: Quality Implications of Continuous Manufacturing*, PHARMACEUTICAL PROCESSING WORLD (Mar. 26, 2019), https://www.pharmaceuticalprocessingworld.com/converting-to-a-batch-less-world-quality-implications-of-continuous-manufacturing/; *See also* Lee, *supra* note 85.

90. *See* Woodcock, *supra* note 27 (discussing the need for advanced manufacturing, such as continuous manufacturing); *See also* The Brookings Institute, *supra* note 87; *See also* Sarah Massey, *Making The Switch: Continuous Manufacturing vs. Batch Processing of Pharmaceuticals*, LIFE SCIENCE BLOGS (May 5, 2016), https://xtalks.com/Continuous-And-Batch-Manufacturing-Pharmaceuticals/ (reviewing the increase in recalls of 1200% from 2004–2015 and wastes of up $50 billion annually due to recalls and inefficiency).

91. Badman et al., *supra* note 86, at 3523; Jhamb, *supra* note 87; J. Christopher McWilliams et al., *The Evolving State of Continuous Processing in Pharmaceutical API Manufacturing: A Survey of Pharmaceutical Companies and Contract Manufacturing Organizations*, 22 ORGANIC PROCESS RESEARCH & DEV. 1160–61 (2018) (discussing the hesitation of corporations investing in continuous manufacturing because of risks associated with new technology).

still in the innovation stage and comes with significant risks when initiating continuous manufacturing.[92] As a result, although some of the major originator manufacturers are slowly transitioning to continuous manufacturing, generics manufacturers are reluctant to initiate transitioning.[93] To generic manufacturing companies, the costs and risks appear to currently outweigh the benefits.[94] However, generics switching to continuous manufacturing can reduce the estimated $50 billion spent on inefficient manufacturing processes.[95] As such, continuous manufacturing should become a more appealing method as costs increase in China and machinery begins to deteriorate.[96]

To further incentivize generic and originator companies into adapting continuous manufacturing, the government should provide subsidies.[97] Such subsidies would reduce costs of adoption of a risky, innovative technology while also enhancing the manufacturing infrastructure within the United States. Further, as with the reshoring taxes, these subsidies should be contingent on companies locally manufacturing necessary generics. This would increase generics manufacturing, would eventually offset patients' costs for buying generics,[98] and would reduce the vulnerability of the United States' supply chain.

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92. Badman et al., *supra* note 86, at 3523; McWilliams et al., *supra* note 91, at 1160–61.

93. Michael Mezher, *Continuous Manufacturing: Industry Calls for Changes to FDA's Draft Guidance*, REGULATORY FOCUS (May 31, 2019), https://www.raps.org/news-and-articles/news-articles/2019/5/continuous-manufacturing-industry-calls-for-chang.

94. *See generally id*.; Jhamb, *supra* note 87. As discussed above, the competitive nature of generic manufacturing and the lower profit margins deter generic companies from taking higher risks. *See supra* text accompanying notes 22–25.

95. *See* Shula Neuman, *Pharmaceutical Industry Wastes $50 Billion a Year Due to Inefficient Manufacturing*, THE SOURCE (Oct. 6, 2006), https://source.wustl.edu/2006/10/pharmaceutical-industry-wastes-50-billion-a-year-due-to-inefficient-manufacturing/ (referring to a study conducted by Jackson Nickerson and Jeffrey Macher). As mentioned above, batch manufacturing generally requires multiple buildings and starting and stopping multiple processes for production of a pharmaceutical. *See* Jhamb, *supra* note 87; Massey, *supra* note 90.

96. Experts suggest that most batch manufacturing equipment has a life cycle of about 4 to 12 years. *See* Jhamb, *supra* note 87.

97. Subsidies, such as grants, were mostly given to universities thus far. Pharmaceutical Technology Editors, *FDA Awards Five Grants for Advanced Biomanufacturing Research*, ADVANCING DEVELOPMENT AND MANAGEMENT (Sept. 24, 2018), http://www.pharmtech.com/fda-awards-five-grants-advanced-biomanufacturing-research. Instead, directly providing funding to pharmaceutical companies might encourage buy-in from industry players.

98. U.S. Food and Drug Admin., *New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, GENERIC COMPETITION AND DRUG PRICES, (Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

C. Using Government Subsidies and Prizes to Incentivize Universities and Private Entities to Develop Better Continuous Manufacturing

Aside from using tax incentives and grants for pharmaceutical companies, expanding grants to universities and private institutions to further develop continuous manufacturing processes and to train the workforce are also important investments.[99] Providing such grants will target two reasons for hesitation of transitioning manufacturing back to the United States: high upfront costs and risky transitioning due to newer technology and a less skilled workforce.[100]

If companies choose to reshore in order to take advantage of grants or tax incentives for continuous manufacturing, they still face the risks of transitioning to a newer technology. And experts suggest that there are very technical and significant modifications that must be made depending on the type of pharmaceutical manufactured, the size of the batch, and switching between products.[101] Indeed, changing of medications can cause differing pressures on the steel mechanisms and may cause damage if proper modifications are not made.[102] By collaborating with leaders in engineering and manufacturing processes at universities and private organizations, the government can take out some of the risk by providing needed basic research that provides further knowledge regarding risks and necessary modifications.[103] For instance, in 2018, the FDA provided five grants to universities in order to provide further research into the most effective and best practices in continuous manufacturing.[104] These grants were for the exploration of continuous manufacturing of biologics, but this type

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99. NAT'L ACADS. OF SCIS., ENG'G, & MED.; DIV. ON EARTH & LIFE STUDIES; BD. ON CHEMICAL SCIS. & TECH., CONTINUOUS MANUFACTURING FOR THE MODERNIZATION OF PHARMACEUTICAL PRODUCTION: PROCEEDINGS OF A WORKSHOP 1, 4 (Jan. 30, 2019). (discussing current grant projects to universities to increase research for advancements in continuous manufacturing. The workshop also discussed the importance of private-public partnerships to promote adoption of and innovation in continuous manufacturing).

100. Badman, *supra* note 86, at 3523; Miller, *supra* note 44.

101. Rakesh Singh Chaudhary, Ajay Pazhayattil, & Jana Spes, *Continuous Manufacturing: A Generic Industry Perspective¸* ADVANCING DEV. AND MFG. (May 30, 2017), http://www.pharmtech.com/continuous-manufacturing-generic-industry-perspective.

102. *Id.*

103. U.S. Food and Drug Admin., *New Evidence Linking*, in GENERIC COMPETITION AND DRUG PRICES, *supra* note 98. (The FDA partnered with Biomedical Advanced Research and Development Authority (BARDA) to promote advancements).

104. Pharmaceutical Technology Editors, *FDA Awards Five Grants for Advanced Biomanufacturing Research*, ADVANCING DEV. AND MFG. (Sept. 24, 2018), http://www.pharmtech.com/fda-awards-five-grants-advanced-biomanufacturing-research. These could be expanded to further promote advancements.

of grant program could be expanded to increase knowledge of what modifications are necessary for various generics. Prizes should also be implemented to further incentivize efficacious practices of continuous manufacturing.[105] These prizes would provide reinforcement to better the process rather than just grants that provide funding for exploration.[106]

Furthermore, universities and private industries also hold the keys to training a skilled workforce to further reduce risks. Most pharmaceutical companies spent time and money training the workforce in China to complete very technical skills related to batch manufacturing.[107] Furthermore, as manufacturing shifted significantly to China and other countries, the skilled United States' manufacturing workforce transitioned to other jobs.[108] As a result, a skilled workforce must be trained to conduct the technical and complex tasks within continuous manufacturing.[109] Partnering with universities and technical schools to recruit skilled workers from their pools of students is necessary. Pharmaceutical companies and other private industries should supplement such programs by hiring and training students.[110] Grants from the government will help incentivize such recruitment and training of skilled workers.

V. INCENTIVIZING ALTERNATIVE MANUFACTURING COMPETITORS TO INCREASE LOCAL PRODUCTION

Aside from luring pharmaceutical companies back from China through incentives, the United States also possesses the ability to attract new local competitors into the generics industry. For example, hospital organizations are often major buyers of pharmaceuticals and as a result, are substantially affected when pharmaceutical shortages occur or medications are adulterated.[111] Hospital administration stated that surgeries and treatments

105. While subsidies such as grants can help fund projects to further knowledge, prizes can further innovation by rewarding not only exploration, but also invention of efficacious processes. *See generally* ABBOTT & DUKES, *supra* note 75, at 44, 53–54.

106. *Id.* Although not as cost-effective as choosing either a grant or a subsidy, this system provides the necessary funds for basic research while also rewarding those coming up with practical solutions.

107. *See generally* Carter Smyth, *The Viability of Reshoring Manufacturing to the U.S.*, BUS. INTELLIGENCE (Dec. 5, 2018), https://www.mbtmag.com/business-intelligence/article/13248105/the-viability-of-reshoring-manufacturing-to-the-us (discussing the barriers to reshoring to the United States for general industries).

108. GIBSON, *supra* note 6, at 282 (2018).

109. Badman, *supra* note 86, at 5523.

110. *Id.* (discussing the importance of providing ways to train skilled workers).

111. Reed Abelson and Katie Thomas, *Fed Up with Drug Companies, Hospitals Decide to Start Their Own*, N.Y. TIMES (Jan. 18, 2018), https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html.

were delayed or cancelled as a result of such shortages.[112] Additionally, with the increasing prices of pharmaceuticals, hospital organizations exhibited interest in entering the pharmaceutical generics competition to reduce costs.[113]

Indeed, in 2018, over 500 hospital organizations with over $100 million in start-up money from philanthropic groups initiated the process of manufacturing generics.[114] Named Civica Rx, this non-profit pharmaceutical manufacturer is now capable of providing needed medications to over 1,200 hospitals with up to twenty generic pharmaceuticals.[115] Although Civica Rx partnered with manufacturers around the world, diversifying their manufacturers between Ireland, Portugal, and other countries, the non-profit suggested they are dedicated to increasing manufacturing in the United States as well ensuring a safe supply chain.[116]

As such, the United States government should also engage non-traditional pharmaceutical manufacturers through incentives to increase local production. New alternative manufacturers will increase competition and should lead to lower generic prices.[117] Not only should the government use tax incentives, such as those given to traditional pharmaceutical companies, incentives and prizes should also be introduced to guide these hospital organizations into green continuous manufacturing.[118] By placing

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112. Civica Rx, *Quality.Supply.Price. How Civica Rx Aims to Solve the US Hospital Drug Shortage Crisis*, EXEC. SUMMARY (Oct. 2019), https://civicarx.org/wp-content/uploads/2019/10/Civica-Rx-White-Paper-FINAL-10.01.19-1.pdf.

113. Alison Kodjak, *Hospitals Prepare to Launch Their Own Drug Company to Fight High Prices and Shortages*, NPR (Sept. 6, 2018), https://www.npr.org/sections/health-shots/2018/09/06/644935958/hospitals-prepare-to-launch-their-own-drug-company-to-fight-high-prices-and-shor.

114. Carolyn Y. Johnson, *Hospitals Are Fed Up with Drug Companies, So They're Starting Their Own*, WASH. POST (May 6, 2020), https://www.washingtonpost.com/national/health-science/hospitals-are-fed-up-with-drug-companies-so-theyre-starting-their-own/2018/09/05/61c27ec4-b111-11e8-9a6a-565d92a3585d_story.html.

115. John George, *St. Luke's Receives First Shipment from Nonprofit Generic Drug Company*, HEALTH CARE (Mar. 5, 2020), https://www.bizjournals.com/philadelphia/news/2020/03/05/st-lukes-receives-first-shipment-from-nonprofit.html.

116. *See* Civica Rx, *Hikma and Civica Rx Sign Long-term Agreement*, CIVICA RX (July 23, 2019), https://civicarx.org/hikma-and-civica-rx-sign-long-term-agreement/ (discussing the partnership with Hikma, which has manufacturing sites in Europe and the Middle East); Civica Rx, *Civica Recognized in Senate Hearing on Coronavirus Supply Chain*, CIVICA RX (Mar. 17, 2020) [hereinafter Civica RX Senate Hearings], https://civicarx.org/civica-recognized-in-senate-hearing-on-coronavirus-supply-chain/.

117. *See* U.S. Food and Drug Admin., *New Evidence Linking*, in GENERIC COMPETITION AND DRUG PRICES, *supra* note 98.

118. *See* Luke Rogers & Klavis F. Jensen, *Continuous manufacturing – the Green Chemistry Promise?*, 21 GREEN CHEMISTRY (2019), https://pubs.rsc.org/en/content/articlehtml/2019/gc/c9gc00773c (reviewing portions of continuous manufacturing that can be done in more environmentally friendly manners).

contingencies on funding, the government is better able to influence long-lasting and efficient manufacturing processes.[119]

Aside from providing incentives for continuous manufacturing, the government should also provide incentives by encouraging or mandating that pharmaceutical benefits managers (PBMs)[120] must contract with these non-traditional generic manufacturers. These PBMs conduct negotiations with pharmaceutical companies in an effort to lower rates for patients.[121] However, PBMs are often influenced into contracting with originators companies, as these brand-name pharmaceutical companies often offer larger rebates, a main contributor of PBM profits.[122] By mandating that PBMs contract with the non-traditional manufacturers for generic pharmaceuticals for all Centers for Medicare and Medicaid Services (CMS) beneficiaries, the government could level the playing field for non-traditional entrants into the pharmaceutical industry.[123] Such was discussed during senate hearings when Civica Rx supporters suggested that more generic manufacturers would enter the market if they could be guaranteed payors.[124] This was the path the Veteran's Administration initiated by joining forces with Civica Rx.[125]

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119. As generally discussed by Abbott and Dukes, prizes can be awarded to those showing innovation that progresses advancements in areas such as green manufacturing. *See generally* ABBOTT & DUKES, *supra* note 75, at 53–54 (discussing the uses of prizes to further innovation in pharmaceuticals).

120. PBMs are third-party companies that negotiate prices and rebates with pharmaceutical manufacturers, set copays, determine formularies, as well as determine reimbursement schemes for pharmacies. *See* Elizabeth J. Seeley & Shawn Bishop, *Missing from the PBM Hearings: Value-Based Drug Reimbursement*, FIRST OPINION (Apr. 11, 2019), https://www.statnews.com/2019/04/11/pbm-hearings-value-based-drug-reimbursement/.

121. *See id*.

122. *See id*. (discussing how PBMs make profits through rebates); The higher the list price, generally the more the PBM makes in profit. See also Wayne Winegarner, *It's Time to Switch Our Pharmacy Benefit Manager*, ECONOSTATS (May 9, 2017), https://www.forbes.com/sites/econostats/2017/05/09/its-time-to-switch-our-pharmacy-benefit-manager/#11f5bc911892.

123. Although the government can step in and ensure payors for local manufacturers, this can also be accomplished by the domestic generic manufacturers contracting that partner hospitals agree to buy a certain amount from the manufacturer. *See* George, *supra* note 115 (discussing how Civica Rx partners agree to buy 50% of necessary medicines from Civica Rx for lower prices). However, the government payor's power to have PBMs buy from local generic manufacturers is significant as a common barrier to more local generic competition is guaranteed payors.

124. *See* Civica Rx Senate Hearings, *supra* note 116.

125. *See* Louis Garguilo, *CDMO-To-Hospital: A Direct Ending for Generic Shortages?*, FROM THE EDITOR (Aug. 15, 2019), https://www.outsourcedpharma.com/doc/cdmo-to-hospital-a-direct-ending-for-generic-shortages-0002. Because the VA has "U.S.-sourced-first regulations," the federal government payors can influence generic manufacturers to reshore by providing guaranteed payors first to domestic manufacturers.

VI. COUNTERARGUMENTS

Both incentivizing pharmaceutical powerhouse companies to reshore and incentivizing new entrants into the local generic manufacturing market come with significant challenges and critiques. Within these counterarguments are the benefits of pursuing more globalist relationships. Technology as well as quality can improve when countries share research and resources.[126] Further, there is some benefit in countries specializing in different processes as these countries excel at manufacturing of APIs or manufacturing of finished pharmaceutical products or improving technology.[127] And in an ideal world, one country should be able to rely on another country for upholding contracts for supplies and goods, including pharmaceuticals.[128] Unfortunately, in attempts to lower prices and strike better trade deals, countries continue to exhibit a willingness to use such supplies as bargaining chips.[129] As a result, governments cannot always count on prior trade deals as tensions sometimes flare between countries. Because resources are finite, countries may never be at a place where they openly and willingly trade resources without pressure regarding what their country receives in return. In order to ensure that supply chains for necessary supplies are kept open, countries must either diversify or must reshore essential supplies to protect their populations.

Others will argue that the costs of reshoring or the environmental impacts are too great for the United States government to bring back pharmaceuticals. However, as China and other countries increase wages and benefits to their populations, the differences in workforce costs will continue to diminish.[130] For example, China is currently increasing environmental regulations

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126. As Abbott and Dukes point out, "traditional knowledge, native skills, and natural resources can enrich the overall process to universal benefit." *See* ABBOTT & DUKES, *supra* note 75, at 287.

127. Such countries as China and India have specialized knowledge of processes that help make manufacturing efficient that other countries might not have. This can increase efficiency in processing and reduce costs. *See* David Alvaro, Emilie Branch, & Cynthia A. Challener, *Glocalization of Drug Manufacturing: Glocalization: Balancing Global and Local Concerns in Manufacturing and the Supply Chain*¸ PHARMA'S ALMANAC (Oct. 28, 2019), https://www.pharmasalmanac.com/articles/glocalization-of-drug-manufacturing.

128. However, as COVID–19 has shown, countries halted and disrupted exportation of materials even though companies had relied on the materials and related contracts. *See generally* Ana Swanson, *Coronavirus Spurs U.S. Efforts to End China's Chokehold on Drugs*, N.Y. TIMES (Mar. 11, 2020), https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html.

129. Chinese economists suggested that Chinese pharmaceutical companies could halt exportation of needed medications to the United States as a retaliatory measure or bargaining chip during the trade war. *See* Tang, *supra* note 10.

130. *See* Buchanan, *supra* note 64, (pointing out that Chinese wages have tripled from 2005–2016).

after seeing the effects of manufacturing on its environment.[131] As such, companies will continue to see profits dwindle as environmental regulations stiffen. Within the United States, if the pharmaceutical companies switch to greener continuous manufacturing, they can reduce their carbon footprint and create more sustainable and efficient processes that require less resources.[132] Thus, incentivizing continuous manufacturing will not only reduce costs but also should reduce problems meeting environmental regulations.[133]

Another counterargument is that reshoring will drive up pharmaceutical costs. Indeed, bringing back pharmaceutical manufacturing does potentially see pharmaceutical costs rising as costs of production will initially be higher due to higher wages of workers in the United States and the switch to more technologically advanced manufacturing.[134] However, China also currently possesses the ability to increase prices and has increased prices of certain medications and vitamins for which China controls most of the market.[135] China also currently relies on the United States for finished pharmaceutical products[136] and as such, may keep generic prices down so that Chinese residents will not see significant increases in finished pharmaceutical products coming from the United States. Nevertheless, as China improves its own finished pharmaceutical product manufacturing processes,[137] China's government will have less incentive to maintain lower exported generic prices. As such, pharmaceutical prices will most likely rise. Additionally, as their residents and skilled workforce advocate for

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131. Swarna Jayakumaran, *The Impact of China's Environmental Law on the Procurement of API and Excipients*, BEROE WHITE PAPER (July 16, 2019), https://www.beroeinc.com/whitepaper/the-impact-chinas-environmental-law-on-procurement-of-api-and-excipients/.

132. Rogers & Jensen, *supra* note 118, at 3483 (reviewing an example of green manufacturing that could be expanded to domestic manufacturing. "GlaxoSmithKline's creation of a commercial-scale continuous system in Singapore, a site that promises 50% reduction in carbon footprint and 50% reduction in costs, demonstrates the pharmaceutical industry's willingness to adapt to continuous manufacturing").

133. *Id.* (describing methods to reduce environmental footprint and methods to reduce costs).

134. *See* Buchanan *supra* note 64; *But see* Pofeldt, *supra* note 65 (suggesting that even with rising wages, Chinese Workers only make $8,060 annually); *See also* Ned Pagliarulo, *Pharma's Slow Embrace of Continuous Manufacturing*, DEEP DIVE (Sept. 24, 2018), https://www.biopharmadive.com/news/pharmas-slow-embrace-of-continuous-manufacturing/532811/.

135. *See* GIBSON, *supra* note 6, at 91–104.

136. *See* Huang, *supra* note 43.

137. *See id.*; WHO China, *supra* note 9, at 18–19.

higher wages and stricter environmental regulations,[138] China will likely be forced to raise prices to offset benefits to their workforce and the increasing manufacturing costs due to regulations. Finally, if more local competitors are introduced into the United States' generics market, prices should ideally go down.

VII. CONCLUSION

As it stands, the United States is not prepared for potential attacks on its pharmaceutical supply chain. By allowing other countries, such as China, to control substantial amounts of manufacturing without any true alternative plans in place, our supply chains of essential medications are in the same positions of the Germans' supply chains in World War II. Should China decide to halt exports, thousands, if not millions, of Americans would be in jeopardy as their health falters without necessary pharmaceuticals.

As such, the United States government must act to incentivize traditional as well as non-traditional manufacturers to initiate manufacturing of necessary medications on the United States' soil.[139] This can be achieved through the use of tax incentives and grants to encourage reshoring and utilization of continuous manufacturing as well as grants, subsidies, and other incentives for further research. Such research will reduce the risks manufacturers fear in reshoring. Further, engaging alternative manufacturers, such as hospital organizations, is also a viable method of increasing manufacturing locally and securing pharmaceutical resources. By engaging these suggestions, the United States will further protect our essential pharmaceutical supply chain from surprise and shocking attacks and will be out of the danger zone.

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138. *See* Ellen Chang, *American Companies Face Changing China Manufacturing Industry*, U.S. CHINA BUSINESS (Dec. 15, 2016), https://www.eastwestbank.com/ReachFurther/en/News/Article/American-Companies-Face-Changing-Manufacturing-Industry-in-China; *See also* Chris Devonshire-Ellis et al., *China's Rising Manufacturing Costs: Challenges and Opportunities*, CHINA BRIEFING (July 8, 2014), https://www.china-briefing.com/news/chinas-rising-manufacturing-costs-challenges-opportunities.

139. Diversification in the interim is most likely necessary until local continuous manufacturing is available.

THE INTERNATIONAL CRIMINAL COURT MUST PRIORITIZE THE PALESTINIAN CHILD PRISONERS

Re: International Human Rights Law; International Criminal Law; International Criminal Court, December 2020

NABEHA SHAER

ABSTRACT

In the Occupied Palestinian Territories, thousands of Palestinian children have been the subject of numerous human rights abuses through their subjugation to Israeli prisons and military court system. The International Criminal Court (ICC) must hear and prioritize the cases involving Israeli crimes against these Palestinian children. A review of the history of Palestine, an analysis of applicable international law, and a description of the role of the ICC will illustrate the necessity of the ICC's intervention on the crimes committed against the Palestinian children.

I. THE PALESTINE SITUATION

A. Identity

A historical analysis on recognition of 'Palestine' as a state provides analytical context to the present situation of Palestine. Early references to Palestine date at least as far back as the 12th century B.C., during which the "Philistines" inhabited the location of present-day Palestine, also known as Philastine (or Falasteen) in Arabic.[1] It is believed that the name of Palestine derived from these early inhabitants, the Philistines.[2] From 1517 to 1917 A.D., Palestine was under Ottoman imperial governance, with its own internal governance.[3] The internal Palestinian government of this time oversaw the historic outlines of the entire territory of historical Palestine.[4] This entailed the issuing of money and identity cards, and control over political diplomacy.[5] A crucial point in formalizing and nationalizing Palestinian identity was the 1834 Palestinian Peasant Revolt against Egypt.[6] This Revolt is

1. *Palestine*, HISTORY.COM (May 11, 2021), https://www.history.com/topics/middle-east/palestine.

2. *See* Joshua J. Mark, *Palestine Timeline*, ANCIENT.EU (Oct. 25, 2018), https://www.ancient.eu/timeline/palestine/ (last visited Jan. 25, 2021).

3. *Id.*

4. *Id.*

5. *Id.*

6. Ami Isseroff, *An Early Palestinian Revolt and the Beginnings of Palestinian National Consciousness*, MIDEASTWEB, http://www.mideastweb.org/palrevolt.htm (last visited Dec. 11, 2020).

recognized as the first application of the "concept of territorial state" and is observed as a catalyst for Palestinian collective identity.[7]

B. The Balfour Declaration

In 1917, just prior to the end of World War I, the British government issued a public statement, the Balfour Declaration.[8] In this declaration, Britain pledged to establish a "national home for the Jewish people" in Palestine, where indigenous Palestinian Muslims and Christians made up more than ninety percent of the population but where Arab-Jews made up less than ten percent.[9] The British army ruled over Palestine from the end of 1917, until a civil administration was established in 1920.[10] In 1920, Britain was awarded a mandate of Palestine that was later approved by the League of Nations in 1922.[11] While initially issued in 1917, the Balfour Declaration, as an aspect of the Zionist movement, is recognized as a catalyst for the 1948 Nakba ("the Catastrophe").[12]

C. The White Papers

The Zionist movement had two main axes: the acquisition of land and immigration.[13] After decades of Palestinian revolt to British occupation and Zionist movements, Britain, in 1939, issued the White Paper which states Palestine should be a bi-national state—one to be inhabited by both Arabs and Jews.[14] The result was a five-year limitation of Jewish immigration into Palestine, with required Arab consent to the immigration.[15] It additionally restricted land purchases by the immigrated Jews.[16] Zionist organizations responded by organizing illegal immigration to Palestine until British rule ended.[17] In 1947, the British

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7. *Id.*

8. *Id.*

9. *Balfour's Legacy in Palestine: A Century of Unjust Reign*, GENEVA INT'L CENTER FOR JUSTICE (Mar 11, 2017), https://www.gicj.org/positions-opinons/gicj-positions-and-opinions/1281-balfour%E2%80%99s-legacy-in-palestine-a-century-of-unjust-reign.

10. Avital Ginat, *British Mandate for Palestine,* 1914–1918–ONLINE. INTERNATIONAL ENCYCLOPEDIA OF THE FIRST WORLD WAR (Dec. 7, 2018), https://encyclopedia.1914-1918-online.net/article/british_mandate_for_palestine#:~:text=The%20British%20army%20ruled%20Palestine,by%20the%20League%20of%20Nations.

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

government announced its intention to terminate the mandate and return the Palestine question to the United Nations (UN).[18]

D. Palestine Partition Plan

On November 29, 1947, the UN General Assembly adopted a resolution to partition Palestine.[19] At the time of this partition, there were 1.2 million Arabs and only 608,000 Jews living in Palestine.[20] Resolution 181 gave up 54 percent of Palestine for the creation of a Jewish state, despite the Zionist movement owning only 7 percent of the land at this time.[21] This partition plan upset the indigenous Palestinians for taking the majority of Palestinian territory for a minority colonial settler population, and it upset Zionists who wanted a larger percentage of the land.[22] The Zionists, however, accepted the plan, granting them international recognition of a right to a Jewish state, while concurrently undermining the plan by saying its borders "will be determined by force and not by the partition resolution."[23] To this day, this statement, made by Israel's first prime minister, remains in effect, as Israel has yet to set its borders.[24]

E. Al-Nakba

The Zionist desire for an ethnically pure state led to the mass exodus of the native Palestinians, referred to as Al-Nakba by the Palestinians. Between 1947 and 1949, at least 750,000 Palestinians of the 1.9 million population, were forced to become refugees outside the borders of Palestine.[25] In these years, Zionist forces took over 78 percent of historic Palestine, ethnically cleansed and destroyed more than 530 villages and cities, and murdered over 15,000

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18. *Id.*

19. *Id.* See generally *G.A. Res. 181/2*, *Future Government of Palestine*, A/RES/181 (II) (Nov. 29, 1947), available at: undocs.org/en/A/RES/181(II).

20. *The Nakba – Introduction*, AMERICAN MUSLIMS FOR PALESTINE (2012), https://www.ampalestine.org/palestine-101/history/al-nakba/nakba-introduction (last visited Jan. 25, 2021).

21. *Id.*

22. *UN Partition Plan*, BBC NEWS (Nov. 29, 2001, 11:37 AM), http://news.bbc.co.uk/2/hi/in_depth/middle_east/israel_and_the_palestinians/key_documents/1681322.stm.

23. *Id.*; *The Nakba, 65 Years of Dispossession and Apartheid*, INSTITUTE FOR MIDDLE EAST UNDERSTANDING (May 8, 2013), https://imeu.org/article/the-nakba-65-years-of-dispossession-and-apartheid.

24. *UN Partition Plan*, BBC NEWS (Nov. 29, 2001, 11:37 AM), http://news.bbc.co.uk/2/hi/in_depth/middle_east/israel_and_the_palestinians/key_documents/1681322.stm.

25. *The Nakba Did Not Start or End in 1948*, AL JAZEERA (May 23, 2017), https://www.aljazeera.com/features/2017/5/23/the-nakba-did-not-start-or-end-in-1948.

Palestinians in a series of more than 70 massacres.[26] While Zionists recognize May 14, 1948 as Israeli Independence Day, May 15 marks the commemoration for Al-Nakba by the Arabs.[27] To today, Israel continues to oppress and dispossess Palestinians, although sometimes through less explicit methods than those used during the Nakba.[28]

F. Al-Naksa

The final 22 percent, of Palestine—the Gaza Strip and the West Bank—that remained out of the grasp of Israel in 1948 was later captured in 1967.[29] In a six-day war from June 5 to June 10, Israeli forces launched a surprise attack on Egypt, defeating its air force, and then occupied the Gaza Strip and West Bank.[30] In this attack, Israel also captured the Sinai Peninsula and the Golan Heights in Syria, allowing Israel to maintain military occupation and control over the land and resources without giving rights or citizenship to those living on the land.[31] Palestinians refer to this war as Al-Naksa, or the setback.[32] Nearly 20,000 Arabs were killed and over 300,000 additional Palestinians were displaced from Gaza and the West Bank.[33]

G. The First Intifada

The first Palestinian uprising against the Israeli occupation, the Intifada, occurred in late 1987 after an Israeli truck rammed into a line of Palestinian workers waiting to return to the Gaza Strip, killing four and resulting in spontaneous demonstrations.[34] The First Intifada (derived from Arabic verb meaning "to shake off") began in the Gaza Strip and quickly spread to the West Bank.35

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26. *Id.*

27. *Id.*

28. *Id.*

29. *1967 WAR*, AMERICAN MUSLIMS FOR PALESTINE, https://www.ampalestine.org/palestine-101/history/1967%C2%A0war (last visited Jan. 25, 2021).

30. *Id.*

31. *Id.*

32. *Id.*

33. Nour Abu Aisha, *Palestinians Recall 1967 War, Observe Setback Day,* ANADOLU AGENCY (May 6, 2020), https://www.aa.com.tr/en/middle-east/palestinians-recall-1967-war-observe-setback-day-/1866274#:~:text=The%20war%20began%20with%20an,dead%20(soldiers%20and%20civilians).

34. *The First Intifada – Introduction*, AMERICAN MUSLIMS FOR PALESTINE (2009), https://www.ampalestine.org/palestine-101/history/intifadas/first-intifada-introduction (last visited Jan. 25, 2021).

35. *Id.*

The Palestinians engaged in demonstrations, rock-throwing against Israeli troops, and civil disobedience, such as commercial strikes and tax revolts.[36] Israeli governmental response was one of "force, might, and beatings," as described by the Prime Minister.[37] Between 1987 and the end of the First Intifada in 1993, Israel killed many Palestinians through live ammunition, deliberately broke demonstrator's limbs after capture, detained and tortured thousands without charges, and suspected Intifada leaders were deported or assassinated.[38] The United Nations Security Council Resolution 605 condemned Israel for the large number of Palestinian deaths occurring in the first weeks of the Intifada as a violation of the Geneva Conventions.[39]

H. Second Intifada

In late 2000, the Second Intifada, often referred to as Al-Aqsa Intifada, arose out of Israeli occupation policies that continued to violate international law and deprive Palestinians of their basic human rights.[40] In an attempt to provoke Palestinians, Israel's Prime Minister, Ariel Sharon, appeared before the Al-Aqsa compound with more than 1,000 Israeli police while repeating a phrase utilized during the 1967 Six-Day War, "[t]he Temple Mount is in our hands."[41] The Palestinians reacted almost immediately to the threat of Al-Aqsa, one of the holiest sites in Islam and a trust placed on the Palestinians as custodians of the site.[42] The Israeli Occupational Forces military offensives and administrative policies launched were structured to collectively punish Palestinians for the uprising.[43]

Although the UN released Resolution 1322 condemning Israel for its use of excessive force against the Palestinians within three weeks after the start of Israeli violence, hundreds of Palestinians had already been murdered and many more injured.[44] The

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36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*; *see generally* S.C. Res. 605 (Dec. 22, 1987) (adopted by the Security Council at its 2777th meeting.)

40. *The Second Intifada – Introduction*, AMERICAN MUSLIMS FOR PALESTINE, (2012), https://www.ampalestine.org/palestine-101/history/intifadas/second-intifada-introduction (last visited Jan. 25, 2021).

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*; *see* S.C. Res. 1322 (Oct. 7, 2000) (the situation in Middle East, including the Palestinian question).

Palestinian Center for Human Rights reported more than 4,973 Palestinian civilians killed during the Second Intifada, with at least 1,262 children amongst them.[45] In the five years of violence, more than 10,000 children were wounded.[46] Most of the deaths and injuries inflicted resulted from Israel's utilization of collective punishment, including mass airstrikes against densely populated areas in the Gaza Strip and major land assaults on West Bank cities, villages, and refugee camps.[47] Israel further demolished about 5,000 Palestinian homes and damaged another 6,500 beyond repair.[48] Other human rights violations conducted include an oppressive siege on all of Palestine, severe restrictions on Palestinian movements, checkpoints, and curfews. Israel also constructed the Apartheid Wall in 2002, which served as a land grab tactic, that the International Court of Justice ruled illegal.[49]

I. Negotiations

1. Oslo Accords

During the failed Madrid Peace Conference and talks the following year in 1992 in Washington, D.C., the Palestinian political delegation, comprised under the Palestinian Liberation Organization (PLO), focused its efforts on negotiating an end to the illegal Israeli settlements in the occupied West Bank and Gaza Strip.[50] In the subsequent "peace processes," the Oslo Declaration of Principles (Oslo Accords or Oslo I and Oslo II), Israel set aside such issues of settlements, the status of Jerusalem, and refugees.[51] Rather than serve as an actual peace treaty, the Oslo Accords' aim was to establish interim governance and create a framework for further negotiations for a final agreement to be concluded in 1999.[52]

The Oslo Accords were intended to last five years, but to this day, there has been virtually no progress.[53] The Accords changed

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45. *Id.*

46. *The Second Intifada – Introduction*, AMERICAN MUSLIMS FOR PALESTINE, (2012), https://www.ampalestine.org/palestine-101/history/intifadas/second-intifada-introduction (last visited Jan. 25, 2021).

47. *Id.*

48. *Id.*

49. *Id.*; *see generally* Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion, 2004 I.C.J. 131 (July 9).

50. Rawan Damen, *The Price of Oslo*, PALESTINE REMIX (2013) https://interactive.aljazeera.com/aje/palestineremix/the-price-of-oslo.html#/14 (last visited Sept. 6, 2020).

51. *Id.*

52. *Id.*

53. *Id.*

control of major Palestinian cities to the newly formed Palestinian Authority (PA).[54] Oslo II, signed in 1995, divided the illegally occupied West Bank into three non-contiguous regions, Areas A, B, and C.[55] In Areas A and B, Israel has full control of external security thereby giving Israel the ability to enter at any time, usually to detain individuals or conduct extra-judicial execution, while the PA remains in charge of social aspects, such as education.[56] While the PA was assigned control over Area C, which represents 60 percent of the West Bank, Israel has retained control over all matters, and transfer of control over Area C to the PA has yet to happen.[57]

2. Camp David Summit

In 2000, there was another attempt for a "peace agreement" with the insistence of U.S. President Bill Clinton.[58] PLO Chairman, Yasser Arafat, and the Palestinian negotiators offered concessions that were far beyond international consensus for what a peace agreement should include; concessions such as Israeli sovereignty over parts of East Jerusalem.[59] Yet, the only proposals offered to Palestine by Israel were oral, vague, and only to be used as "bases for negotiations" rather than serve as serious negotiations in itself.[60] The oral proposals included grave concessions for the Palestinians, such as signing away the Palestinian refugee's right to return to Palestine.[61] Ultimately, the Camp David Summit ended without an agreement and a short few months later, the Second Intifada began.[62]

J. Wars

1. The 2008 Gaza War

There are three central wars of the 21st century, against the Gaza Strip, of special significance. First is the 2008 war in which Israel waged a three-week military offensive against the Gaza Strip

54. *Id.*
55. *Id.*
56. *Id.*
57. *Id.*
58. *What Did, in Fact, Happen at Camp David in 2000?*, INSTITUTE FOR MIDDLE EAST UNDERSTANDING (Oct. 28, 2005), https://imeu.org/article/what-did-in-fact-happen-at-camp-david-in-2000.
59. *Id.*
60. *Id.*
61. *Id.*
62. *Id.*

from the 27th of December to the 18th of January.[63] In the initial strike at the start of the offensive, Israel launched "80 jets, war planes, and helicopters dropp[ing] over 100 bombs on dozens of targets. . . ." [64] According to the United Nations Fact-Finding Mission on the Gaza Conflict, referred to as the Goldstone Report, Israel "launched at least 300 air and sea strikes against the Gaza Strip," targeting "37 houses; 67 security and training sites; 20 workshops; 25 public and private institutions; 7 mosques; and 3 educational institutions."[65] Police stations and the small fishing port were particularly under deliberate attack across Gaza.[66] On the eighth day, Israel, with one of the world's strongest and best-equipped armed forces, launched a ground invasion of Gaza, with support by artillery fire and fighter jets. [67] In contrast, the Palestinians in Gaza have no artillery, heavy weapons, tanks, air force, or navy.[68] The Goldstone Report details Israel's attempt to cut the Gaza Strip in two before focusing the attack on the northern portion.[69]

The Report details allegations of Israel's use of human shields, widespread mistreatment of civilians, detention, and transfer of a large number of Palestinians to Israeli prisons in unlawful circumstances. [70] Investigations and reports by human rights organizations, including Amnesty International, found that Israel "made extensive use of white phosphorous . . . in residential areas, causing death and injuries to civilians."[71] According to the Israeli human rights organization, B'Tselem, 1,390 Palestinians were killed in this offensive, including 344 children.[72] Thousands more were injured.[73]

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63. Rebecca Stead, *Remembering Israel's 2008 War on Gaza*, MIDDLE EAST MONITOR (Dec. 27, 2018, 8:33 AM), https://www.middleeastmonitor.com/20181227-remembering-israels-2008-war-on-gaza/.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. Rebecca Stead, *Remembering Israel's 2008 War on Gaza, MIDDLE EAST MONITOR* (Dec. 27, 2018), https://www.middleeastmonitor.com/20181227-remembering-israels-2008-war-on-gaza/.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

2. The 2012 Gaza War

In November 2012, tensions between Israeli occupying forces and Gaza increased, leading up to the Israeli offensive from the 14 to 21 of November.[74] On November 10, Israel killed four Palestinian teenagers playing football in a Gaza sports stadium, in response to an attack on a military Jeep.[75] This was followed by days of rocket fire on both sides, leading to Israel's official offensive launch.

Israel began by targeting a chief of the Hamas military wing, resulting in widespread protests.[76] Israel also struck twenty other points in the Gaza Strip and continued its missile strikes through the night. Hamas responded with rocket fire into Israeli cities the following day, no one was killed.[77] In the following days, Israel broadened its targets to include Hamas government sites. The World Health Organization condemned the strikes, stating Gaza's hospitals were overwhelmed with casualties and faced an imminent shortage of medical supplies.[78] At the same time, Israel's Interior Minister stated, "[t]he goal of the operation is to send Gaza back to the Middle Ages."[79] Days later, Israel agreed to a ceasefire.[80] 174 Palestinians were killed during this offensive, as well as 4 Israelis, and over 1,000 Palestinians were injured.[81]

3. The 2014 Gaza War

Two years later, from July 8 to August 26 of 2014, Israel launched its deadliest military offensive in recent history.[82] A month prior to the start of the offensive, a second Palestinian unity government was being formed between the democratically elected Hamas of the Gaza Strip and the Palestinian Authority (PA) of the West Bank.[83] Israeli Prime Minister, Benjamin Netanyahu, warned

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74. Hana Hussain, *Remembering Israel's 'Operation Pillar of Defence',* MIDDLE EAST MONITOR, (Nov. 14, 2017, 8:30 AM), https://www.middleeastmonitor.com/20171114-remembering-israels-operation-pillar-of-defence/.

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. Hana Hussain, *Remembering Israel's 'Operation Pillar of Defence'*, MIDDLE EAST MONITOR, (Nov. 14, 2017, 8:30 AM), https://www.middleeastmonitor.com/20171114-remembering-israels-operation-pillar-of-defence/.

80. *Id.*

81. *Id.*

82. Hana Hussain, *Remembering the 2014 Israeli offensive against Gaza,* MIDDLE EAST MONITOR, (July 8, 2018, 8:30 AM), https://www.middleeastmonitor.com/20180708-remembering-the-2014-israeli-offensive-against-gaza/).

83. *Id.*

the PA it had to choose between peace with Hamas or with Israel. Ten days later, three Israeli settlers went missing in the West Bank.[84] While Israel blamed Hamas, high-ranking Hamas officials denied involvement and there was no evidence to back allegations.[85] Israeli historian, Ilan Pappé, said any motivation for the kidnapping was caused by the murder of two Palestinian teenagers who were killed by Israeli forces in May.[86] The autopsy report was released the day before the kidnapping and showed the teenagers were killed by Israeli soldiers' live fire.

Widespread protests ensued in the Gaza Strip and West Bank; meanwhile, Israel bombarded the Gaza Strip, prompting rocket fire in response.[87] Following failed attempts to a ceasefire, Israel announced its start of the offensive on July 7.[88] Israel dropped 400 tons of bombs on Gaza within only the first 48 hours.[89]

Over the next two months, over 6,000 airstrikes were launched on the Gaza Strip, an area roughly the size of Washington DC. 500,000 Palestinians were displaced, 300,000 forced to shelter in UN schools, and electricity to hospitals was cut off.[90] Hamas fired rockets at Israeli military targets, but they lacked precision guidance systems.[91] In contrast, Israel used high-powered, U.S.-financed precision-guided arsenal, targeted at civilian areas including homes, schools, hospitals, and places of worship.[92]

Israel destroyed 32 tunnels that have been recognized as "Gaza's lifeline" during the 11-year Israeli-enforced blockade.[93] Over 20,000 buildings were destroyed, with costs for reconstruction estimated by the UN to be at $295 million.[94] By the end of hostilities, 2,251 Palestinians were killed, including 500 children, 67 Israeli soldiers and six civilians were also killed.[95] According to the UN, over 11,000 more Palestinians were wounded.[96] In 2015, the UN affirmed that Israel committed war crimes during the offensive due to its

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84. *Id.*

85. *Id.*

86. *Id.*

87. Hana Hussain, *Remembering the 2014 Israeli Offensive against Gaza,* MIDDLE EAST MONITOR, (July 8, 2018, 8:30 AM) https://www.middleeastmonitor.com/20180708-remembering-the-2014-israeli-offensive-against-gaza/.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

targeting of civilian areas, and supported the Palestinians in filing a petition with the International Criminal Court.[97]

K. The International Criminal Court, The Palestine Situation

The International Criminal Court (ICC or the Court) has accepted the State of Palestine's referral to investigate the Palestine situation. The Office of the Prosecutor is satisfied that there is a reasonable basis to proceed with an investigation and that war crimes have been or are being committed in the West Bank, including East Jerusalem, and the Gaza Strip. Prosecutor Bensouda has found jurisdiction over the Palestine situation.[98] On December 20, 2018, Prosecutor Fatou Bensouda's Office concluded that the statutory criterion under the Rome Statute for opening an investigation has been met.[99] These criteria include finding a reasonable basis that war crimes have been or are being committed in the Palestine territories of the West Bank, East Jerusalem, and the Gaza Strip (Gaza), potential cases arising from the situation would be admissible, and there are no substantial reasons to believe an investigation would not serve the interests of justice.[100] However, the Prosecutor requested a Pre-Trial Chamber jurisdictional ruling on the scope of the territorial jurisdiction in Palestine under the Rome Statute.[101] This ruling was specifically aimed to determine that the scope of the "territory" overseen by the Court's jurisdiction comprises of the West Bank, East Jerusalem, and Gaza.[102] The Pre-Trial Chamber's decision held that the ICC's territorial jurisdiction "in the Situation in Palestine extends to the territories occupied by Israel since 1967, namely Gaza and the West Bank, including East

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97. *Id.*

98. Statement, Office of the Prosecutor, *Statement of ICC Prosecutor, Fatou Bensouda, on the Conclusion of the Preliminary Examination of the Situation in Palestine, and Seeking a Ruling on the Scope of the Court's Territorial Jurisdiction*, ICC (Dec. 20, 2019), https://www.icc-cpi.int/Pages/item.aspx?name=20191220-otp-statement-palestine.

99. *Id.*

100. *See generally*, *Occupied Palestinian Territory,* ILO, https://www.ilo.org/beirut/countries/occupied-palestinian-territory/WCMS_532917/lang--en/index.htm (last visited Oct. 11, 2021); *Gaza Situation Report 87*, U.N. RELIEF AND WORKS AGENCY, https://www.unrwa.org/newsroom/emergency-reports/gaza-situation-report-87 (last visited Oct. 11, 2021); *State-backed Settler Violence*, B'TSELEM (Nov. 11, 2017), https://www.btselem.org/settler_violence.

101. *Id.*

102. *Statement of ICC Prosecutor, Fatou Bensouda, on the Conclusion of the Preliminary Examination of the Situation in Palestine, and Seeking a Ruling on the Scope of the Court's Territorial Jurisdiction*, *supra* note 98.

Jerusalem." [103] The Prosecutor's next step is to determine the priorities in the investigation. [104] The Palestinian child prisoners must be prioritized.

L. Gaza's Great March of Return

Starting on March 30, 2018, every Friday for over one year, Palestinians in Gaza have protested along the fence separating the besieged Strip from Israel. [105] The Palestinian protestors are demanding the right to return to their ancestors' homes—which they were expelled from in the 1948 Nakba—and an end to the continued Israeli blockade that has been deemed a collective punishment by the UN. [106] Throughout the year, Israeli snipers opened fire at protestors; killing 266 people—including 50 children—and injured 30,398 Palestinians. [107] The Gaza protests continued despite this.

M. Contemporary Diplomacy

The Trump administration has effectively ousted the United States from the role of mediator in the Palestinian-Israeli Situation by abandoning dialogue with Palestinian leadership while enthusiastically promoting Israeli far-right interests.[108] Prior to his Middle East Plan, the Trump administration oversaw the closure of the Palestine Liberation Organization in Washington, suspended aid to the Palestinian Authority, illegally transferred the US embassy in Tel Aviv to Jerusalem, and repealed all funding to the UN Relief Works Agency for Palestine Refugees in the Near East (UNRWA).[109]

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103. Situation in the State of Palestine, ICC-01/18, Decision on the 'Prosecution request pursuant to article 19(3) for a ruling on the Court's territorial jurisdiction in Palestine', 60 (Feb. 5, 2021), https://www.icc-cpi.int/CourtRecords/CR2021_01165.PDF.

104. *See* Statement, Office of the Prosecutor, *Statement of ICC Prosecutor, Fatou Bensouda, Respecting an Investigation of the Situation in Palestine* (Mar. 3, 2021), https://www.icc-cpi.int/Pages/item.aspx?name=210303-prosecutor-statement-investigation-palestine.

105. Huthifa Fayyad, *Gaza's Great March of Return Protests Explained*, AL JAZEERA (Mar. 30, 2019), https://www.aljazeera.com/news/2019/03/gaza-great-march-return-protests-explained-190330074116079.html.

106. *Id*.

107. *Id*.

108. Giulia Macario, *The (Farce) "Deal of the Century": A Perfect Distraction*, OPINIO JURIS (Mar. 2, 2020), https://www.opiniojuris.it/deal-of-the-century-3/.

109. Marwan Bishara, *Trump's 'Peace Plan': The Farce, the Fraud and the Fury*, AL JAZEERA (Jan. 29, 2020), https://www.aljazeera.com/indepth/opinion/trump-peace-plan-farce-fraud-fury-200128164004266.html.

Trump's Middle East Plan has four major points, any one of which would provide sufficient reason for any Palestinian negotiator to summarily reject the plan. The four points are: a redrawing of the boundaries to incorporate illegal Israeli settlements into Israeli territory and annexing the Jordan Valley (a fertile area that represents 30% of the Palestinian West Bank) [section 4]; recognizing Jerusalem as the "undivided capital" of Israel with Palestinian ability to name a remote, ancient village of Jerusalem as its own [section 5]; requiring a demilitarized "state" for Palestine without control of borders [section 7]; and denying the internationally-recognized right of return by Palestinian refugees [section 16].[110] The reference to Palestine as a "state" is euphemistic, as Israeli settlements would be scattered within and give no real right to self-determination.[111] Palestinian Authority (PA) President Mahmoud Abbas indeed did reject the plan, calling it the "final phase of the Balfour Declaration."[112] Some find that the plan was written in a way intended to make the Palestinians have no option but to reject it.[113]

In June 2020, the PA sent international mediators known as the Quartet—an international body comprised of the UN, European Union, US, and Russia—a Palestinian counterproposal. [114] This Palestinian proposal aims to create a "sovereign Palestinian state, independent and demilitarized" with East Jerusalem as its capital. [115] It leaves the door open to border modifications and exchanges of land equal "in size and volume and value—one to one," according to the Palestinian Prime Minister, Mohammad Shtayyeh. [116] This plan came as a response to Trump's plan providing the green light for Israel to annex large areas of the occupied West Bank, including illegal settlements, and the Jordan Valley.[117] Shtayyeh warned that if Israel moves ahead with planned annexation, the Palestinian government "will issue an announcement to establish a constitution for the state [of Palestine] and establish a founding council" to function in the place of

110. Macario, *supra* note 108.

111. *Id.*

112. President Mahmoud Abbas, Address following the emergency meeting of Palestinian leadership in Ramallah (Jan. 28, 2020).

113. Macario, *supra* note 108.

114. Ali Younes, *PA Proposes Demilitarised State as Counterproposal to Trump Plan,* AL JAZEERA (June 9, 2020), https://www.aljazeera.com/news/2020/06/pa-proposes-demilitarised-state-counterproposal-trump-plan-200609180154873.html.

115. *Id.*

116. *Id.*

117. *Id.*

Parliament.[118] Some, however, like Diana Buttu, a former member of the Palestinian negotiating team, criticized the Palestinian attempt at counterproposals.[119] Buttu argued, "[t]he only legitimate counter-proposal is to end this Israeli occupation" and that such counterproposals are self-destructive.[120]

II. THE PALESTINIAN CHILD PRISONERS

In the West Bank, occupied by Israel, about 45 percent of the approximately 2.9 million Palestinians are under the age of 18.[121] Israel is the only country in the world that automatically and systematically prosecutes children in military courts that lack fundamental fair trial rights and protection.[122] Since 1967, Israel has operated two separate legal systems, one for the Israeli settlers comprised of the civilian and criminal legal system, and one where Palestinians live under military law. [123] Israel prosecutes approximately 700 Palestinian children each year. [124] They are arrested, interrogated, and detained by Israeli army, police, and security agents.[125]

A clear, persistent, and systematic use of ill-treatment and abuse against the Palestinian child prisoners by Israeli officials has been clearly documented. The volume, consistency, and persistence of the allegations on such ill-treatment for over a decade is based upon the UN Children's Fund's (UNICEF) report of Children in Israeli Military Detention Observations and Recommendations. This report is also supported by monitoring and reporting mechanisms on grave child rights violations and by interviews conducted by UNICEF with Palestinian and Israeli lawyers and Palestinian children.[126]

The UNICEF report found that the pattern of ill-treatment includes arresting children at their homes between midnight and 5:00 AM by heavily armed soldiers, often with threats to the child

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118. *Id.*

119. Daoud Kuttab, *Palestinians Make 'Counter-Proposal' to Trump Peace Plan*, ARAB NEWS (June 9, 2020), https://www.arabnews.com/node/1687176/middle-east.

120. *Id.*

121. About section of the No Way to Treat a Child Campaign, DEFENSE FOR CHILDREN INTERNATIONAL – PALESTINE: NO WAY TO TREAT A CHILD (2020), https://nwttac.dci-palestine.org/about [hereinafter NO WAY TO TREAT A CHILD: About].

122. *Id.*

123. *Id.*

124. UNICEF, CHILDREN IN ISRAELI MILITARY DETENTION: OBSERVATIONS AND RECOMMENDATIONS 21 (2013), https://unispal.un.org/pdfs/UNICEF_CHILDINDET.pdf [hereinafter CHILDREN IN ISRAELI MILITARY DETENTION].

125. *Id.* at 9.

126. *Id.* at 2.

and their family. The children then experience extreme hardship from the actions of the armed soldiers. UNICEF found a pattern during the transfer to an interrogation site, which can last an hour to a whole day, that includes blindfolding the children and tying their hands with plastic ties; physical and verbal abuse, including the use of painful restraints amongst other abuses; and lack of access to water, food, toilet facilities, and medical care.

Once relocated to the Israeli interrogation site, the children are inflicted with physical violence; threats of physical violence, death, solitary confinement, and sexual assault against themselves or a family member; coerced confessions; interrogators forcing the child to sign forms and orders, in most cases, written in Hebrew which the vast majority of Palestinian children do not understand; and a complete lack of access to lawyers or family members throughout the interrogation.

During court appearances, treatment that is in contravention to the rights of the child persists.[127] In court, the children are shackled; denied bail and imposed with custodial sentences; and transferred outside of occupied Palestinian territory to serve sentences inside Israel, inconsistent with the Fourth Geneva Convention Article 76.[128] The emotional distress inflicted through these incarcerations has further lasting harmful effects, including additional distress from being isolated from their families—sometimes for months—and lack of access to education.[129]

A study of 739 Palestinian children detained by Israeli forces between 2013 and 2018 conducted by the Defense for Children International Palestine (DCIP) illustrates the severity and prevalence of the abuse inflicted onto these children. The DCIP study found that 73 percent experienced physical violence following arrest; 96 percent were interrogated without the presence of a family member; 49 percent signed documents in Hebrew; 74 percent were not properly informed of their rights; 20 percent were subject to stress positions; 64 percent faced verbal abuse, humiliation, or intimidation; 95 percent were hand tied; 86 percent were blindfolded; and 49 percent were detained from their homes in the middle of the night.[130]

These practices, in their entirety and on their own, are in violation of international law that protects all children against ill-treatment when in contact with law enforcement, military, and

127. *Id.* at 14.

128. *Id.* at 12–14.

129. *Id.* at 13.

130. NO WAY TO TREAT A CHILD: About, *supra* note 121.

judicial institutions.[131] International law, applicable in both Israel and Palestine, prohibits the use of torture and other cruel, inhuman, and degrading treatment or punishment under any circumstances.[132] This prohibition is absolute and unconditional.[133] There are no exceptions permissible for this prohibition, including security considerations or even the threat of war.[134]

III. BACKGROUND ON SELECT INTERNATIONAL TREATIES

Under international law, children who are accused, suspected, or convicted of breaking the law must be treated differently from adults in a similar position. The United Nations Convention on the Rights of the Child (CRC or the Convention) is a legally-binding, international agreement that sets out the civil, political, economic, social, and cultural rights of every child, without distinction.[135] The basic fundamental rights of every child include the rights to life, survival, and development; protection from violence, abuse, or neglect; an enabling education; be raised by, or have a relationship with, their parents; and express their opinions and be listened to.[136] The CRC is the most widely adopted international treaty in history, as 196 out of the 197 UN member states have ratified it, the United States being the one exception.[137]

While the Convention is essential in its entirety, a number of the Articles are crucial in their applicability to the Palestinian child prisoners.[138] Article 3, for instance, emphasizes that the best interests of the child must be the primary consideration in all of a States actions, and States Parties are required to ensure the child protection and care for their well-being.[139] Article 37 prohibits "torture or other cruel, inhuman or degrading treatment or punishment" to be inflicted upon children.[140] Children shall not "be deprived of [their] liberty unlawfully or arbitrarily[, and] arrest,

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131. CHILDREN IN ISRAELI MILITARY DETENTION, *supra* note 124, at 9, 12–14.

132. *Id.* at 2.

133. *Id.*

134. *Id.*

135. Convention on the Rights of the Child, *opened for signature* Nov. 20, 1989, 1577 U.N.T.S. 3 (entered into force. Sept. 2, 1990) [hereinafter CRC].

136. *Id.* at art. 6, 9, 12, 19, 40.

137. *Frequently Asked Questions on the Convention on the Rights of the Child*, UNICEF, https://www.unicef.org/child-rights-convention/frequently-asked-questions (last visited Oct. 17, 2021).

138. *See* CRC, *supra* note 133, at art. 3, 9, 12, 16, 19–20, 24, 35, 37–38, 40.

139. *Id.* at art. 3.

140. *Id.* at art. 37.

detention or imprisonment of a child shall . . . only [be] a measure of last resort and for the shortest appropriate period of time."[141] "Every child deprived of [their] liberty shall [also] be treated with humanity and respect for the inherent dignity of the human person, and in a manner" that accounts for the child's age.[142] The child must also "have the right to maintain contact with [their] family [via] correspondence and visits, save in exceptional circumstances."[143]

Through Article 40, "every child . . . accused of, or recognized as having infringed the penal law [is] to be treated in a manner consistent with the promotion of the child's sense of dignity and worth."[144] Particularly, the child must be "presumed innocent until proven guilty;" "be informed promptly and directly," through their parents, of charges against them and have legal defense; "[t]o have the matter determined without delay by a competent . . . and impartial authority, . . . in the presence of legal" assistance and their parents; to not "be compelled to give testimony or . . . confess guilt;" and "[t]o have free assistance of an interpreter."[145] Under the CRC, children are entitled to the full spectrum of socio-economic human rights, with the child's best interests playing a primary role in consideration of all action taken by States. [146] Further, all protections given to adults under the Universal Declaration of Human Rights (UDHR) and the International Covenant on Civil and Political Rights (ICCPR) apply to children. [147] The CRC contextualizes the principles enshrined in the UDHR and ICCPR to children's rights and the heightened level of protection guaranteed for them.

In addition to the CRC, basic standards relevant to the administration of juvenile justice derives from the United Nations Guidelines for the Prevention of Juvenile Delinquency (the Riyadh Guidelines), the United Nations Standard Minimum Rules for the Administration of Juvenile Justice (the Beijing Rules), and the United Nations Rules for the Protection of Juveniles Deprived of

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141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.* at art. 40.

145. *Id.*

146. *The International Human Rights Community Affirms that Immigration Detention is a violation of the Rights of Children*, END CHILD DETENTION, https://endchilddetention.org/toolbox/issue-child-immigration-detention/international-law/child-rights/ (last visited Oct 2, 2020).

147. *Id.*; *see generally* G.A. Res. 217 (III) A, Universal Declaration of Human Rights (Dec. 10, 1948) [hereinafter UDHR]; International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S. 171; S. Exec. Doc. E, 95-2 (1978); S. Treaty Doc. 95-20; 6 I.L.M. 368 (1967) [hereinafter ICCPR].

their Liberty. [148] The fundamental consideration of these instruments is that the imprisonment of young people should be avoided whenever possible, and the younger the person is, the greater the deference to avoiding detention.[149]

Important to the context on the abolition of torture is Article 2 of the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT).[150] Through CAT, State Party's are required to take effective measures to prevent torture in any territory under its jurisdiction; clarifies that "[n]o exceptional circumstances whatsoever . . . may be invoked as a justification of torture;" and prevents justifying torture on the basis of an order from a superior officer. [151] The aforementioned declarations and treaties, applicable in Palestine and Israel, establish the legal framework for international human rights as particularly applied for children.

IV. INTERNATIONAL CRIMINAL LAW AND THE INTERNATIONAL CRIMINAL COURT

International criminal law is meaningful in a number of its objectives, including deterrence, denunciation and education, victim vindication, and reconciliation. Deterrence and denunciation provide an international notice that communicates the nature of the wrong, reaffirming the norm, and educating all facets of society. Victim vindication and reconciliation ensure the protection of those harmed by the violation of international law and allow the victimized society to heal and move forward.

For the International Criminal Court (ICC or the Court) to have jurisdiction, the material crime must be encompassed in Article 5 of the Rome Statute.[152] The case of the Palestinian child prisoners falls within the meaning of crimes against humanity and war crimes.[153] The ICC must also have personal jurisdiction under Article 26, therefore, the perpetrators must be over the age of 18. [154] The

148. OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER FOR HUMAN RIGHTS, HUMAN RIGHTS AND PRISONS: MANUAL ON HUMAN RIGHTS TRAINING FOR PRISON OFFICIALS 157–64 (2005), https://www.ohchr.org/documents/publications/training11en.pdf.

149. *Id.*

150. Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Dec. 10, 1984, 1465 U.N.T.S. 85, 113; S. Treaty Doc. No. 100-20 (1988); 23 I.L.M. 1027 (1984) [hereinafter CAT].

151. *Id.* at Article 2.

152. Rome Statute of the International Criminal Court, U.N. Doc. 2187 U.N.T.S. 90, entered into force July 1, 2002 [hereinafter Rome Statute].

153. *Id.* at art. 7–8.

154. *Id.* at art. 26.

situation must also meet the preconditions to the exercise of jurisdiction under Article 12 of accepting the jurisdiction of the Court.[155] This case falls under the territorial link of Article 12(2)(a), as the State on the territory of which the conduct in question occurred, in this case the State of Palestine, is a party or has accepted the jurisdiction of the Court.[156] There are only three trigger mechanisms for how a case can come before the Court.[157] In the case of Palestine, a self-referral was sufficient to trigger an investigation.[158]

The ICC serves as a court of "last resort," meaning that it works in complementarity with national courts. There is a required two-step test to be answered before a case will be considered admissible before the ICC. The first question is to ask if there is an investigation or prosecution occurring at the national level that is being conducted properly.[159] This is relevant to ensure that one is not punished for the same thing twice.[160] The second question is if the party is unwilling or unable to genuinely carry out an investigation or prosecution.[161] There is currently no meaningful investigation or prosecution on the Palestine Situation at the national level, nor is there willingness to do so.

The third question is if an investigation would serve the interests of justice. When jurisdiction and admissibility are found in the affirmative, the Prosecutor can still deny investigation of a situation if it 'would not serve the interests of justice' when taking into account all relevant circumstances including the 'gravity of crime' and 'interests of victims.'[162] In the *Gaza Flotilla* case, the Pre Trial Chamber I and the Prosecutor agreed on the five factors that influence whether or not a situation would serve the interests of justice.[163] The first factor is focused on the perpetrator, namely, whether or not prosecution would focus on the persons with the greatest responsibility.[164]

The four additional factors focus on the nature of the crimes and require sufficiently high levels of investigation: the scale of crimes

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155. *Id.* at art. 12.

156. *Id.*

157. *Id.* at art. 13.

158. *Id.* at art. 14.

159. *Id.* at art. 17.

160. *Id.*

161. *Id*

162. *Id.*

163. Situation on the Registered Vessels of Comoros, Greece and Cambodia, Article 53(1) Report, ¶¶ 135–36 (Nov. 6, 2014), https://www.icc-cpi.int/iccdocs/otp/otp-com-article_53(1)-report-06nov2014eng.pdf [hereinafter *Gaza Flotilla*].

164. *Id.* at ¶ 135.

(although not decisive); the nature of crimes (including consideration of the evidence of pain, suffering, and ill-treatment of victims); the manner of commission of crimes (such as the use of force); the impact of crimes (including effects on families, although this is not decisive).[165] Prosecutor Bensouda has previously found that an investigation on the Palestine Situation does not show any significant reason it would not further the interests of justice and has accepted jurisdiction on the Situation.[166]

The jurisdiction of the ICC is limited by the most serious crimes of concern to the international community, as established through the Rome Statute.[167] These crimes are comprised of the crime of genocide, crimes against humanity, war crimes, and the crime of aggression.[168] Of important interest in the context of the Palestinian child prisoners are the crime against humanity and war crimes.[169]

A. Elements of Crimes Against Humanity

For an act to be deemed a crime against humanity, a number of contextual elements are required. The act must be part of a widespread or systematic attack directed against any civilian population; the perpetrator must be aware of the factual circumstances that established the character (the nature and gravity) of the act; and the perpetrator must know that the conduct was part of or intended to be part of a widespread or systematic attack against a civilian population.[170]

The initial creation of the crimes against humanity was done to fill the gap left by the creation of the war crimes cause of action. Contextually, crimes against humanity occur as part of a widespread or systematic attack against any civilian population. Multiple attacks are sufficient to meet this context and it does not necessarily have to consist of armed force.[171] There is no requirement for a nexus with armed conflict or for discrimination to be present.[172] It is sufficient for the perpetrator to have

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165. *Id.* at ¶ 138–41.

166. *Id.* at ¶ 149.

167. Rome Statute, *supra* note 152, at Preamble.

168. *Id.*

169. *Id.* at art. 7–8.

170. Preparatory Comm. for the International Criminal Court, Report of the Preparatory Commission for the International Criminal Court: Part II Finalized draft text of the Elements of Crimes, art. 7, U.N. Doc. PCNICC?2000/1/Add.2 (Nov. 2, 2000) [hereinafter *Elements of Crimes*].

171. Rome Statute, *supra* note 152, at art. 7.

172. *Elements of Crimes*, *supra* note 170, at art. 7.

awareness of the context and there is no heightened requirement for the intention in relation to the prohibited act.[173]

The acts encompassed in the meaning of 'crime against humanity' of heightened importance in the discourse on Palestinian child prisoners are deportation or forcible transfer of the population; imprisonment or other severe deprivation of physical liberty in violation of fundamental rules of international law; torture; persecution against any identifiable group in connection with any crime within jurisdiction of the ICC; enforced disappearance of persons; and other inhumane acts of a similar character intentionally causing great suffering.[174]

B. Applying Crimes Against Humanity

The acts committed by Israel are sufficient to show a violation of Article 7(1)(d) on the crime against humanity of deportation or forcible transfer of one or more persons.[175] Officers of Israel have forcibly transferred Palestinian children from their homes in the Occupied Palestinian Territories to locations in Israel.[176] The 'forcible' relocation is not restricted merely to physical force, but also includes the threat of force or coercion caused by fear of violence, duress, detention, psychological oppression or abuse of power, or by taking advantage of a coercive environment.[177] These Palestinian children, who are, or were, lawfully present in the Occupied Palestinian Territories, often suffer from abuse and intimidation throughout the process of being arrested, through their transfer to Israeli sites, throughout their court hearings, and in their detention sentencing.[178]

The acts of Israel come in conflict with Article 7(1)(e) of the crime against humanity of imprisonment or other severe deprivation of physical liberty.[179] Israeli officials imprison approximately seven hundred Palestinian children a year, depriving them of their physical liberty and in such a way that is a violation of the fundamental rules of international law.[180] Additionally, the manner

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173. *Id.*

174. Rome Statute, *supra* note 152, at art. 7.

175. *Elements of Crimes*, *supra* note 170, at art. 7(1)(d).

176. *See* NO WAY TO TREAT A CHILD: About, *supra* note 121; *see* CHILDREN IN ISRAELI MILITARY DETENTION, *supra* note 124.

177. *Elements of Crimes*, *supra* note 170, n.12.

178. *See* NO WAY TO TREAT A CHILD: About, *supra* note 121; *see* CHILDREN IN ISRAELI MILITARY DETENTION, *supra* note 124.

179. Rome Statute, *supra* note 152, at art. 7(1)(e).

180. *See* NO WAY TO TREAT A CHILD: About, *supra* note 121; *see* CHILDREN IN ISRAELI MILITARY DETENTION, *supra* note 124.

in which the Palestinian children are arrested, detained, and tried is an act of the crime against humanity of torture under Article 7(1)(f).[181] The pain and suffering experienced by these children did not arise only from, and was not inherent in or incidental to, lawful sanctions.[182] As relates to this crime, no specific purpose for the torture needs to be proven.[183]

The frequent occurrence of this situation rises to an act of a crime against humanity of persecution under Article 7(1)(h) as Israel severely deprives Palestinians of their fundamental rights.[184] The Palestinians have collectively been targeted by reason of their national identity.[185] While these children are being particularly persecuted for their connection with such an identifiable group, their families and communities are also being harmed by the situation at a level that rises to collective punishment.[186] The extent of the emotional harm instituted by Israel through its detention of approximately seven hundred Palestinian children per year extensively disrupts and harms the livelihoods of these Palestinian communities.[187] There is no further mental element necessary for a showing of this crime, beyond that of the perpetrator knowing the conduct was part of a widespread or systematic attack against a civilian population.[188]

Israel has also committed the crime against humanity of apartheid as of Article 7(1)(j).[189] The experience of a child's arrest by Israeli forces is entirely dependent on the identity of the child. While Israeli settler children, who reside in the West Bank in violation of international law, are given due process rights and are tried in a civilian legal system, Palestinian children are automatically and systematically prosecuted in military courts under military law.[190] Israeli army, police, and security agents treat the Palestinian children inhumanely throughout the arrest, interrogation, detention, and trial process through an institutionalized regime

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181. Rome Statute, *supra* note 152, at art. 7(1)(f).

182. *Elements of Crimes*, *supra* note 170, at art. 7(1)(f)(4).

183. *Id.* at n.14.

184. Rome Statute, *supra* note 152, at art. 7(1)(g)-(h).

185. *Elements of Crimes*, *supra* note 170, at art. 7(1)(h)(1)-(3).

186. *Id.*

187. NO WAY TO TREAT A CHILD: About, *supra* note 121; CHILDREN IN ISRAELI MILITARY DETENTION, *supra* note 124.

188. *Elements of Crimes*, *supra* note 170, n.22.

189. *See* Rome Statute, *supra* note 152, at 4.

190. The Issues section of the No Way to Treat a Child Campaign, DEFENSE FOR CHILDREN INTERNATIONAL – PALESTINE: NO WAY TO TREAT A CHILD (2020), https://nwttac.dci-palestine.org/about [hereinafter NO WAY TO TREAT A CHILD: The Issues].

of systematic oppression and domination to promote the superiority of an Israeli race and the degeneration of the Palestinian nationality.[191]

Israel has violated the crime against humanity of other inhumane acts under Article 7(1)(k) through the infliction of great suffering and serious injury to body, mental, or physical health by inhumane acts against these Palestinian children.[192] This repeated mistreatment of Palestinian children by Israel demonstrates a clear pattern of disregard for international law and constitutes clear crimes against humanity. The ICC must, therefore, hear and prioritize the case of crimes against humanity inflicted against the Palestinian child prisoners.

C. Elements of War Crimes

Required for war crimes, under Article 8, is the context of an international armed conflict. [193] Encompassed in the term "international armed conflict" is military occupation; this understanding applies to each crime under article 8(2)(a).[194] Each act encompassed under war crimes requires that the person be:

> protected under one or more of the Geneva Conventions of 1949; the perpetrator was aware of the factual circumstances that established the protected status; the conduct took place in the context of an international armed conflict; and the perpetrator was aware of the factual circumstances that established the existence of an armed conflict.[195]

The context of the presence of a military occupation is sufficient to meet the requirement of a nexus to armed conflict for an act to constitute a war crime, a serious violation of international humanitarian law.[196] The crimes included in Article 8 of the Rome Statute are an exhaustive list that serves to limit the jurisdiction of the ICC.

The acts, derived from Article 8(2)(a), of particular interest on the situation of Palestinian child prisoners are the acts of willfully depriving a prisoner of war or other protected person of the rights of fair and regular trial; unlawful deportation or transfer or unlawful

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191. *Elements of Crimes*, *supra* note 170, at 16.

192. *Id.* at 17.

193. *Id.* at 18.

194. *Id.* at n. 34.

195. *Id.* at 19.

196. *Elements of Crimes*, *supra* note 170, n. 34.

confinement; torture or inhumane treatment; and willfully causing great suffering, or serious injury to body or health.[197]

D. Applying War Crimes

The studies conducted show evidence of acts of war crimes committed by Israeli officials against the Palestinian child prisoners.[198] These children have been denied a fair and regular trial by denying judicial guarantees, as has been defined in the third and the fourth Geneva Conventions of 1949.[199] This is evidenced by the forced signing of legal documents written in Hebrew, coerced confessions, familial separation, and a complete lack of representation.[200] Further, the automatic and systematic prosecution of the Palestinian children in military courts is in contravention of the fundamental fair trial rights and protection for children.[201]

Inherent in this system is the discrimination faced by these children who are placed in military courts by virtue of their Palestinian identity. Throughout their court appearances, Israeli officials continue to inflict ill-treatment on the children.[202] The children are shackled, denied bail, and are imposed with custodial sentences.[203] The children are not given access to lawyers or family members while undergoing interrogations nor when they are coerced into confessions or the signing of legal orders.[204] Through their arrest, the Palestinian children are deported or transferred to another location outside of Palestine and are confined to that location, in contravention of their rights to not be forcibly transferred to another State or location.[205] This situation meets the requirements for finding a war crime of denying fair trial, of unlawful deportation and transfer, and of unlawful confinement.[206]

The Palestinian children are continually inflicted with severe physical or mental pain or suffering. This is evidenced by the showing of high percentages of these children experiencing physical violence following their arrests, being subject to stress position,

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197. *See* Rome Statute, *supra* note 152, at 5.

198. *See* NO WAY TO TREAT A CHILD: The Issues, *supra* note 190.

199. *See Elements of Crimes*, *supra* note 170, at 21.

200. *See* NO WAY TO TREAT A CHILD: The Issues, *supra* note 190.

201. *Id.*

202. *Id.*

203. *Id.*

204. *Id.*

205. *See Elements of Crimes*, *supra* note 170, at 7.

206. Rome Statute, *supra* note 152, at art. 8.

facing verbal abuse, humiliation, or intimidation.[207] Additionally, the vast majority of the children were hand tied, blindfolded, and all experience trauma through the process and means by which they are arrested, detained, and transferred.[208] The pain and suffering is additionally inflicted for purposes of obtaining information or a confession, punishment, intimidation or coercion, and for reasons based on discrimination. [209] This is shown by the systematic placement of the children into military courts due to their Palestinian identity, by the nearly uniform experience of being interrogated without a family member's presence, by not being properly informed of their rights, and by the forced signage of legal documents, often in Hebrew.[210] This situation illustrates the war crime of torture, of inhuman treatment, and of willfully causing great suffering. The ICC should accordingly hear and prioritize this case.[211]

V. POTENTIAL CHALLENGES

A. Accountability

Jurisdiction for the Palestine Situation in the ICC arises under the territoriality principle—although jurisdictional requirements in this situation could also be met under the principle of passive nationality or universal jurisdiction. [212] However, Israel has not consented to the jurisdiction of the Court.[213] This will predictably lead to issues of Israeli cooperation with the Court's investigation, failing to adhere to arrest warrants issued by the Court, and preemptive attempts to undermine the Court's legitimacy. International criminal law requires that individuals are held criminally responsible for the acts, which raises issues for ensuring prosecution for the crimes committed against the Palestinian child prisoners.[214] Without Israel's cooperation to obtain the necessary information in conducting thorough investigations, it may be

207. *See supra* notes 121–34.

208. *Id.*

209. *Elements of Crimes*, *supra* note 170, at art. 8.

210. *See supra* notes 121–34.

211. Rome Statute, *supra* note 152, at art. 8(ii-iii).

212. *Informal Expert Paper: The Principle of Complementary in Practice*, ICC-OTP (2003), at 20, https://www.icc-cpi.int/nr/rdonlyres/20bb4494-70f9-4698-8e30-907f631453ed/281984/complementarity.pdf.

213. Antony J. Blinken, *The United States Opposes the ICC Investigation into the Palestinian Situation*, U.S. DEPT. OF STATE (Mar. 3, 2021), https://www.state.gov/the-united-states-opposes-the-icc-investigation-into-the-palestinian-situation/.

214. Rome Statute, *supra* note 152, at art. 25.

difficult for the Court to know which individuals to prosecute. Further, the Court cannot try someone without their presence, thereby creating a reliance on Israel—and Member States—to adhere to any issued arrest warrants. This potential avenue for lack of adherence to the Court's authority may cause not only delays, but also a potential complete inability to prosecute this case.

B. Political Intervention

On June 11, 2020, the U.S. Trump Administration issued the Executive Order on Blocking Property of Certain Persons Associated with the International Criminal Court. [215] These sanctions, which include economic and legal repercussions, were in response to the Court's decision to investigate alleged war crimes of the U.S. in Afghanistan.[216] The U.S. Secretary of State, however, made clear that the sanctions were also geared towards defending Israel from the Palestine Investigation.[217] As of September 2, 2020, economic sanctions on the Prosecutor and a member of her Office were imposed, which were quickly condemned by the Court. [218] While a newly elected Biden Administration has promised to enact a series of executive actions to undo the many foreign policy actions of the Trump Administration, it has refused to repeal the previous Administration's executive actions, thereby retaining a narrative of undermining the ICC's jurisdiction over the Situation in Palestine.[219]

C. Efficiency

Even so, this does not change serious concerns that an investigation could take years to complete and face logistical and evidentiary obstacles throughout. Out of the three convictions held by the ICC, the first on Germain Katanga took ten years between

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215. Exec. Order No. 13928, 85 Fed. Reg. 36139 (June 15, 2020).

216. Julian Borger, *Trump Targets ICC with Sanctions After Court Opens War Crimes Investigation*, THE GUARDIAN (June 11, 2020), https://www.theguardian.com/us-news/2020/jun/11/trump-icc-us-war-crimes-investigation-sanctions.

217. Antony J. Blinken, *The United States Opposes the ICC Investigation into the Palestinian Situation*, U.S. DEPT. OF STATE (Mar. 3, 2021), https://www.state.gov/the-united-states-opposes-the-icc-investigation-into-the-palestinian-situation/.

218. Fadi El Abdallah, *International Criminal Court Condemns US Economic Sanctions*, ICC (Sept. 2, 2020), https://www.icc-cpi.int/Pages/item.aspx?name=pr1535.

219. Eric Bradner & Sarah Mucha, *Biden Plans Executive Actions that Would Undo Trump's Policies*, CNN POLITICS (Nov. 8, 2020), https://www.cnn.com/2020/11/08/politics/biden-first-day-executive-actions/index.html/; Antony J. Blinken, *The United States Opposes the ICC Investigation into the Palestinian Situation*, U.S. DEPT. OF STATE (Mar. 3, 2021), https://www.state.gov/the-united-states-opposes-the-icc-investigation-into-the-palestinian-situation/.

referral and sentencing, the second on Thomas Lubanga took eight years between referral and sentencing, and the third on Ahmad Al Mahdi took four years between referral and sentencing.[220] It is clear that it can take nearly a decade to receive sentencing, not including the potential appeals and further decisions on victim reparations, yet, there is still hope.

The ICC is recognized as a young court and has advanced greatly since its inception in 2002. The ICC has become more efficient over the years and has actively been working to decrease the length of the prosecution while maintaining accuracy and effectiveness.[221] An example of this on the Palestine Situation is Prosecutor Bensouda's early request from the Pre-Trial Chamber I to issue a jurisdictional ruling on the scope of the territorial jurisdiction of the ICC in Palestine.[222] The intentions behind this were to have the unique territorial circumstances resolved before the start of an investigation, so as to not hinder any investigations by delaying settlement by the judges.[223] Prosecutor Bensouda believed that clarity through the Chamber's assistance will allow for greater legitimacy of any rulings and will better support swiftness in the interest of the victims and affected communities.[224] Actions like this can assist the process for prosecution and allow for a more effective approach to the Palestine investigations.

VI. FURTHER CONSIDERATIONS

A. Last Resort

The International Criminal Court owes a duty to the Palestinian children to investigate and prosecute their situation. The ICC serves as a court of last resort; this is the last resort for the Palestinian children. Israel is an unwilling party to investigate or meaningfully try any of these crimes against these children, while Palestine does

220. Prosecutor v. Katanga, ICC-01/04-01/07, Judgment (Mar. 7, 2014); Prosecutor v. Lubanga, ICC-01/04-01/06, Judgment (Mar. 14, 2012); Prosecutor v. Ahmad Al Faqi Al Mahdi, ICC-01/12-01/15, Judgment (Mar. 8, 2018).

221. *International Criminal Justice: Mass Atrocities, the International Criminal Court, and the Role of States*, ICC PROJECT (Apr. 10, 2014), https://www.international-criminal-justice-today.org/news/international-criminal-justice-mass-atrocities-the-international-criminal-court-and-the-role-of-states/.

222. Fatou Bensouda, *Statement of ICC Prosecutor, Fatou Bensouda, on the Conclusion of the Preliminary Examination of the Situation in Palestine, and Seeking a Ruling on the Scope of the Court's Territorial Jurisdiction*, ICC (Dec. 20, 2019), https://www.icc-cpi.int/Pages/item.aspx?name=20191220-otp-statement-palestine.

223. *Id.*

224. *Id.*

not have the capacity to try these cases or enforce a judgment.[225] The ICC has the jurisdiction and the power to investigate, prosecute, and judge on this situation in an instrumental way to achieve justice and reparations for the victims.

B. Erga Omnes

The United Nation's International Court of Justice's (ICJ) Advisory Opinion on the Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory (Israeli Wall) provides increased justification in the prosecution of this situation by the ICC.[226] The ICJ in Israeli Wall observed that the obligations erga omnes ("towards all") violated by Israel is the requirement to respect the right of the Palestinian people to self-determination and certain of its obligations under international humanitarian law.[227] Citing to Barcelona Traction, the ICJ observed that such obligations are "by their very nature 'the concern of all States' and, '[i]n view of the importance of the rights involved, all States can be held to have a legal interest in their protection."[228] Referring to the Legality of the Threat or Use of Nuclear Weapons in regard to international humanitarian law, the ICJ stated that "a great many rules of humanitarian law applicable in armed conflict are so fundamental to the respect of the human person and 'elementary considerations of humanity,'" that they are "to be observed by all States whether or not they have ratified the conventions that contain them, because they constitute intransgressible principles of international customary law."[229] The ICJ found that these rules incorporate obligations that are "essentially of an erga omnes character."[230]

The ICJ held that the fundamental principle that "the well-being and development of such peoples form 'a sacred trust of civilization' " applies to all former mandated territories that have not gained independence, thereby being valid today for the Occupied Palestinian Territory.[231] This, according to the ICJ, makes "the future of the Palestinian people [a] sacred trust of civilization" that is the direct responsibility and concern of the United Nations.[232] The ICJ found that judicial settlement could not be circumvented by an

225. Rome Statute, *supra* note 152.

226. Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, Advisory Opinion, 2004 I.C.J. GL No. 131 (July 9) [hereinafter Israeli Wall].

227. *Id.* at 199.

228. *Id.*

229. *Id.*

230. *Id.* (emphasis in original).

231. *Id.* at 165.

232. *Id.*

incorrect contention that the context of the subject-matter was a bilateral dispute between Israel and Palestine.[233] Rather, "it was directly of concern to the United Nations".[234]

By virtue of the ICC's capacity to admissibly hear the case, its functioning within an international legal order, and its mandate to "fight against impunity and [establish] the rule of law by ensuring that the most severe crimes do not go unpunished and by promoting respect for international law," it is imperative that the ICC follows the reasoning by the ICJ to meaningfully try this situation.[235] The strong language contained in the Israeli Wall Advisory Opinion on the erga omnes character of Israeli violations, the importance of the rights involved implicating all States to have a legal interest, and the nature of the foundational rights involved with violations of humanitarian law as is applicable in this situation bolsters the ICC's obligation to intervene.[236]

By understanding the international nature of the plight of the Palestinian peoples, it is clear that the Court must hear the case of the Palestinian children is the ICC. The laws violated directly implicate civilization, at large, and must be deemed a priority for the ICC. Insofar as the ICC has discretion on the cases it hears and prioritizations of the chosen cases, the situation of the Palestinian child prisoners must be at the forefront.

C. Children are Different

This situation does not merely involve crimes against humanity and war crimes, but crimes inflicted against children. Children are a uniquely protected class of vulnerable individuals, whom, inherent to their special status, deserve the utmost protection and utilization of resources for protection and vindication. According to recent findings in developmental psychology and neuroscience, "children are different."[237] Children are legally considered to be less culpable than adults and it violates the dignity of a child to treat a child not as a child.

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233. *Id*. at 159.

234. *Id*.

235. Sang-Hyun Song, THE ROLE OF THE INTERNATIONAL CRIMINAL COURT IN ENDING IMPUNITY AND ESTABLISHING THE RULE OF LAW, UN CHRONICLE, https://www.un.org/en/chronicle/article/role-international-criminal-court-ending-impunity-and-establishing-rule-law#:~:text=The%20core%20mandate%20of%20the,or%20unwilling%20to%20do%20so (last viewed Mar. 16, 2022).

236. Israeli Wall, *supra* note 226, at 199.

237. Paolo Annino, *Children are Different: The Abolition of Mandatory Minimum Sentencing in Florida*, FSU College of Law, Public Law Research Paper No. 821 (July 5, 2016), available at: https://ssrn.com/abstract=2853626 or http://dx.doi.org/10.2139/ssrn.2853626.

Additionally, under the 1959 UN Declaration of the Rights of the Child (DRC), a key principle promulgated is that a child is to enjoy "special protection" and "opportunities and facilities, by law and by other means," for healthy and normal development "in conditions of freedom and dignity."[238] Included in the DRC principles is a child's entitlement to nationality and protection against neglect, cruelty and exploitation, and discrimination.[239] The DRC pledges that, "mankind owes to the child the best it has to give."[240]

D. The Future

The ICC's prosecution of violations committed against Palestinian child prisoners would do more than vindicate the tens of thousands of children previously harmed and the hundreds experiencing such abuse today. Employing the ICC in this situation can protect and defend the hundreds of children who are currently at risk of becoming the next Palestinian child prisoner; to protect these vulnerable children from a guaranteed abuse to their rights and freedoms at the hands of Israeli officials. There is no other entity with the capacity to achieve the duties owed to the Palestinian children and to protect them in a way consistent with international legal doctrine other than the ICC. Diplomacy has proven futile, UN Resolutions ineffectual, and internal pressure obsolete. Taking into consideration the ICC's mandate, the admissibility of this situation, the interests of justice, and the special protection owed to children, the ICC should hear the case of the Palestinian child prisoners and ensure its prioritization before the Court.

The State's Parties have a further duty and obligation to support the ICC in its investigations as understood by the unique nature of the Palestine Situation and their duty to give children the "best it has to give." This special context should assist in bolstering the legitimacy of the Court's hearing of this case and its external validity to those observing the Court's effectualness.

The ICC does not operate in a vacuum, but in a larger international legal order that is banned together with a duty to protect the vulnerable and, in doing so, legitimize a comprehensive, integrated legal system in which international legal standards are upheld and reinforced. Looking at this international legal system from a distance, it becomes clear the ICC is the only organization with the capacity to vindicate the Palestinian child prisoners. With

238. Declaration of the Rights of the Child, A/RES/1386(XIV) (1959), [hereinafter DRC].

239. *Id.*

240. *Id.*

the unique protections instituted for children, it is with increased urgency that this situation must be a priority for the Court. The interests to protect these children go beyond the harm of the children who suffered in the past, those suffering currently in Israeli detention, but also of those who will suffer if the ICC does not intercede.

VII. CONCLUSION

The International Criminal Court has an obligation to investigate, prosecute, and prioritize the situation inflicting the Palestinian children in the Occupied Palestinian Territories and Israel. The Court serves as the last resort to achieve justice for the Palestinian children and the hundreds of potential victims in the years to come. The ICC is the only legal entity with the capacity to effectuate the special protection owed to the Palestinian children and ensure that the international human rights obligations are upheld.

APPENDIX

For more information, see generally:

1) Rome Statute of the International Criminal Court: https://www.icc-cpi.int/resource-library/documents/rs-eng.pdf

2) Elements of Crimes (of the Rome Statute): https://www.icc-cpi.int/NR/rdonlyres/336923D8-A6AD-40EC-AD7B-45BF9DE73D56/0/ElementsOfCrimesEng.pdf

3) Convention on the Rights of the Child: https://www.ohchr.org/documents/professionalinterest/crc.pdf

4) UN Declaration of the Rights of the Child (1959): http://www.cirp.org/library/ethics/UN-declaration/

5) Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment of punishment: https://www.ohchr.org/en/professionalinterest/pages/cat.aspx

6) Universal Declaration of Human Rights: https://www.un.org/en/universal-declaration-human-rights/

7) International Covenant on Civil and Political Rights: https://www.ohchr.org/Documents/Professionalinterest/ccpr.pdf

8) United Nations (UN) Guidelines for the Prevention of Juvenile Delinquency (The Riyadh Guidelines): https://humanrights.gov.au/sites/default/files/Annexure%20F%20-%20Riyadh%20Guidelines.pdf

9) UN Standard Minimum Rules for the Administration of Juvenile Justice (The Beijing Rules): https://www.ohchr.org/Documents/ProfessionalInterest/beijingrules.pdf

10) UN Rules for the Protection of Juveniles Deprived of their Liberty: https://www.unodc.org/pdf/criminal_justice/United_Nations_Rules_for_the_Protection_of_Juveniles_Deprived_of_their_Liberty.pdf

11) Israeli Wall Case, Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory: https://www.fidh.org/IMG/pdf/il2302a.pdf

12) Gaza Flotilla Case, Situation on the Registered Vessels of the Union of the Comoros, the Hellenic Republic and the Kingdom of Cambodia, Union of Comoro: https://www.icc-cpi.int/RelatedRecords/CR2019_07299.PDF

13) The Balfour Declaration: https://avalon.law.yale.edu/20th_century/balfour.asp

14) The 1939 British White Papers: https://www.historycentral.com/Israel/documents/White.html

15) United Nations General Assembly (UNGA) Resolution 181 (II), Future Government of Palestine: https://unispal.un.org/DPA/DPR/unispal.nsf/0/7F0AF2BD897689B785256C330061D253

16) United Nations Security Council (UNSC) Resolution 605 (1987): https://unispal.un.org/DPA/DPR/unispal.nsf/0/A734F62E7C6F8EF9852560DE00695C66

17) Geneva Convention Relative to the Treatment of Prisoners of War (Third Geneva Convention): https://www.un.org/en/genocideprevention/documents/atrocity-crimes/Doc.32_GC-III-EN.pdf

18) Geneva Convention Relative to the Protection of Civilian Persons in Time of War (Fourth Geneva Convention): https://www.un.org/en/genocideprevention/documents/atrocity-crimes/Doc.33_GC-IV-EN.pdf

19) UNSC Resolution 1322 (2000): https://unispal.un.org/unispal.nsf/0/22f8a95e5c0579af052569720007921e?OpenDocument

20) Oslo Accords: https://peacemaker.un.org/sites/peacemaker.un.org/files/IL%20PS_930913_DeclarationPrinciplesnterimSelf-Government%28Oslo%20Accords%29.pdf

21) "Peace to Prosperity" (Trump Middle East Plan): https://www.whitehouse.gov/peacetoprosperity/

22) UN Children's Fund's (UNICEF) Children in Israeli Military Detention Observations and Recommendations: https://www.unicef.org/oPt/UNICEF_oPt_Children_in_Israeli_Military_Detention_Observations_and_Recommendations_-_6_March_2013.pdf