

#### ARTICLE

# Decolonizing Human Rights Law in Global Health - the Impacts of Intellectual Property Law on Access to Essential Medicines: A Perspective from the **COVID-19 Pandemic**

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(Received 19 May 2023; revised 25 September 2023; accepted 17 October 2023)

#### Abstract

The global impacts of COVID-19 have been calamitous, unleashing widespread human suffering and exacerbating health crises, all while worsening pre-existing inequalities and transgressing fundamental human rights. Despite earnest pleas from the United Nations and developing nations for an equitable distribution of COVID-19 vaccines, these appeals were largely unheeded. Instead, major pharmaceutical manufacturers and high-income countries (HICs) had maintained a stranglehold on vaccine technology through the safeguarding of intellectual property rights (IPRs), leading to exorbitant pricing and preferential distribution to affluent regions. This vaccine hoarding has left low- and middle-income countries (LMICs) with delayed and insufficient supplies, endangering the lives of the most vulnerable. The stringent enforcement of IPRs mechanisms, rather than aligning with international human rights obligations, has further marginalised the right to life, health, and access to vaccines and medicines, particularly in LMICs. This study ardently advocates for a policy shift that promotes the decolonisation of human rights in the context of IPRs and global health law.

**Keywords:** Human rights; access to medicines; global health; neo-colonialism; decolonization; COVID-19; intellectual property rights; TRIPS

#### I. COVID-19 and Global Public Health

The COVID-19 pandemic has had a profound impact on global health, leading to widespread illness, loss of life, and significant disruptions to healthcare systems worldwide. As of September 2023, the global count of confirmed COVID-19 cases rose above 695 million, while the death toll linked to the virus has surpassed 6.9 million. Although several COVID-19 vaccines were successfully developed in a short timeframe of one year, most low- and middle-income countries (LMICs) faced significant challenges in obtaining access

<sup>&</sup>lt;sup>1</sup> "COVID - Coronavirus Statistics" (accessed 22 September 2023), online: Worldometer https://www. worldometers.info/coronavirus/.

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to these vaccines, largely due to restrictive patents and intellectual property (IP) laws. The presence of stringent patents and more onerous IP regulations often leads to monopolies in production, resulting in increased costs and limited availability. This creates a significant disparity in access to vaccines and pharmaceuticals between countries in the Global North and those in the Global South, as well as between the rich and the poor within countries, resulting in extensive ramifications.

Even though the COVID-19 pandemic is no longer a global health emergency,3 it created a pervasive global concern about the availability and accessibility of COVID-19 vaccinations, therapeutics, the latest medications, and medical procedures associated with this disease. The global community experienced a notable discrepancy in the access to vaccines between high-income countries (HICs) and LMICs. The global distribution of these vaccines and pharmaceuticals has been asymmetric, resulting in "vaccine apartheid",5 "vaccine hoarding", or "vaccine nationalism", which are now crucial warnings in the regime of global public health. Vaccines that showed high efficacy were primarily developed in select rich countries. At the same time, other HICs secured Advanced Purchase Agreements (APAs). They procured a significant portion of the vaccines during the early stages of the pandemic to prioritize their own populations.<sup>8</sup> However, many LMICs faced challenges in terms of limited technical production capacity and financial resources, which hindered their ability to secure vaccines through APAs. Vaccine manufacturing countries and HICs with ample vaccine supplies have also utilized "vaccine diplomacy"9 as a means to achieve non-trade goals from LMICs by using vaccines as a political tool. Some former colonial countries in the Global South, India, for example, benefitted financially from this imbalanced system as they also participated in the "vaccine hoarding" process against other ex-colonial countries. 11 This politicization and monopolization of COVID-19 pharmaceuticals seems to be a reincarnation of neo-colonialism in the realm of global health. This situation clearly pit some ex-colonized countries against other ex-colonized countries. 12

<sup>&</sup>lt;sup>2</sup> Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, WTO Doc. WT/MIN (01)/DEC/2 (20 November 2001), para. 3.

<sup>&</sup>lt;sup>3</sup> WHO, "Statement on the fifteenth meeting of the IHR (2005) Emergency Committee on the COVID-19 pandemic" (5 May 2023), online: WHO https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic.

<sup>&</sup>lt;sup>4</sup> Gavin YAMEY et al., "It is not too late to achieve global covid-19 vaccine equity" (2022) 376 BMJ e070650, online: https://www.bmj.com/content/376/bmj-2022-070650.

<sup>&</sup>lt;sup>5</sup> Simar Bajaj SINGH, Maki LWANDO, and Fatima Cody STANFORD, "Vaccine Apartheid: Global Cooperation and Equity" (2022) 399 The Lancet 1,452.

<sup>&</sup>lt;sup>6</sup> BBC, "Covid Vaccine: WHO Warns of "Catastrophic Moral Failure" (18 January 2021), online: BBC https://www.bbc.com/news/world-55709428.

<sup>&</sup>lt;sup>7</sup> Caitlin R. WILLIAMS, Jocelyn Getgen KESTENBAUM and Benjamin Mason MEIER, "Populist Nationalism Threatens Health and Human Rights in the COVID-19 Response" (2020) 110 American Journal of Public Health 1,766; RAND Corporation, "COVID-19 and the Cost of Vaccine Nationalism" (25 January 2021), online: GAVI https://www.gavi.org/vaccineswork/covid-19-and-cost-vaccine-nationalism.

<sup>8 &</sup>quot;COVID-19 Vaccine Access: Knowledge Portal", online: Knowledge Portal https://www.knowledgeportalia. org/covid-19-vaccine-access.

<sup>&</sup>lt;sup>9</sup> Peter J. HOTEZ, "'Vaccine Diplomacy: Historical Perspectives and Future Directions" (2014) 8 PLoS Neglected Tropical Diseases e2808.

 $<sup>^{10}</sup>$  Sharifah SEKALALA et al., "Decolonising human rights: How intellectual property laws result in unequal access to the COVID-19 vaccine" (2021) 6 BMJ Glob Health e006169.

<sup>&</sup>lt;sup>11</sup> Achal PRABHALA and Leena MENGHANEY, "The world's poorest countries are at India's mercy for vaccines. It's unsustainable" *The Guardian* (2 April 2021), online: The Guardian https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable.

<sup>&</sup>lt;sup>12</sup> Eve TUCK and K. Wayne YANG, "Decolonization Is Not a Metaphor" (2012) 1 Decolonization: Indigeneity, Education & Society 1; Sekalala et al., *supra* note 10; Candace FUJIKANE, "Asian American critique and Moana

"Neo-colonialism" refers to powerful states' continued economic and political control over a former colony or dependent territories, typically through indirect means such as economic domination or cultural hegemony. 13 Regarding human rights, neo-colonialism may refer to the notion that powerful countries or multinational corporations (MNCs) may exert significant influence over weaker countries' human rights policies and practices, particularly in the Global South, through their economic and political power. Thus, even if the formal and typical concept of colonialism is less pervasive today, its covert presence is omnipresent in most sectors of society, including global public health, particularly through the commodification of essential medicines. Strict protection of intellectual property rights (IPRs), as implemented in cases of COVID-19 vaccines and other essential pharmaceuticals, is a strategy used to commodify life-saving medicines, allowing manufacturers and manufacturing nations to place a higher value on financial gains rather than human life. Despite achieving political independence and sovereignty in various aspects, most Global South nations remain dependent on influential Global North countries and, to an increasing degree, on MNCs. 14 This is a facet of neocolonialism. The aversion to prioritizing a human rights approach to global public health, the adamant refusal of MNCs to share cutting-edge medical technologies with capable manufacturers in the Global South, and, above all, the strict protection of IP rights over medicines and medical technologies are indistinguishable from neo-colonialism.

Against this context, this article posits that the existing framework of IP law exacerbates pre-existing significant disparities in global public health at both international and national levels. Furthermore, it impedes many nations in the Global South from making incremental progress in realizing the right to health for their populations. The stringent laws and regulations governing IPRs are among the foremost contributors to the worsening of these inherent disparities in global public health. This neo-colonial approach to IP laws impedes all countries, and LMICs in particular, from gradually recognizing the right to health for their population. This incapacity ultimately amounts to a breach of the human rights obligations committed to in multiple international human rights treaties and legal instruments. Through a critical legal analysis, this study proposes that embracing a "decolonized approach" towards human rights in the context of global health may prove to be the most efficient strategy for tackling the systemic disparities that exist across the world.

The term "decolonization" generally refers to the process of dissolving the political, economic, and social systems of colonial powers, ending their authority over colonized regions and peoples. However, the contemporary concept of decolonization now encompasses the emancipation of minds from colonial ideology, specifically by challenging the entrenched notion that leading an inferior human life filled with indignity and subservience is a form of colonialism. This approach or methodology enables the investigation of power dynamics and the governing culture, allowing for a critical examination of these aspects. The demand for the decolonization of global health through the incorporation of human rights principles into its governing rules is an old concept; it represents a political movement originating from the Global South that actively opposes colonizing

Nui 2011: Securing a future beyond empires, militarized capitalism and APEC" (2012) 13 Inter-Asia Cultural Studies 189.

<sup>&</sup>lt;sup>13</sup> Lionel TIGER, "Neo-Colonialism. The Last Stage of Imperialism by Kwame Nkrumah" (1966) 22 International Journal 161.

<sup>&</sup>lt;sup>14</sup> Ibid.; Mark LANGAN, Neo-Colonialism and the Poverty of 'Development' in Africa (Springer International Publishing, 2018) at 149.

<sup>&</sup>lt;sup>15</sup> Sekalala et al., supra note 10; Linda Tuhiwai SMITH, Decolonizing Methodologies: Research and Indigenous Peoples, 2nd ed. (London: Zed Books, 2012) at 97-8, 108.

<sup>&</sup>lt;sup>16</sup> Sekalala et al., supra note 10.

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ideologies, exploitative "development" practices, apartheid, and unequal access to public health services, including the assurance of life-saving pharmaceuticals.<sup>17</sup> Nevertheless, COVID-19 has rejuvenated the demand for embracing a decolonized approach to human rights in global health and has emphasized the existing power imbalances that became evident during the pandemic.<sup>18</sup>

# II. Access to Medicine: An Inherent Human Right in Global Health

International human rights law is set to transform moral and ethical responsibilities into legal obligations. It provides a universal framework for sustainable health and advancing global health and justice. The preamble to the 1946 World Health Organization (WHO) constitution affirms that every human being, regardless of race, religion, political belief, and economic or social status, has a fundamental right to the "highest attainable standard of health". In 1948, two years after the adoption of the WHO's Constitution, the Universal Declaration of Human Rights (UDHR) vowed that every person has an entitlement to a standard of living that supports their health and well-being, which includes access to medical care for themselves and their families.<sup>20</sup> In 1966, the International Covenant on Economic, Social, and Cultural Rights (ICESCR) reaffirmed that the right to health encompasses the availability of "health facilities, goods, and services" to all individuals.<sup>21</sup> Numerous international organizations and entities, such as the United Nations (UN), the World Trade Organization (WTO), and the World Health Organization (WHO), have acknowledged the "right to health" as a fundamental human right. The UN has periodically adopted resolutions acknowledging the "right to health", which encompasses access to medical care and medications as needed.<sup>22</sup> In 2015, the UN endorsed seventeen Sustainable Development Goals (SDGs) to be achieved by 2030. The third goal, which aims to "ensure healthy lives and promote well-being for all at all ages", encompasses a range of targets, including addressing non-communicable diseases, substance abuse, and environmental health.<sup>23</sup>

As per the ICESCR preamble, the right to have life-saving medicines is a component of the broader right to "the highest achievable standard of health", which is firmly embedded in international human rights laws. Within the scope of the right to health, individuals are entitled to obtain essential medication and benefit from a properly operating healthcare system. This means governments are accountable for guaranteeing their citizens access to essential medicines to maintain their well-being and establishing a healthcare framework that facilitates such access. Although individual countries are primarily

<sup>&</sup>lt;sup>17</sup> Ibid.; Clara AFFUN-ADEGBULU and Opemiposi ADEGBULU, "Decolonising Global (Public) Health: From Western Universalism to Global Pluriversalities" (2020) 5 BMJ Global Health e002947; Lisa FORMAN, "Global Health Governance from Below: Access to AIDS Medicines, International Human Rights Law, and Social Movements" in Andrew F. COOPER and John J. KIRTON, eds., Innovation in Global Health Governance: Critical Cases (Surrey, England: Ashgate Publishing Group, 2009), 193.

<sup>&</sup>lt;sup>18</sup> Sriram SHAMASUNDER et al., "COVID-19 reveals weak health systems by design: Why we must re-make global health in this historic moment" (2020) 15 Global Public Health 1083.

 $<sup>^{19}</sup>$  WHO, "The Constitution of the World Health Organisation", Preamble, online: WHO <a href="https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1.">https://apps.who.int/gb/bd47/EN/constitution-en.pdf?ua=1.</a>

<sup>&</sup>lt;sup>20</sup> Universal Declaration of Human Rights, GA Res. 217 (III), UN Doc. A/810 (1948) [UDHR], art. 25.

<sup>&</sup>lt;sup>21</sup> International Covenant on Economic, Social and Cultural Rights, 16 December 1966, S. Exec. Doc. D, 95-2 (1977), 993 U.N.T.S. 3 (entered into force Jan. 3, 1976) [ICESCR], art. 25.

 $<sup>^{22}</sup>$  The UN Decade of Healthy Ageing (2021 - 2030), United Nations General Assembly, UN Doc. A/RES/75/131 (21 December 2020).

<sup>&</sup>lt;sup>23</sup> United Nations Development Programme, "What are the Sustainable Development Goals?" (25 April 2023), online: UNDP https://www.undp.org/sustainable-development-goals.

<sup>&</sup>lt;sup>24</sup> ICESCR, supra note 21, Preamble.

responsible for safeguarding their citizens' right to access essential medicines, this responsibility is not exclusive to governments: other non-state entities also bear a share of this obligation. As per the former UN Special Rapporteur on the Right to Health, pharmaceutical enterprises also bear human rights obligations that require them to take every practical measure to ensure that new medications are made accessible to those who need them most. Furthermore, the UN Guiding Principles on Business and Human Rights, which received unanimous endorsement from the UN Human Rights Council (UNHRC) in 2011, mandate that the private sector is accountable for any human rights transgressions associated with access to medicines. When confronted with a socio-economic crisis like the COVID-19 pandemic, the global community holds a responsibility to provide humanitarian assistance and disaster relief expeditiously by providing medical supplies. The social responsibility to provide humanitarian assistance and disaster relief expeditiously by providing medical supplies.

In reality, access to medicine is an intricate inter-governmental dilemma, especially in LMICs. Often, LMICs are deficient in adequate resources and the infrastructure needed to guarantee universal access to essential medicines for their entire populations. Moreover, the exorbitant prices for life-saving medicines, coupled with insufficient regulation of the pharmaceutical industry, also impede access to these medicines. When patent protection of vaccines, medical products, and processes is strictly enforced, even in a disastrous global health crisis such as the COVID-19 pandemic, it exacerbates the intricacies of achieving access to these pharmaceuticals across the nations. Therefore, LMICs' responsibility to guarantee their population's right to health is largely qualified by their constrained capacity to procure essential vaccines and pharmaceuticals from the global pharmaceutical market.

# III. Human Rights-Based Approach to Access COVID-19 Vaccines and Pharmaceuticals

The human rights-based approach (HRBA) to accessing medicines prioritizes the right to the best achievable physical and mental health level, encompassing the availability of essential medicines. The approach stresses the importance of upholding the right to health by governments, pharmaceutical companies, and other stakeholders by ensuring that medicines are within reach, accessible, and reasonably priced for all individuals, irrespective of their socio-economic status and geographic location. The HRBA indicates that, when devising and implementing policies and programmes pertaining to access to medicines, the needs and viewpoints of underprivileged groups, such as those living in poverty, should be carefully considered. Adopting the HRBA approach can guarantee that access to essential medicines is not merely an act of kindness, charity, donation, or benevolence but is acknowledged as a fundamental human right that all actors within the healthcare system must safeguard and advance. This can include measures such as increasing domestic investment in research and the development of new medicines, implementing fair and transparent pricing policies, and strengthening healthcare systems

<sup>&</sup>lt;sup>25</sup> Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, United Nations General Assembly, UN Doc. A/63/263 (11 August 2008).

<sup>&</sup>lt;sup>26</sup> Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie, UN Human Rights Council, UN Doc. A/HRC/17/31 (21 March 2011).

<sup>&</sup>lt;sup>27</sup> Substantive Issues Arising in the Implementation of the International Convention on Economics, Social and Cultural Rights, UN Committee on Economic, Social and Cultural Rights, General Comment No. 14, UN Doc. E/C.12/2000/4, para. 40.

 $<sup>^{28}</sup>$  Xavier SEUBA, "A Human Rights Approach to the WHO Model List of Essential Medicines" (2006) 84 Bulletin of the World Health Organization at 405–11.

to ensure that all individuals have equitable access to the medicines they need. In practical terms, the HRBA approach helps realize that access to medicines is a human rights issue, not just a public health matter. It can help to ensure that the needs of marginalized groups are taken into account in policy and practice: it highlights that everyone has the right to live a healthy life and access medications.

The United Nations Committee on Economic, Social and Cultural Rights (CESCR) is primarily responsible for interpreting the ICESCR. With regard to the accessibility of COVID-19 vaccines and medicines, this Committee expressed its concerns. It reiterated that individual countries "have a duty to prevent intellectual property and patent legal regimes from undermining the enjoyment of economic, social and cultural rights" and that the IP regime should be interpreted and implemented in a manner that is consistent with the obligation of states "to protect public health". 29 This responsibility now encompasses ensuring fair worldwide dissemination of vaccines and pharmaceuticals to tackle the spread of infectious diseases such as COVID-19.30 Access to life-saving vaccines and pharmaceuticals should not depend on acts of generosity or donations<sup>31</sup> but on states upholding their international human rights obligations. The unavailability of COVID-19 vaccines and treatments obstructs the fulfilment of various human rights, such as the right to life, the right to receive equal benefits from scientific progress, and the right to health. Favouring the HRBA, CESCR has contended that the commercialization of COVID-19 vaccines and pharmaceuticals has propagated unfairness and breached international human rights obligations.<sup>32</sup> The prevailing restrictive public health policy, which is heavily influenced by pharmaceutical patent regulations, requires a thorough re-evaluation to ensure that it aligns with global human rights principles.

# IV. Simplified Correlation between Human Rights and IP Rights

The issue of access to patented medicines epitomizes the conflicts between human rights and IP rights. Governments issue patents to inventors and creators, giving them exclusive rights over their inventions for a limited time to promote innovation and creativity. The current international IPRs regime under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>33</sup> incentivizes pharmaceutical companies to invest in research and development of advanced drugs, potentially resulting in the emergence of new treatments for illnesses and access to medications that may not have been available otherwise. New medicines and innovative medical procedures do not fall from the sky. These products result from substantial financial investments and extensive research spanning several years or even decades, with many having minimal or no therapeutic benefits. If granting universal access to the latest vaccines and pharmaceuticals were to impede such research, it could result in reduced medical innovation and fewer treatments for

<sup>&</sup>lt;sup>29</sup> UN Committee on Economics, Social and Cultural Rights, "Statement on Universal Affordable Vaccination against Coronavirus Disease Covid-19, International Cooperation and Intellectual Property" (2021) 10 International Human Rights Law Review 180 at 184, online: https://brill.com/view/journals/hrlr/10/1/article-p180 180.xml.

<sup>&</sup>lt;sup>30</sup> Sekalala et al., *supra* note 10; Lawrence O. GOSTIN, Safura Abdool KARIM and Benjamin Mason MEIER, "Facilitating Access to a COVID-19 Vaccine through Global Health Law" (2020) 48 Journal of Law, Medicine & Ethics 622.

<sup>31</sup> COVAX falls short on this point.

<sup>&</sup>lt;sup>32</sup> Sekalala et al., *supra* note 10; Koen BYTTEBIER, "Final Conclusions" in Koen BYTTEBIER and Kim VAN DER BORGHT, eds., *Covid-19 and Capitalism: Success and Failure of Legal Methods for Dealing with a Pandemic* (Springer International Publishing, 2022), 1,067.

<sup>&</sup>lt;sup>33</sup> WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1995, 33 I.L.M 81 (1994), as amended on 23 January 2017 [TRIPS].

new diseases. The outcomes of granting such universal access to medications would undoubtedly conflict with international human rights law principles, if not the exact wording.<sup>34</sup> However, strict enforcement of IPRs or patents leads to the products being prohibitively expensive or inaccessible to many individuals, including low-income populations in wealthy nations and almost everyone in developing countries. The concepts of morality, ethics, and human rights contradict the notion of withholding life-saving drugs from those with fatal or debilitating illnesses, especially when palatable alternatives exist that are both cost-effective and efficient.<sup>35</sup>

A strictly regulated system of patents can benefit private entities such as the pharmaceutical industry, allowing them to recover their research costs and generate expected profits by enforcing their IP rights over their products. In addition to generating financial profits, an IPRs-based medical innovation system offers various social advantages. This system encourages the exploration of novel medical research, enforces the public disclosure of medical procedures and products to foster future innovation, and permits pharmaceutical companies to produce and distribute generic drugs at low cost after the patent protection has expired. Nonetheless, a strict patent system or stringent IP protection provides little comfort to individuals suffering from life-threatening illnesses who cannot afford potentially life-saving medications protected under such patents. It is a delicate balance to strike; different countries approach this issue in different ways. Despite having commitments under TRIPS Articles 7 and 8, most HICs prioritize pharmaceutical industries' interests at the expense of the majority of people's right to health.

# V. The Historical Dichotomy Between IP Rights and Human Rights

The American Declaration on the Rights and Duties of Man is the earliest contemporary international instrument on human rights. It was passed in 1948, just before the adoption of the UDHR.<sup>36</sup> The drafters of this first international human rights instrument undertook significant consideration for IPRs by recognizing the literary, artistic, and scientific works of any author, as well as the innovations of any individual.<sup>37</sup> The wording and framework of Article 13 in the American Declaration provided the basis for Article 27 of the UDHR, but with a caveat that the UDHR does not expressly acknowledge IPRs or regard innovative creations as human rights.<sup>38</sup> The UDHR is not legally binding on the nations. Still, the provisions in Article 27 have had a domino effect, resulting in the incorporation of equivalent measures in the ICESCR,<sup>39</sup> regional declarations and treaties,<sup>40</sup> and national constitutions.<sup>41</sup> The human rights provisions of these documents create a predicament when it comes to the intersection of human rights and IP rights. They preserve the creators' fundamental rights over their inventions while recognizing the general public's right to

<sup>&</sup>lt;sup>34</sup> Commission on Intellectual Property Rights [CIPR], "CIPR Final Report", online: http://www.iprcommission.org/graphic/documents/final\_report.htm.

<sup>&</sup>lt;sup>35</sup> Thomas POGGE, "Access to Medicines" (2008) 1 Public Health Ethics 73.

 $<sup>^{36}</sup>$  The American Declaration on Human Rights was signed in April 1948, which came into effect on 2 May. The UDHR was signed on 10 December 1948.

<sup>&</sup>lt;sup>37</sup> American Declaration on the Rights and Duties of Man, 2 May 1948, online: http://www.oas.org/dil/access\_to\_information\_human\_right\_American\_Declaration\_of\_the\_Rights\_and\_Duties\_of\_Man.pdf.

<sup>38</sup> UDHR, supra note 20, art. 27.

<sup>&</sup>lt;sup>39</sup> ICESCR, supra note 21, art. 15(1)(b)-(c).

<sup>&</sup>lt;sup>40</sup> See, e.g., Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador), Organisation of American States [OAS] (16 November 1999), art. 14, online: https://extranet.who.int/mindbank/item/1255#:~:text=Description,and%20the%20right%20to%20education.

<sup>&</sup>lt;sup>41</sup> See, e.g., Constitution of Bhutan (2008), art. 7(13); Constitution of Burundi (2005), art. 58; Constitution of Congo (2002), art. 29; Constitution of Croatia, art. 69 (1990).

benefit from cultural and scientific innovations made by the creators. More specifically, these provisions reflect the dichotomy between the inventors' incentives for innovation and profitless public access to the advantages of innovation.<sup>42</sup>

The European Convention on Human Rights (ECHR), another major international human rights instrument, does not mention or acknowledge IP rights as human rights. The ECHR does not refer to or recognize IP rights as standalone. It is conceivable that the ECHR was adopted in the 1950s with the primary goal of safeguarding civil and political rights in response to the heinous crimes perpetrated by authoritarian regimes during the Second World War, resulting in the omission of IPRs from its purview.

Conversely, when recognizing human rights within the global intellectual property regime, international IP treaties have historically neglected the impact, mutual correlation, and role of human rights in protecting intangible assets. Both the Paris and Berne Conventions were signed at the end of the nineteenth century, before the inception of the international human rights framework. Therefore, it is presumable that these two foundational international legal instruments on IP rights are silent about recognizing and protecting human rights while undertaking measures to protect IP rights. The 1961 Rome Convention on Related Rights also adopts a similar oblivious approach to the post-Second World War other treaties on intellectual property rights.<sup>43</sup> Nevertheless, there was a change in this track when, in 1994, TRIPS was adopted as a "single undertaking" as part of the Marrakesh Agreement Establishing the World Trade Organization.<sup>44</sup>

Two provisions within TRIPS undeniably impact human rights. Article 7 states that IP rights should be protected and enforced to benefit both the producers and "the users" of technological information, promote social and economic well-being, and maintain a balance between rights and obligations. This is the first clause in an international IPRs treaty that requires interpreters to consider the rights of "the users" of intellectual assets while interpreting the treaty. TRIPS Article 8 requires WTO members to balance public health needs and the protection of IPRs. It allows WTO members to adopt IP measures to protect new innovations while promoting "public interest". However, neither of these TRIPS articles provides explicit guidelines or criteria for achieving the desired balance, as stated in their texts. This allows WTO members to adopt any intellectual property measure suitable for protecting new innovations. The limited scope of these provisions creates a paradoxical situation in maintaining a balanced and harmonious relationship between intellectual property rights and human rights. Achieving a synchronized balance between safeguarding innovation and promoting public health interests often exposes a challenging or even unattainable task.

Even though TRIPS encourages countries to implement measures that promote a balance, it creates a supremacy of intellectual property rights over human rights. TRIPS Articles 7 and 8 compel WTO members to resolve potential conflicts within the specific IP framework, where human rights assume a subservient position compared to the innovators' interests in intellectual property. This is particularly obvious in its requirement that exceptions to intellectual property laws are deemed "necessary" to safeguard the public interest. The term "necessary" is construed as adopting a "least restrictive

<sup>&</sup>lt;sup>42</sup> Laurence R. HELFER, "Toward a Human Rights Framework for Intellectual Property" 40 U.C. Davis Law Review 971.

<sup>&</sup>lt;sup>43</sup> Laurence R. HELFER and Graeme W. AUSTIN, Human Rights and Intellectual Property: Mapping the Global Interface (Cambridge: Cambridge University Press, 2011) at 32.

<sup>44</sup> TRIPS, supra note 33.

<sup>&</sup>lt;sup>45</sup> The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: Report of the High Commissioner, Economic and Social Council, E/CN.4/Sub.2/2001/13, online: https://digitallibrary.un.org/record/446005.

<sup>&</sup>lt;sup>46</sup> TRIPS, supra note 33, art 8(1).

approach", which obliges WTO members to undertake a less harmful measure for the interests of the IP owners.<sup>47</sup> If this is not enough, the "consistency" requirement could also require WTO members to implement stricter measures. For example, countries could be forced to follow strict three-step tests when putting copyright and patent exceptions into place under Articles 13 and 30. This vague and feeble consideration of human rights in TRIPS was a significant catalyst for the acceptance of the 2001 Doha Declaration on TRIPS and Public Health, which restated the significance of public health in international intellectual property laws.<sup>48</sup>

To put it briefly, neither WTO nor the TRIPS agreement clearly recognizes human rights within the purview of IP rights. However, as the mandatory global standard-setting framework for intellectual property, TRIPS articulates variations of IP standard rules as a matter of state public policy. By doing this, TRIPS permits WTO members to substitute the fundamental value of human dignity as the primary rationale for enforcing detrimental intellectual property rights. This Agreement enables governments to advance any intellectual property policies and regulations that take precedence over inherent human rights or international human rights laws. Individuals are entitled to acknowledgement of their inherent rights, including access to medicines, only to the degree that they align with TRIPS and concomitant governmental policies. Identical circumstances continue to play a role in all other international instruments relating to IPRs, such as the WIPO Copyright Treaty or the Performances and Phonogram Treaty. 50

## VI. IP Rights Prioritized Over Right to Health in Global Health Law

Global health law comprises legal norms, procedures, and institutions that enable individuals worldwide to achieve "the highest possible level of physical and mental health". The regulatory structure for global health is not well-integrated. It is seemingly a consolidated fragmentation of divergent stakeholders and frameworks, including health security, border management, consistent domestic monitoring, reciprocal trade relations, and intellectual property rights. This disintegrated structure of global health law is further impaired at the juncture of International Health Regulations (IHR) and international human rights law. The complexity of this situation has resulted in an urgent demand for harmonising IHR and human rights laws.

The development and distribution of COVID-19 vaccines have demonstrated persistent inequalities in access to medicines between the rich and the poor countries. The prioritization of IP rights over human health has facilitated "neo-colonialism". It shows that the

<sup>&</sup>lt;sup>47</sup> Henning Grosse RUSE-KHAN, "Assessing the need for a general public interest exception in the TRIPS Agreement" in Kur ANNETTE, ed., *Intellectual Property Rights in a Fair World Trade System* (Edward Elgar Publishing, 2011), 167.

<sup>&</sup>lt;sup>48</sup> Frederick M. ABBOTT, "The Trips Agreement, Access to Medicines, and the WTO Doha Ministerial Conference" (2002) 5 The Journal of World Intellectual Property 15.

<sup>&</sup>lt;sup>49</sup> TRIPS, supra note 33, art. 1.1.

<sup>&</sup>lt;sup>50</sup> WIPO Copyright Treaty, 20 December 1996, WIPO Lex No. TRT/WCT/001, Preamble; WIPO Performances and Phonograms Treaty, 20 December 1996, WIPO Lex No. TRT/WPPT/001, Preamble.

<sup>&</sup>lt;sup>51</sup> WHO Constitution, *supra* note 19, Preamble; Lawrence O. GOSTIN and Allyn L. TAYLOR, "Global Health Law: A Definition and Grand Challenges" (2008) 1 Public Health Ethics 53.

 $<sup>^{52}</sup>$  Lawrence O. GOSTIN et al., "The legal determinants of health: Harnessing the power of law for global health and sustainable development" (2019) 393 The Lancet 1,857.

<sup>&</sup>lt;sup>53</sup> Sekalala et al., supra note 10.

<sup>&</sup>lt;sup>54</sup> Sam JARIFI, "Harmonizing Global Health Law and Human Rights Law to Develop Rights-Based Approaches to Global Health Emergencies" (24 February 2021), online: Opinio Juris http://opiniojuris.org/2021/02/24/harmonizing-global-health-law-and-human-rights-law-to-develop-rights-based-approaches-to-global-health-emergencies/.

"life and health" of some human beings in HICs are more important than the lives and health of the humans living in LMICs. Simultaneously, the concurrent body of global health law legitimizes "vaccine hoarding", "vaccine nationalism", and "vaccine apartheid". The current IP protection regime under TRIPS allows for global health laws that promote inequality, which goes against human rights commitments outlined in the ICESCR, UDHR, and other international human rights agreements. Due to the lack of a distinct acknowledgement and expression of human rights within TRIPS, there is an operational and ideological disengagement between IP law, global health law, and international human rights law. This disengagement significantly contributes to the widening defragmentation of global health law, which the following factors can evince.

#### A. IP Rights Favour Corporate Insatiability over Health

The central argument in favour of IP protection is that IP rights are *sine-qua-non* for future investments in research and innovation. As per TRIPS regulations, WTO member countries must ensure patent protection for pharmaceuticals for at least twenty years.<sup>57</sup> One of the main objectives of this protection is to incentivize pharmaceutical companies and other innovators to achieve returns from their research and development, both domestically and throughout the global markets; however, this much-talked argument does not apply to COVID-19 vaccines and pharmaceuticals. Substantial public funding for the urgent development of these vaccines casts doubt on the rationale of this argument. Also, some facts tend to disprove the typical connection between research and development and the incentives for inventing COVID-19 vaccines.<sup>58</sup>

An independent health research report reveals that the global public sector has invested at least €93 billion in developing COVID-19 vaccines. €85.6 billion of this fund was used to create the vaccines. <sup>59</sup> The primary sponsorship for the research, development, and production of most of the top-quality COVID-19 vaccines came from public funds. The US federal government's Operation Warp Speed (OWS) provided roughly \$12 billion in public funds to support pharmaceutical companies' research and development into COVID-19 vaccines. Moderna received \$2.5 billion from OWS, whereas Pfizer was granted \$1.95 billion from a public fund. <sup>60</sup> The German government provided BioNTech, a partner of Pfizer, with \$445 million to support the development of the vaccine. <sup>61</sup> In addition to public funding for the development of vaccines in the US and Europe, China directly funded the Sinovac and Sinopharm pharmaceuticals. <sup>62</sup> Likewise, Sputnik V was developed at the Gamaleya Research Institute, a government-operated research centre in Russia. <sup>63</sup> Without substantial public funds, developing COVID-19 vaccines so quickly and effectively would not have been possible.

<sup>&</sup>lt;sup>55</sup> See supra notes 4-14.

<sup>&</sup>lt;sup>56</sup> See supra notes 19-25.

<sup>&</sup>lt;sup>57</sup> TRIPS, supra note 33, arts. 33 and 70.8.

<sup>&</sup>lt;sup>58</sup> Patrice TROUILLER et al., "Drug development for neglected diseases: A deficient market and a public-health policy failure" (2002) 359 The Lancet 2,188.

<sup>&</sup>lt;sup>59</sup> Madeleine HOECKLIN, "€93 Billion Spent By Public Sector On COVID Vaccines And Therapeutics in 11 Months, Research Finds" (12 January 2021), online: Health Policy Watch https://healthpolicy-watch.news/81038-2/; also cited in Sekalala et al., *supra* note 10.

<sup>&</sup>lt;sup>60</sup> Matthew M. KAVANAGH, Lawrence O. GOSTIN and Madhavi SUNDER, "Sharing Technology and Vaccine Doses to Address Global Vaccine Inequity and End the COVID-19 Pandemic" (2021) 326 JAMA 219.

<sup>&</sup>lt;sup>62</sup> Olivier J. WOUTERS et al., "Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment" (2021) 397 The Lancet 1,023.

Between 2021 and 2022, Moderna and Pfizer generated more than \$34 billion each in revenue, translating to a profit of \$1,000 per second. Even though 98 per cent of the individuals in LMICs were not completely vaccinated, Pfizer raised their vaccine price from \$22.60 to \$25.50, while Moderna increased their vaccine price from \$18.30 to \$23.00. Given the substantial contribution of public funding to the research and development of COVID-19 vaccines, it can be argued that all COVID-19 vaccine brands should have been considered a "public good". Considering COVID-19 vaccines as a public good would have been a more humane and fair approach in times of a pandemic. However, vaccine manufacturers seemed unwilling to reduce prices, relax or relinquish their intellectual property rights, or transfer technology to LMICs. Despite the detrimental impact of strict intellectual property protections on COVID-19 vaccines on public health in the Global South, wealthy nations such as the US, the EU, and Germany seem determined to uphold their own pharmaceutical corporations' interests.

## B. The COVAX Initiative: Is it a Relaxation of IP Rights or a Manifestation of Human Rights Law?

The COVAX or "COVID-19 Vaccines Global Access" is a programme collaboratively developed by Gavi, the Vaccine Alliance, the WHO, and the Coalition for Epidemic Preparedness Innovations (CEPI) and is supported by donations from various contributors. The primary objective of this worldwide effort was to provide fair and equal access to COVID-19 vaccines for individuals across all nations, irrespective of their financial status. It is crucial to note that the COVAX programme is separate from any measures that involve the relaxation of IPRs, the transfer of vaccine technology, or other alternative approaches to strict enforcement of IP laws. While COVAX represents a compassionate initiative, it is not to be misunderstood as having any direct link or correlation to contemporary global human rights law or relaxation of IPRs.

The COVAX initiative encountered a significant deficit in fulfilling worldwide demand, and, in practical terms, it fell short of accomplishing its goals.<sup>67</sup> This vaccine initiative experienced a variety of constraints that impeded its capacity to guarantee fair access to COVID-19 vaccines. The main reasons for the failure of COVAX were a shortage of supplies, inadequate funding, uneven distribution, delivery delays, vaccine hesitancy, and, most importantly, "vaccine nationalism", as exhibited by HICs.<sup>68</sup> From a legal point of view, the main shortcoming of COVAX was that it was a charity-based programme. Some experts believe it failed because the programme was not designed to push for IP sharing, an essential lifeline to produce sufficient vaccines.<sup>69</sup> COVAX begged for vaccines from vaccine-rich nations instead of promoting equitable access to technology and enhancing production and distribution capacity. One of the most detrimental policies implemented by COVAX involved the utilization of a strategy that relied on charitable contributions and market purchases of vaccines through its facilities. This programme generated a weaker ethical responsibility for the countries contributing to it. It did not provide any legal entitlement or legal right, particularly for those recipients in dire

<sup>&</sup>lt;sup>64</sup> Oxfam, "Pfizer, BioNTech and Moderna Making \$1,000 Profit Every Second While World's Poorest Countries Remain Largely Unvaccinated - World" (16 November 2021), online: Oxfam https://www.oxfam.org/en/pressreleases/pfizer-biontech-and-moderna-making-1000-profit-every-second-while-worlds-poorest.

<sup>65</sup> Ibid.

<sup>&</sup>lt;sup>66</sup> GAVI, "COVAX Facility", online: GAVI https://www.gavi.org/covax-facility.

<sup>&</sup>lt;sup>67</sup> Ann Danaiya USHER, "A Beautiful Idea: How COVAX Has Fallen Short" (2021) 397 The Lancet 2,322.

<sup>&</sup>lt;sup>69</sup> Olivia GOLDHILL, "Naively ambitious: How COVAX failed on its promise to vaccine the world" (8 October 2021), online: StatNews <a href="https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/">https://www.statnews.com/2021/10/08/how-covax-failed-on-its-promise-to-vaccinate-the-world/</a>.

need of life-saving vaccines and pharmaceuticals. As seen in this system, the COVAX approach focused on "charity" rather than rights, aligning with the outdated notions of public health and human rights that require decolonization. The failure of COVAX can serve as a lesson for the future, prompting the WHO and the global community to discourage voluntary and charity-based vaccine distribution programmes.

Even though the UNHRC has released joint statements in which nations have concurred that all states possess the right to utilize TRIPS flexibilities and access vaccines, the statement is predominantly rhetoric; it does not create any corresponding obligations of states to provide such flexibilities to countries in need. The inbuilt disconnection between rights and obligations within the TRIPS flexibility rules has made it possible for countries from the Global North and a small number of their allies from the Global South to support this rhetoric. This group of countries regularly objects to any appeals for easing IP rights or TRIPS waivers at the WTO, thereby cementing their resistance to utilizing TRIPS flexibilities. The state of the

### C. TRIPS Flexibility: How Flexibly Does it Work for Access to Medicines?

Theoretically, WTO Members, including LMICs, can invoke TRIPS flexibilities; for example, by compulsory licencing and parallel importing, with or without any general waiver from their WTO obligations. <sup>72</sup> In practice, these flexibilities are impractical and do not serve the interests of LMICs. The flexibilities offered by TRIPS are inherently vague, complex, and ambiguous, necessitating frequent clarifications.73 During the peak of the HIV-AIDS pandemic in 2001, Zimbabwe requested a clarification of Article 31(f), leading to a waiver that allowed the export of critical generic medicines to LMICs that had limited or no ability to produce them.<sup>74</sup> This "clarification" issue ultimately led to the adoption of the Doha Declaration on TRIPS and Public Health (DDTPH) in November 2001.<sup>75</sup> A temporary waiver of TRIPS Article 31(f) was granted in August 2003 based on the DDTPH. Finally, TRIPS made this temporary waiver a permanent clause. This was the first-ever amendment to any WTO Agreement. Article 31bis was added to the treaty as a permanent exemption to Article 31(f), which became effective in 2017.76 However, this TRIPS amendment appears to be useless; it does not fulfil the objective for which it was intended. Because of its inherent procedural and administrative complexities, it took five years to utilize a TRIPS Article 31bis waiver. It was only in September 2008 that Canada used the waiver for the first time and shipped its first generic drug exports to Rwanda. 77 Apotex, the drug

<sup>&</sup>lt;sup>70</sup> Timothy HODGSON and Rossella DE FALCO, "Human Rights and Universal Access to COVID-19 Vaccines: Does the Human Rights Council Resolution Go Far Enough" (23 March 2021), online: Opinio Juris http://opiniojuris.org/2021/03/23/human-rights-and-universal-access-to-covid-19-vaccines-does-the-human-rights-council-resolution-go-far-enough/.

<sup>&</sup>lt;sup>71</sup> Khorsed ZAMAN, "The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence" (2022) 13 European Journal of Risk Regulation 295.

<sup>72</sup> TRIPS, supra note 33, arts. 31 and 31bis.

<sup>&</sup>lt;sup>73</sup> Zaman, supra note 72.

<sup>&</sup>lt;sup>74</sup> Minutes of the Meeting: Held in the Centre William Rappard from 2 to 5 April 2001, Council for Trade-Related Aspects of Intellectual Property Rights, WTO Doc. IP/C/M/30 (1 June 2001), paras. 229–52.

<sup>&</sup>lt;sup>75</sup> Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, WTO Doc. WT/MIN(01)/DEC/2 (14 November 2001), online: https://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.htm.

<sup>&</sup>lt;sup>76</sup> WTO, "WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines" (23 January 2017), online: WTO https://www.wto.org/english/news\_e/news17\_e/trip\_23jan17\_e.htm.

<sup>&</sup>lt;sup>77</sup> Canada was the first country to export the first shipment of generic drugs to Rwanda in 2008. See ICTSD, "First Generic Drugs En Route to Africa under 5-Year-Old WTO Deal" (2008) 12 Bridges Weekly Trade News Digest 4.

maker involved in the Canadian export deal said it "will not go through the complicated and costly process again unless the regulations are amended". This was not done. So far, after it was finally adopted in 2003, this was the only use of TRIPS Article 31 bis in the last nineteen years. Moreover, it is also uncertain whether an Article 31 bis waiver can be used to export pharmaceuticals manufactured under TRIPS Article 73. Consequently, utilizing TRIPS flexibilities as a mechanism to gain access to life-saving drugs remains an impossible task for LMICs. One of the complex to the complex transfer of the complex transfer of

A similar dilemma emerged in the context of exporting COVID-19 vaccines and pharmaceuticals despite having a newly amended provision on exemption, waiver, and TRIPS flexibility on the matter of exporting life-saving pharmaceuticals to LMICs. In October 2020, India and South Africa approached the WTO with a proposal to temporarily waive TRIPS regulations for COVID-19 vaccines, diagnostics, and therapeutics. Following a prolonged period of deliberation and resistance from HICs, a temporary and partial waiver of patent rights for COVID-19 vaccines was finally approved during the WTO's 12th Ministerial Conference on 17 June 2022. This second TRIPS waiver decision at the WTO only waives obligations under TRIPS Article 31(f) with respect to COVID-19 vaccines. This waiver does not include COVID-19 diagnostics and therapeutics, which are essential for patients already infected by the disease. Enabling broader global access to COVID-19 diagnostics and therapeutics is essential for reducing the number of hospitalizations, morbidity, and other fatalities caused by the virus, particularly in LMICs where vaccination rates are low and vulnerable populations face a greater risk of severe medical complications.

As a result of the second TRIPS waiver, COVID-19 vaccines produced under compulsory licences can now be temporarily exported to LMICs. However, it should be noted with great caution that there is nothing unique about this 2022 TRIPS waiver since it is a recurring exemption of TRIPS Article 31(f). The fact that two waivers were needed within two decades to address global public health crises arising from a single provision under the TRIPS indicates a significant flaw in the current IPRs regime concerning global public health. The need to negotiate two distinct waivers to meet public health requirements highlights the unsettling nature of the IP restrictions imposed by that particular provision. As a result, the right to access essential medicines has been significantly compromised in favour of IPR owners, violating the human right to health

A critical legal analysis of TRIPS flexibilities and IP waivers has shown that they are mostly symbolic and do not provide adequate flexibility for patients needing essential pharmaceuticals, including COVID-19 vaccines.<sup>84</sup> Counting from the 2003 waiver decision, it took five years to invoke the first waiver due to its intrinsic complicated

 $<sup>^{78}</sup>$  See, in general, ICTSD, Bridges Weekly Trade News Digest (2008) Vol 12(42).

<sup>&</sup>lt;sup>79</sup> Medicines Law and Policy, "TRIPS Flexibility Database" (accessed 16 September 2023), online: http://tripsflexibilities.medicineslawandpolicy.org/

<sup>&</sup>lt;sup>80</sup> Khorsed ZAMAN and Rafiqul ISLAM, "The Proposal to the WTO for a New Patent Waiver on COVID-19 Vaccines and Pharmaceuticals: Is it Necessary under TRIPS?" (2021) 46 European Intellectual Property Review 651.

<sup>&</sup>lt;sup>81</sup> The Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa, Council for Trade-Related Aspects of Intellectual Property Rights, WTO Doc. IP/C/W/669 (2 October 2020).

<sup>&</sup>lt;sup>82</sup> WTO, "TRIPS Council welcomes MC12 TRIPS waiver decision, discusses possible extension" (6 July 2022), online: WTO https://www.wto.org/english/news\_e/news22\_e/trip\_08jul22\_e.htm.

<sup>&</sup>lt;sup>83</sup> Jayashree WATAL, "Analysis of the 12th WTO Ministerial Conference Decision on the TRIPS Agreement" (8 July 2022), online: EJIL:Talk! https://www.ejiltalk.org/analysis-of-the-12th-wto-ministerial-conference-decision-on-the-trips-agreement/.

<sup>84</sup> Zaman, supra note 72.

nature.<sup>85</sup> This first TRIPS waiver was excessively intricate and challenging to comprehend, resulting in just one country utilizing it on one occasion.<sup>86</sup> So far, no other country has successfully invoked this waiver to date. Most importantly, thirty-seven HICs, including the EU, the US, the UK, Canada, Japan, Australia, Belgium, and Germany, do not accept and recognize this waiver and flexibility under TRIPS Article 31bis.<sup>87</sup>

Considering this, it can be argued that the flexibility provisions embedded in TRIPS Articles 31 and 31 bis are highly complex and manifestly inadequate for achieving a proper balance between intellectual property rights and access to medicine, a subset of essential human rights. The waiver did not meet its objectives in the spectre of the HIV-AIDS pandemic in 2001. It also proved its inbuilt ineffectiveness during the influx of deaths in COVID-19 pandemic. Hypothetically, LMICs have an open option to use TRIPS flexibilities, but they often cannot do so since the process of utilizing the flexibilities is frequently skewed against them, replicating the neo-colonial dynamics. It seems that various factors, such as regulatory hurdles, political and economic limitations, and insufficient transparency, collaborate to facilitate the maintenance and exacerbation of global health inequalities by the concurrent global intellectual property regime.

# VII. The way Forward: Decolonizing Human Rights

COVID-19 will not be the last pandemic to impact human civilization. The expansion of industrial agriculture, urbanization, and globalization increases the likelihood of a new virus or pathogen jumping from animals to humans and quickly spreading across the globe. Before COVID-19, the twenty-first century witnessed pandemics such as SARS, H1N1, MERS, and Ebola. As we navigate through the COVID-19 pandemic, it is essential to view everything we do and learn through the lens of preparing for the next one. With respect to the current context of IPRs and access to medicine, ensuring that the global community does not have to resort to a third or fourth TRIPS waiver from the WTO within a couple of years if another pandemic breaks out is crucial. One of the essential steps is to undertake a decolonized approach to human rights with respect to access to medicines. A decolonized approach to human rights is tantamount to adopting the HRBA to global health, which requires that access to key treatments such as vaccinations be prioritized through domestic, regional, and international mechanisms to guarantee that all nations have sufficient resources to realize the right to health.<sup>88</sup> This calls for an extensive reconsideration of how the fragmented legal frameworks of international trade law on IP rights and human rights law regarding the right to health interact to entrench patent law to the detriment of access to medicines. This process of decolonization seeks to engrain human rights as an integral part of IP rights. The following ideas might be employed to decolonize human rights in global health.

#### A. Decolonizing the Current Approaches to Human Rights

A decolonized human rights model demands a massive shift from "an emergent trade-related, market-friendly paradigm of human rights" to a human rights model

<sup>&</sup>lt;sup>85</sup> *Ibid.*; Canada was the first country to export the first shipment of generic drugs to Rwanda in 2008. See ICTSD, "First Generic Drugs en Route to Africa under 5-Year-Old WTO Deal" (2008) 12 Bridges Weekly Trade News Digest.

<sup>&</sup>lt;sup>86</sup> TRIPS Flexibility Database, supra note 80.

<sup>&</sup>lt;sup>87</sup> James LOVE, "Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31bis of TRIPS Agreement" (7 April 2020), online: Knowledge Ecology International https://www.keionline.org/32707.

<sup>88</sup> Decolonization in this context is explained in Section I above.

grounded on the experience of the people whose lives and livelihoods are affected by the existing model.<sup>89</sup> It also tends to rectify and infiltrate the colonial attitude of the past from the domains of human rights and IPRs. Consequently, to establish a decolonial approach to human rights in public health, the primary requirement is to ensure that lifesaving medications are universally accessible to all individuals, regardless of their geographic location. If someone is not receiving vaccinations or essential medicines, the decolonized approach ensures that the deprived individual gets the necessary treatment. If IPRs or market access regulations create barriers, those hurdles should be dismantled top-down. To do this, the initial step is to reduce the number of intellectual property monopolies on vaccines and pharmaceuticals supported by the current IP regime under TRIPS. Different UN treaty bodies have made several statements concurring that guaranteeing equal access to essential medicines for everyone is essential to achieving the right to health and that IPRs should never supersede human rights obligations.<sup>90</sup> But these statements are neither mandatory for the states, nor do they bear any legal significance in narrowing the gap or reconciling the conflicts between IPRs and human rights. As shown earlier, the correlation between IPRs and human rights is dichotomous; they fail to acknowledge each other, 91 which is the prime obstacle to the pursuit of decolonizing human rights in public health. The expected decolonization of human rights may not be achieved until TRIPS and the existing IPRs regulatory regime expressly recognize the human right to health as an essential component of enforcing IPRs. Suppose the right to health, as the WHO constitution, UDHR, ICESCO or other international human rights instruments pronounce, is not equally embodied as a critical element of IPRs under the TRIPS framework. In that case, the decolonization of human rights will remain out of reach. If the dichotomy between IPRs and human rights persists, the global community will repeatedly demand IPR waivers for every impending pandemic. Without this, access to vaccines, drugs, treatment, and pharmaceuticals will be constricted, as in the COVID-19 crisis. Demands for a "TRIPs waiver" will be a common phenomenon, and, like the previous two TRIPS waivers, the LMICs' request for IPR waivers will become a recurring issue in all global health crises in the future.

One potential solution for decolonizing human rights in public health can be linked to TRIPS Articles 7, 8, and 66.2, which offer a framework for guiding this process. The aim of Articles 7 and 8 was to create a balance or "mutual benefit" between the rights of innovators or IPRs and human rights in the form of "users' rights". As per these rules, WTO members can take steps to promote social and public goals, such as safeguarding public health, while also promoting technological progress by protecting the rights of inventors. The Appellate Body of the WTO had the chance to establish a landmark legal principle on this matter in the *Canada-Patent* case; instead, it used the concept of "judicial economy" and deferred it to be resolved in future disputes. This decision is one of the most egregious examples of a failure to offer a thorough examination of TRIPS

 $<sup>^{89}</sup>$  Upendra BAXI, "Market Fundamentalisms: Business Ethics at the Altar of Human Rights" (2005) 5 Human Rights Law Review 1 at 1.

<sup>&</sup>lt;sup>90</sup> Measures taken to implement Human Rights Council Resolution 9/8 and obstacles to its implementation, including recommendations for further improving the effectiveness of, harmonizing and reforming the treaty body system: Report of the Secretary-General, Human Rights Council, UN Doc. A/HRC/46/25 (2020); United Nations Office of the United Nations High Commissioner for Human Rights, "COVID-19: UN experts urge WTO cooperation on vaccines to protect global public health" (1 March 2021), online: OHCHR https://www.ohchr.org/en/press-releases/2021/03/covid-19-un-experts-urge-wto-cooperation-vaccines-protect-global-public.

<sup>&</sup>lt;sup>91</sup> See the discussion in Section V above.

 $<sup>^{92}</sup>$  TRIPS, supra note 33, arts. 8.1 and 8.2.

 $<sup>^{93}</sup>$  Appellate Body Report, Canada - Term of Patent Protection, WTO Doc. WT/DS170/AB/R (18 September 2000) at para. 101.

Article 7. The panel in the *United States - Section 211 Omnibus Appropriations Act of 1998* dispute provided a vital explanation of the nature of Article 7; it acknowledged this rule as a provision with the potential to strike an effective balance between IP rights and other social rights. The issue was raised again in the *Australia Tobacco Plain Packaging* dispute, but the primary focus of this case was to assess whether Australian domestic tobacco packaging laws and regulations aligned with the objectives of TRIPS Articles 7 and 8. The *Australia Tobacco Plain Packaging* dispute highlighted the significance of Article 8 in maintaining a balance between IPRs and public health. It emphasized the principle that TRIPS members should have the discretion to implement measures that safeguard public health and advance the public interest, even if these measures limit the exercise of trademark rights. The potential linkage and interdependence of IP rights and human rights could have been clarified through this dispute, yet the WTO dispute settlement body exercised "judicial economy" and bypassed the issue. Consequently, the legal significance of Articles 7 and 8 within the WTO's jurisprudence remains undervalued.

TRIPS Article 66.2 was also intended to establish a practice of transferring technology from the Global North to the Global South. The provision urges developed countries to incentivize enterprises and institutions in their jurisdictions to support and facilitate technology transfer to LMICs, which would help them establish a solid and sustainable technological foundation. This approach prioritizes equipping individuals with the knowledge and skills to catch their own fish rather than just providing them with fish to fulfil their immediate needs. However, this mandatory provision has not been effectively implemented or addressed. HICs, who are responsible for ensuring the operationalization of these TRIPS provisions, have largely disregarded, undermined, and overlooked TRIPS Article 66, and the WTO's institutional approach to the technology transfer issue is quite ambivalent. These unfulfilled obligations within TRIPS should be objectively prioritized to initiate the decolonization of human rights. The mandatory obligation of technology transfer within TRIPs can serve as a starting point to acknowledge human rights within the regulatory framework of IP rights. Creating a systematic connection between IP rights and human rights within the established parameters of WTO law could speed up the decolonization of human rights in global public health.

#### B. Connecting Corporate Responsibility to Human Rights

Countries fail to uphold their ethical and legal obligations to protect "the right to health" when they do not guarantee their populations access to necessary vaccines, treatments, and medications. While the responsibility to safeguard human rights has traditionally rested solely with states and national governments, there has been a policy shift in recent times. It is no longer an anathema that corporations can have obligations under human rights law. The South African Constitutional Court recently decided that, in addition to

<sup>&</sup>lt;sup>94</sup> Panel Report, United States - Section 211 Omnibus Appropriations Act of 1998, WTO Doc. WT/DS176/R (6 August 2002) at para. 8.57.

<sup>&</sup>lt;sup>95</sup> Panel Report, Australia - Tobacco Plain Packaging, WTO Doc. WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R at para. 7.2399.

<sup>96</sup> Ibid.

<sup>&</sup>lt;sup>97</sup> Henning Grosse RUSE-KHAN, "The (Non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO" Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 11–25, online: <a href="https://papers.ssrn.com/abstract=1939859">https://papers.ssrn.com/abstract=1939859</a>; Alison SLADE, "Good Faith and the TRIPS Agreement: Putting Flesh on the Bones of the TRIPS 'Objectives'" (2014) 63 International & Comparative Law Quarterly 353 at 354.

<sup>&</sup>lt;sup>98</sup> Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, WTO Negotiation Doc. MTN.GNG/NG11/W/32/Rev.1 (1989), para. 5.

the government's duties to safeguard human rights, privately owned land corporations in South Africa must also be held accountable for certain human rights responsibilities.<sup>99</sup> Thus, in addition to states' obligations to their citizens, corporations must also prioritize their responsibilities to uphold human rights and carefully consider their potential positive obligations under international human rights laws.

A decolonized approach to human rights requires expanding the definition of corporate responsibilities to encompass a commitment to principles of fairness and non-discrimination in all business decisions. This includes avoiding actions that create artificial shortages and barriers that limit access to life-saving vaccines and medicines, promoting moral and legal accountability, and supporting transparency in countries' interactions related to essential healthcare. 100 Companies need to review how their actions or inactions and those of their business partners could result in real or potential human rights effects within their business operations. Due to the longstanding practice of associating human rights obligations solely with states, it has been difficult for international human rights communities to attribute human rights obligations to corporations. Although international human rights law now recognizes that corporations have a direct responsibility to respect human rights, including the right to health, <sup>101</sup> this responsibility has typically been perceived as a negative duty. Also, these are mostly soft laws that ask corporations not to violate human rights. 102 The calls for decolonizing human rights urge making these obligations mandatory for corporations. To achieve this, it is necessary to articulate the standards and guidelines for human rights that apply to corporations and other non-state actors. 103 The states must enforce such regulatory norms, guidelines, and standards through domestic, regional, and international platforms, including multilateral frameworks of the WTO and the WHO.

#### **VIII.** Conclusion

The COVID-19 pandemic has not been eradicated, nor will it be the last pandemic in this world. It has left a trail of devastation on our societies, economies, and almost all aspects of our lives, including the legal domains of IP rights and human rights law. In highlighting the right to access COVID-19 vaccines and pharmaceuticals as an essential human rights component, this study has demonstrated that the strict IP protection regime under TRIPS has constricted contemporary human rights law's established norms and commitments. This is analogous to neo-colonialism and has prompted calls for the decolonization of human rights relating to access to essential life-saving medicines and pharmaceuticals.

The historical dichotomy between human rights and IP rights is quite evident. In a broader sense, even if a few international legal instruments on human rights superficially recognize IP rights as human rights, the current IPR regime is unwilling to embrace human rights within its purview. This divergence delivers a clarion call for the

<sup>99</sup> Daniels v. Scribante and Another (2017) SA (CC), (2017) BCLR (CC), [2017] ZACC 13, paras. 37-9.

<sup>&</sup>lt;sup>100</sup> Baxi, supra note 90; Human Rights Watch, "Universal and Equitable Access to Covid-19 Vaccines, Testing, Treatments: Companies' Human Rights Responsibilities" (11 February 2021), online: Human Rights Watch https://www.hrw.org/news/2021/02/11/universal-and-equitable-access-covid-19-vaccines-testing-treatments-companies-human

<sup>&</sup>lt;sup>101</sup> General comment No. 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities, United Nations Economic and Social Council, E/C.12/GC/24 (10 August 2017); OHCHR, "Guiding Principles on Business and Human Rights", online: OHCHR https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr\_en.pdf.

<sup>102</sup> Ibid

<sup>&</sup>lt;sup>103</sup> Sofia GRUSKIN and Zyde RAAD, "Are Drug Companies Living Up to Their Human Rights Responsibilities? Moving Toward Assessment" (2010) 7 PLOS Medicine e1000310.

decolonization of human rights and tends to integrate the inherent humane principles within the perimeters and parameters of global, regional, and domestic IPR laws. It is crucial to acknowledge and uphold certain fundamental human rights norms, such as the right to access essential medicines, within the framework of modern IPR law. Simultaneously, recognizing the essence of IPRs within the current human rights regime can also facilitate the process of its decolonization.

Acknowledgements. The author would like to thank the reviewers for their inspiring and helpful comments.

Funding statement. None.

Competing interests. The author declares none.



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Cite this article: ZAMAN K (2024). Decolonizing Human Rights Law in Global Health - the Impacts of Intellectual Property Law on Access to Essential Medicines: A Perspective from the COVID-19 Pandemic. Asian Journal of International Law 1–18. https://doi.org/10.1017/S2044251323000747