Intellectual property, COVID-19 vaccines and equity: A public health and human rights critique

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Abstract

The debates surrounding Intellectual Property (IP) have opened a front in the geopolitical struggle for COVID-19 vaccine access and distribution. Specific to vaccine manufacture, one route by which local production can be encouraged in low- to middle-income countries would be to ease IP restrictions by such mechanisms as a temporary waiver under the TRIPS [Trade-Related Aspects of Intellectual Property Rights] agreement. High-income states have resisted the measure, arguing that IP restrictions for COVID-19 vaccines should remain in place. Their preference is to provide vaccines to poorer states, notably through the COVAX allocation plan, or through bilateral initiatives where excess vaccines are distributed once local supply needs are met. It is argued here that retaining such IP restrictions constitutes an international public health risk and a potential breach of human rights in the context of international law.

Keywords: COVID-19 vaccines, Intellectual Property, waiver, public health, human rights law

Introduction

Vaccine nationalism has been described as a parochial "my country first" approach in securing supplies of vaccines through exclusive supply agreements or export bans upon precious reserves. In so doing, insecurity has been "medicalised" (Bollyky & Brown, 2020; Elbert, 2012). This paper seeks to examine one distinct aspect of that nationalism in considering intellectual property (IP) issues regarding COVID-19 vaccines. From a structural viewpoint, the IP regime has served to demonstrate that such nationalistic tendencies can arise in ensuring excess supply, preventing general licensing of pharma products to low-income states, and preserving corporate monopolies over development and supply chains. In preventing the cheaper production and distribution of such drugs, including the manufacture of generics, an argument can be made that this goes, not only against the spirit, but the letter of public international law in terms of the right to health and seeing such products as public goods. Such a state of inequality has the effect of posing a global risk to all populations, including those in High-Income Countries (HICs), given the continuing risk of mutations and variants. Far from being in the national interest to retain such a regime, it can be argued that the conditions created by the pandemic make it vital that temporary suspensions of traditional IP regimes are warranted.

The discussion unfolds as follows. The proposal of IP waivers in the context of COVID-19 vaccines is first considered, along with opposition case. The premise that such vaccines are global health goods within an international legal system is then elaborated upon. The issue of public health in international law then forms the basis for an argument that a waiver of IP rights is not only necessary but justified.

IP restrictions and failed waivers

The intellectual property rights of vaccine manufacturers have been considered one of several impediments in preventing a globally equitable distribution of vaccines, notably regarding COVID-19. Manufacturers are required to obtain licenses from pharmaceutical companies with patents prior to producing their own vaccine. This presents problems with cost, notably for middle to low-income countries. Patent holders can duly discriminate and withhold the granting of licenses to companies operating in developing states. In an environment of high demand and few distributors, equitable access becomes critical (Laad, 2021).

Specific to vaccine manufacture, one route by which local vaccine production can be encouraged in low- to middle-income countries is via easing IP restrictions by means of a temporary waiver. The legal and diplomatic basis of such a waiver can be found in the Marrakesh Agreement which established the WTO. Article IX.3 stipulates that, "In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements". The decision to do so must be agreed to by three-fourths of the Members "unless otherwise provided for in this paragraph" (World Trade Organization, 1994).

Pursuant to Article 31, Member States may provide for the compulsory licensing of patents even in the absence of authorisation from the patent holder where a national emergency or instances of extreme urgency arises. Each Member State may also determine what constitutes a national emergency or other circumstances of extreme urgency. We know that "national emergency" in this context includes matters pertaining to public health, including epidemics and pandemics in accordance with the Doha Declaration on TRIPS and Public Health adopted on November 14, 2001 (World Trade Organization, 2001, Articles 5(a)-(c)).

The COVID-19 Vaccines Global Access (COVAX) initiative, led by the GAVI vaccine alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization (WTO), was launched in April 2020 to ameliorate, at least in design, the problems of equitable access to COVID-19 technologies. The scheme also features the COVID-19 Technology Access Pool (C-TAP), established to share intellectual property, knowledge and data on COVID-19 health technologies. Despite receiving support, in principle, from 41 high-, middle- and low-income countries, it had received no contributions by the time the report of the Independent Panel on Pandemic Preparedness had been published (Independent Panel for Pandemic Preparedness & Response, 2021, p. 43). Many manufacturers showed little interest in the scheme (Wouters, et.al, 2021). On June 26, 2021, COVAX revealed that it had no doses of AstraZeneca, Serum Institute of India, and Johnson & Johnson vaccines in stock (Amnesty International, 2021). This was happening while vaccine doses were expiring by the thousands in more affluent countries.

Traditional approaches, with pharmaceutical corporations negotiating deals with High Income Countries, have been adopted. Pfizer and Moderna have notably declined requests to enter into voluntary licensing arrangements with low and middle-income countries (Gleeson, 2021). As an April 2021 letter to the newly appointed World Trade Organization chief Ngozi Okonjo-Iweala, signed by 250 international organisations, remarked, "Most of the existing bilateral agreements to produce COVID-19 vaccines are contract manufacturing agreements through which the contracted entity manufactures on behalf of a licensor that maintains full control of the use of its technology, the volume of production and where and at what prices vaccines may be supplied."¹

In such asymmetrical conditions of knowledge and distribution, drug companies have provided a patchwork of uneven concessions. Moderna Therapeutics declared that it would not enforce relevant patents against companies seeking to market COVID-19 treatments. AstraZeneca/Oxford University promised to avoid making profits while Pfizer/BioNTech has sought to make affordable doses for low-income countries while insisting on the need to make profits and enforce IP protections (Houldsworth, 2021). But this was based purely upon a conditional, voluntary understanding as dictated by companies traditionally motivated by market initiatives.

In October 2020, India and South Africa submitted a proposal for waiving "certain provisions of the TRIPS [Trade-Related Aspects of Intellectual Property Rights] agreement for the prevention, containment and treatment of COVID-19." The limited temporary waiver would be granted to WTO members to exempt them from having to apply or enforce certain provisions under Part II of the TRIPS Agreement, namely section 1 (copyrights and related rights), 4 (industrial design), 5 (patents), and 7 (protection of undisclosed information). The waiver would be in place for a duration agreed to by the General Council and till widespread global vaccination had taken place, with the majority of the world's population rendered immune (TRIPS, 1994).

The significance of the proposal lies in easing problems associated with pricing (in patent monopolies, the price is dictated by conditions that are non-competitive) and the technological aspect of manufacture and production. The TRIPS Agreement itself mandated all WTO Members, excepting Least Developed Country Members) to permit patents for pharmaceutical products by January 1, 2005 (Garrison, 2004, p. 2).

Mindful of the challenges of convincing wealthier nations to acquiescence in such a policy, a briefing document on the proposal, authored by Médecins Sans Frontières (MSF), asserted that the proposed waiver would be narrow, applicable only to COVID-19 and not "all TRIPS obligations, nor does it suggest a waiver beyond what is needed for COVID-19 prevention, containment and treatment." Were the waiver to be granted, patents would not be enforced or granted on "all COVID-19 drugs, vaccines, diagnostics, and other technologies, including masks and ventilators, for the duration of the pandemic" (Médecins Sans Frontières, 2020). Collaboration in research and development (R&D), manufacturing, scaling up and supplying COVID-19 tools could also take place.

In discussions held by WTO members at the TRIPS Council over October 15-16, 2020 the opponents, mostly state from the higher-income bracket, made their position clear. Australia, Brazil, Canada, the EU, Japan, Norway, Switzerland, the United Kingdom and the United States were either formally opposed to the measure, or not in support of it. China, on the other hand, arrogated itself a prominent role in advocating the interests of developing countries in the context of the waiver. In May 2021, China's Commerce Ministry spokesman Gao Feng revealed that Beijing would support the WTO exemption proposal "for anti-epidemic materials such as the COVID vaccine to enter the text consultation stage" (Reuters, 2021). The COVID-19 vaccine world had

¹ Letter to Ngozi Okonjo-Iweala. (2021, April 13).

 $https://www.twn.my/title2/intellectual_property/trips_waiver_proposal/CSOLetter_Dr.\%20Ngozi.pdf.$

been clearly demarcated along the lines of wealth, production capacity and means of distribution.

The justifications for retaining the IP structure, even in the face of a pandemic, were very much those endorsed by pharmaceutical companies. All centre on one essential theme: the importance of maintaining ironclad IP protections in the name of innovative practice and, it should be said, the profit motive despite the extensive public investment by governments in the development of COVID-19 vaccines. To not assure such protections would undermine both innovation and investor confidence, the latter keen to ensure returns on their capital investments (Nawrat, 2021). According to the International Federation of Pharmaceutical Manufacturers, "diluting national and international IP frameworks during this pandemic is counterproductive". IP regimes enabled "research and development and ensures that the next generation of inventors and investors will remain engaged." The body further argued that it was committed to international collaboration and coordination, citing such initiatives as ACT-A, ACTI and CEPI. Any such waiver would not accelerate research, development or access and would "undermine confidence in what has proven to be a well-functioning IP system" (International Federation of Pharmaceutical Manufacturers & Associations, 2020).

Patrick Kilbride, senior vice-president of the Global Innovation Policy Center of the US Chamber of Commerce, found proposals to waive IP rights "misguided and a distraction from the real work of reenforcing supply chains and assisting countries to procure, distribute and administer vaccines to billions of the world's citizens." While the US Chamber of Commerce supported such global vaccine programs as COVAX, diminishing IP rights, in their view, would inhibit the rapid development of vaccines, their distribution and treatments for future pandemics (Kilbride, 2021).

An EU spokesman continued the theme by suggesting that no evident nexus could be shown between access to vaccines and suppressive IP barriers. "There is no evidence that IP rights in any way hamper access to COVID-19 related medicines and technologies." The UK government decided to upend the cart with its reasoning, underlining the importance of having strict IP rules if access to new products to battle the pandemic were to be made available. The chair of the WHO Solidarity Trial of COVID-19, John-Arne Røttingen insists that "IP is the least of the barriers" relative to necessary facilities for production, knowledge and infrastructure (Usher, 2020).

South Africa sought to address such claims on October 16, 2020 at the TRIPS Council meeting and again at the Council Meeting on November 20 (Usher, 2020). Examples submitted included the manufacturers of monoclonal antibody therapeutics, such as Regeneron and Eli Lilly, which had restricted their capacity via bilateral arrangements. Specifically on vaccines, South Africa could point to the legal struggle between MSF and Pfizer being waged in India over the pneumococcal vaccine, protected by a patent effectively blocking the development of alternatives.

As if further proof was needed about efforts by pharmaceutical behemoths to freeze and halt both innovation and access in the field of vaccines under the generous cover of IP shields, one need look no further than the case of South Korea's SK Bioscience. The company was embroiled in patent litigation with Pfizer in developing a pneumococcal conjugate vaccine (PVC) by the name of Skypheumo. SK Bioscience lost the suit, with the Supreme Court ruling that it could not sell Skypheumo until 2026, when Pfizer's composition patent for Prevenar 13 will expire (Han-soo, 2019). Given that WTO decisions are the product of consensus, the waiver proposal found itself stuck in diplomatic purgatory in the TRIPS Council. Requests from Chile, Australia and Canada for evidence that the waiver would achieve increased capacity for vaccine manufacturing and assist ameliorate shortages did not help (Green, 2021). Burcu Kilic, research director for access to medicines at Public Citizen saw a crude agenda at play. "What [high-income countries] are hoping is that they can discuss and drag the issue out that things will be OK by the summer" (Green, 2021).

The WTO General Council meeting held at the start of February 2021 did not see a change of heart from high-income countries towards the South African - Indian proposal. Neither the US nor the EU wished to discuss it. Delegates were instead occupied by a proposal by WTO Director-General Ngozi Okonjo-Iweala to pursue a bland third way alternative. That option would involve the licensing of manufacturing to countries ensuring "adequate supplies while still making sure that intellectual property issues are taken care off" (BBC, 2021). Ahead of officially commencing her duties as Director-General, Okonjo-Iweala reiterated the idea that there was a way of increasing access "through facilitating technology transfer within the framework of multilateral rules" and for pharmaceutical giants to make licensing arrangements permitting other manufacturers to produce vaccines (Green, 2021).

Pressure in favour of the South African - Indian waiver proposal was, however, growing. On February 24, some 115 European Parliamentary members of a total body of 700 members, issued a declaration urging the European Commission and the European Council to review their opposition to the TRIPS waiver proposal (European Parliament, 2021). Certain EU Member States and the European Commission had spoken about COVID-19 medical products "as global goods" but there were no "actionable realities." A waiver, the members argued, would not only cast aside onerous legal barriers to production but enable "the sharing of know-how and technologies with GMP manufacturers from third countries". EU strategy had, however, been tribal, emphasising domestic production with the potential to exacerbate "a dangerous North-South divide when it comes to affordable COVID-19 diagnostics, personal protective equipment, treatment and vaccines."

The Biden administration was also leaned upon to change its view, with a number of Democrats in Congress claiming the IP barrier risked creating a regime of vaccine apartheid. On May 5, 2021, the Biden administration decided to reverse the position held by most affluent states in a volte face that troubled some Member States of the European bloc. "The Administration believes strongly in intellectual property protections," stated Ambassador Katherine Tai of the Office of the US Trade Representative, "but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines" (Tai, 2021). The waiver, it should be noticed, remained specific to vaccines.

This was enough to convince Amnesty International's new Secretary-General Agnès Callamard that something significant was afoot: "By supporting the waiving of intellectual property protections for COVID-19 vaccines, the Biden Administration has put the lives of people around the world ahead of the profits of a few pharma giants and their shareholders. Other rich states – such as Australia, Brazil, and the EU and UK – must now follow suit" (Amnesty International, 2021a). The reaction from the followers of vaccine IP orthodoxy was trenchant, with the German government responding that: "the limiting factors in the [availability] of vaccines are production

capacities and quality standards, not patents." There was no substitute to sophisticated technology: "high-tech shots can't be made at the local soap factory" (Limon, 2021; Der Spiegel, 2021).

Australia, rather predictably after the move by Washington, also announced that it would back the proposal. Australian trade minister, Dan Tehan, claimed that it had "always" been Australian policy to support a waiver with regards COVID-19. But he had also stated in March 2021 that Australia and other states had "to make sure that there are some protections in place of the millions of dollars of investment that has gone into the research to create these vaccines" (Karp & Visontay, 2021).

The revised proposal of May 21, 2021 of the initially sponsored TRIPS waiver narrowed the focus to "health products and technologies" covering the prevention, treatment and containment of COVID-19, while iterating that the waiver would be "limited in scope to COVID-19 prevention, treatment and containment" (Council for Trade-Related Aspects of Intellectual Property Rights , 2021). The revised text also considered the precarious nature of dealing with a novel pathogen. There were still uncertainties associated with many vaccines which would, in turn, affect the scale of manufacturing and scale required. These included the effects upon children and the duration of immunity each vaccine might offer. This therefore required a period of "flexible and practical duration".

Despite this modest advancement by the United States, a number of countries (the EU group, the UK, Norway, and Switzerland) persisted in maintaining a filibustering core. Given that the TRIPS waiver proposal requires the agreement of all 164 WTO member states, any changes on the issue can be susceptible to resistance. By the end of November 2021, Vidya Krishnan would observe that the TRIPS waiver proposal was "dead in the water" (Krishnan, 2021). On returning to the agreement, the proposal faced opposition from China, notably on the proposed provision excluding developing member states which exported more than 10 per cent of the global vaccine doses from the waiver (Baschuk, 2022). Conveniently for developed member states, so goes the argument in Beijing, China is the only developing state that has passed the 10 per cent threshold. Excluding the PRC is, according to Beijing, a strategic, IP measure to frustrate access to mRNA technology developed by Pfizer, BioNTech and Moderna (Baschuk, 2022).

Global public goods

The severe approach in refusing to adopt the waiver by some wealthy states tended to ignore seeing vaccines as global public goods, the equitable manufacture and distribution of which would be in their national interest. The point has been made by the United Nations Office of the High Commissioner that COVID-19 vaccines should be seen as "global public goods, rather than marketplace commodities available only to those countries and people who can afford to pay the asking price" (UN Human Rights Office of the High Commissioner, 2020). The argument that such products be treated as goods of the commons is further strengthened by the enormous public investments made by governments. Corporatising the outcomes of such risk-filled ventures as profit-making measures ignores the public interest aspect of the investment. Declaring COVID-19 vaccines as a "Global Common Good" was, argue Muhammad Yunus, Cam Donaldson and Jean-Luc Perron, a pressing need given the announcement by the US government to allocate US\$1.6 billion to the US biotech

Novovax for its COVID-19 vaccine project as "part of Operation Warp Speed to produce enough to vaccine all Americans by January, 2021" (Yunus, Donaldson & Perron, 2020). The same could be said of the US diagnostics company Cepheid, which maintains a monopoly on the GeneXpert testing system, using high pricing and trade secret protocols, despite receiving \$250 million in public funds from government funds (MSF, 2021).

Such a distortion between the public subsidising of risk-based activities and the profitable returns for a private company transcend traditional IP assumptions. Governments of wealthy states may well claim a central, public good in researching and developing such pharmacological products, but the understanding of the companies, dictated by the complexities of IP law, profits and a need to return dividend yields to investors, can be different. In the absence of waivers, temporary suspensions, or triggers that act as exceptions in the global vaccine regime, wealthy countries can also find themselves facing IP disputes with pharmaceutical giants.

Moderna provides an example of this dilemma. Initially, the company claimed that it would not be enforcing its own COVID-19 vaccine patent during the pandemic. But such assurances have, at stages, proved hollow. The company has refused to share knowledge with the very government which provided funding for its research. The dispute between the US National Institutes of Health and Moderna over vaccine patents shows that even high-income countries must be wary about agreements made with drug companies that do not see their manufactured products through the prism of public health. Moderna's focus on developing mRNA technology interested the US government enough to warrant the granting of some \$2 billion in funding through the 2010s. In 2015, the National Institute of Allergy and Infectious Diseases signed a cooperative R&D agreement with Moderna that covered the development of novel vaccines. The amount of government funding assistance was not disclosed (Ruschman, 2021). From figures that are available, US federal government funding for the development and commercialisation of Moderna's COVID-19 vaccine can be estimated to stand at \$2.5 billion (Clouse, 2020). The funding has also been furnished alongside logistical and experimental support from scientists in the employ of the government. For its part, Moderna has countered with a predictably legal riposte, claiming that merely "because someone is an inventor on one patent application relating to our COVID-19 vaccine does not mean they are an inventor on every patent application relating to the vaccine." (Moderna, 2021).

The grave obstacles posed by IP have been remarked upon with some severity by Helen Clark, co-chair of the Independent Panel for Pandemic Preparedness and Response (IPPPR). "We've talked a lot about vaccines, but many countries have lacked adequate access to other basics such as diagnostics, therapeutics, personal protective equipment, and even oxygen" (Radio New Zealand, 2021). In their co-authored report for the WHO from May 2021, the authors recommended that major vaccine-producing states and manufacturers convene, under the joint auspices of the WHO and the World Trade Organization "to agree to voluntary licensing and technology transfer with intellectual property rights to be waived immediately if voluntary action, including action on the required technology transfer, does not occur within 3 months" (Sirleaf & Clark, 2021, p. 103). To cope with such discrepancies and inequalities, the IPPPR proposes a new architecture of pandemic preparedness, one girded by a treaty. An "end-to-end" platform in terms of developing, manufacturing goods and distributing goods would also have to be built into the system.

The global right to health

Pursuing such global access and limiting restraints on manufacture and supply of COVID-19 vaccines has also generated arguments that can be plausibly hooked upon human rights, seen through the prism of public health needs. The Universal Declaration of Human Rights affirms (Art. 25(1)) that, "Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing, and medical care and necessary social services." The International Covenant on Economic, Social and Cultural Rights remains one of the most important international documents in this field, with parties recognising "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", with Article 12.2 enumerating a number of "steps to be taken by the States parties ... to achieve the full realisation of this right" (UN Committee on Economic, Social and Cultural Rights, 2000, para. 2). A sufficient number of acknowledgments of the right to health can be found across regional human rights instruments to also suggest its normative nature, be it the European Social Charter of 1961, as revised, the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (Art. 10).

A public health-human rights approach to examining the conduct of states in response to vaccines has been adopted in the literature to certain countries. Canada's insistence on remaining neutral on the issue of the waiver, and its failure to reform the Canadian Access to Medicine Regime (CAMR), has been said to "constitute a failure to fulfil its international human rights obligations" (Amnesty International, 2021). Such arguments can also be made resorting to a range of international human rights instruments that buttress the right to health. Article 15 of the ICESCR establishes the right to enjoy the benefits of scientific progress and its applications via the right to science.

Using public international law as a basis of how best to break down vaccine nationalism in the public health context can be seen in various ways. One argument posited here is that human rights in health can be decolonised by addressing the IP regime through cooperative and collaborative mechanisms. Such a decolonial framing of human rights and public health is "based on solidarity and international cooperation that focuses on long-term goals and frees access to medicines from the restrictions of intellectual property law" (Sekala, Forman, Hodgson, et. al, 2021).

From a human rights perspective, we can also argue that segregated access should be ended, overcoming what critics such as Winnie Byanyima, Executive Director of UNAIDS has called "vaccine apartheid". Such an apartheid, she argues, only serves "the interests of the powerful and profitable pharmaceutical corporations while costing us the quickest and least harmful route out of this crisis" (Byanyima, 2021). Characterising such barriers to equal access in such a manner also serves to challenge the very idea of vaccine nationalism, a term and practice justified by the my-countryfirst approach (Sirleaf, 2021).

Theorising barriers to vaccine access from such a perspective is useful and supported by an extant body of international law. Global health law can become a vehicle by which COVID-19 vaccine access can be encouraged, using the very precepts that High-Income States have accepted (Gustin, Karim & Mason Meier, 2020). This point is also accepted by 27 UN Special Rapporteurs and Independent experts, who have stated that, "States have a collective responsibility to use all available means to facilitate faster and more equal access to vaccines worldwide." A temporary waiver on IP rights under TRIPS fell within the scope of such obligations (UN Human Rights Office of the High Commissioner, 2021).

Along similar lines of reasoning, it can also be argued that the no-harm principle under customary law might apply. The rule derives from the principle that States are customarily bound to prevent, reduce and control the risks of environmental harm to others (Brownlie, 2008, pp. 275-285; Birnie, Boyle & Redgwel, 2009, pp.143-152). This body of law exists in addition to undertakings made under treaty and conventions. The obligation of States to protect the health of their citizens can arguably be said to justify nationalist principles, at least provisionally. But this approach is constrained by the need to take measures to avoid harming the health of people in other States, suggesting an extraterritorial dimension to the way such obligations operate. A classic example of this would be acquiring an excessive vaccine supply on the part of one state party which would be detrimental to the broader interest of the international comity. The context of COVID-19 vaccines is, in some ways, even more significant, given that a failure to distribute and use such products globally, notably on the African continent, presents an ongoing risk of future variant mutations. Such mutations pose a genuine danger of undermining and blunting existing vaccines in terms of effectiveness and virulence, thereby posing dangers to *all* countries, irrespective of income bracket. The emergence of the Omicron variant from Southern Africa in November 2021 served as a stark illustration of this point, with public health specialists suggesting that it arose as "a consequence of vaccine inequity in parts of Africa, where the vaccination coverage in many countries is less than 10 percent" (Head, 2021).

Global public health and international law can also furnish the collaborative and cooperative justification for a more open IP regime. Despite criticisms of its inflexible nature, the global public health regime regulated by the International Health Regulations (2005) serves to emphasise a broader cooperative purpose. The Declaration of Astana (2018) goes further in reiterating State commitments towards effective cooperation, development and sharing knowledge and good practices, while respecting human rights, in order to prevent, detect and respond to infectious diseases and outbreaks (UN Human Rights Office of the High Commissioner, 1978). When read alongside such declarations as that of Alma-Mata (1978), and the 2030 Agenda for Sustainable Development, a structure of collaborative health policy at the international level is both encouraged and deemed desirable (World Health Organization, 2018).

Article 2(1) of the ICESCR also outlines a cooperative dimension in dealing with the right to health, with state parties undertaking "to take steps, individually and through *international assistance and cooperation* [author's emphasis], especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant by all appropriate means, including particularly the adoption of legislative measures" (International Covenant on Economic, Social and Cultural Rights, 1966). These measures are also seen to be of "comparable priority" to core obligations regarding the right to health, with the CESCR declaration that "core obligations" are non-derogable (Committee on Economic, Social and Cultural Rights, 2000). This leads human rights organisations such as Amnesty International to conclude that internationally speaking, governments "must cooperate to ensure access to COVID-19 vaccines around the

world, which includes making any necessary adjustments to intellectual property laws, policies and practices to ensure that these do not form a barrier to COVID-19 health products for all people globally" (Amnesty International, 2021).

Concluding remarks

The central contention in this paper is that IP in the field of COVID-19 vaccines is a critical barrier to their equitable and sufficient distribution, including its incidental products. Defenders of the IP system point to its necessity in ensuring innovation based on assured investments. They also claim that lifting such protections would do nothing to address deficient capacity and the means of production. But the arguments behind maintaining IP protections do not consider the public health justifications for such a move, as rooted in international law at both the customary level of state conduct and treaty undertakings. Identifying public health dictates in international law furnishes a formidable rationale as to why vaccines should be seen as public goods to be distributed globally.

The interconnected nature of funding and finance of such vaccines from both private and public bodies also militate against usual IP arguments. The cause, in other words, is of broader, more collective significance, linked to broader public welfare of health. Given the continuing cases of COVID-19 variants, the absence of a waiver will continue to imperil and retard efforts to rein in the pandemic. It would be very much in the selfinterest of all parties to endorse a temporary TRIP Waiver. Furthermore, the principle of not aiding or undertaking measures to assist other countries acquire vaccine, diagnostics and protective equipment readily will perpetuate a potential state of imperilment for all countries, irrespective of income levels, medical access and development.

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