Received: 1 December 2020 | Revised: 18 January 2021 | Accepted: 24 February 2021

DOI: 10.1111/jwip.12187

ORIGINAL ARTICLE

THE JOURNAL OF WORLD INTELLECTUAL PROPERTY WILEY

Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?

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Abstract

The article analyses the global public goods approach to COVID-19 technologies, embedded in 2020 affirmations by the World Health Assembly (WHA), the UN Human Rights Council and G20 on broad immunization against COVID-19. After identifying the access to COVID-19 tools (ACT) Accelerator members, the UN efforts are identified, focusing primarily on the UN human rights bodies, acknowledging how these and the WHA have mutually reinforced each others' efforts. The article finds that the global public goods terminology appeared in UN resolutions in 2020, while wording that included vaccines—on an equal footing as medicines—appeared in 2016, and recognition of generic medicines appeared in 2019. The so-called Trilateral Cooperation on IP and public health between two UN specialized agencies and the World Trade Organization (WTO) has increased awareness of the flexibilities within WTO's TRIPS Agreement. These flexibilities are explained. With notable exceptions, like India, these flexibilities are not widely applied in domestic legislation. A different emphasis characterizes the millennium development goals era as compared to the sustainable development goals era, and this shift is explained by applying

relevant theories. Among pro-TRIPS developed countries there is an acknowledgment of obstacles created by the IP system, but their overall position has not changed.

KEYWORDS

access to COVID-19 tools accelerator, generic medicines, public health and trade, sustainable development goals, trilateral cooperation on IP

1 | A HUMAN RIGHTS AND GLOBAL PUBLIC GOODS APPROACH

The Leaders' Declaration from the G20 summit in Riyadh November 21–22, 2020 reads: "We recognize the role of extensive immunization against COVID-19 as a global public good" (G20, 2020a, para. 3) and these terms are also found in the Statement from a G20 Joint Finance & Health Ministers Meeting September 17, 2020 (G20, 2020b). The statement has three references to intellectual property (IP): on voluntary licensing, effective IP protection, as well as stating that IP has enabled medicines and vaccines and "not been an impediment to the common goal of ending this pandemic" (G20, 2020b).

The same wording on global public goods is found in the Human Rights Council's resolution, adopted without a vote July 16, 2020, with the specification that the vaccines must be "safe, quality, efficacious, effective, accessible and affordable…" (UN Human Rights Council, 2020, para. 7) and in a resolution by World Health Assembly of May 19, 2020 (World Health Organization [WHO], 2020a, para. 6, not including the terms effective and accessible). The two terms "safe and effective" are highlighted in the G20 Declaration and Statement (G20, 2020a, para. 3; 2020b).

Two other differences are noteworthy. First, while the G20 Statement eight times mention medicines and vaccines together and twice applies the terms equitable and affordable together, the others apply the term "equitable access to and fair distribution of *all … health technologies and products …*" (UN Human Rights Council, 2020, para. 5; WHO, 2020a, para. 4; italics added). Second, while G20 said that IP "has not been an impediment" (G20, 2020b), the two others, in the context of access and distribution, called for an "urgent removal of unjustified obstacles thereto, in accordance with … TRIPS … flexibilities …" (UN Human Rights Council, 2020, para. 5; WHO, 2020a, para. 4).

Hence, we see that the IP, more specifically the TRIPS Agreement—Annex 1C to the World Trade Organization (WTO) Agreement—can allegedly serve as an obstacle *or* facilitator for promoting the such equitable access and fair distribution of vaccines and other health technology. The terms equity and equitable are in accordance with the *Oxford Dictionary of Law Enforcement* understood as synonymous to just, fair, and reasonable. The term global public good is in accordance with the *Oxford Dictionary of Economics* understood as a good that provides non-excludable and nonrival benefits on a worldwide scale. Nonexcludable implies that the good is to be accessed by all, and nonrival implies that other's use of the good does reduce one's own possibilities to access the same good.

Immunization by providing vaccines has for decades been a responsibility of particularly the UN Children's Fund (Unicef) in those countries where the health authorities are not capable of providing vaccines. Since 2000, the Global Alliance for Vaccines and Immunization (Gavi) have strengthened domestic capacities for provding immunization. This author is not aware of any countries where individuals must pay for vaccines. Hence, it is reasonable to understand vaccines as standing out from other products produced by pharmaceutical corporations. The global market for vaccines can be characterized as an oligopsony whose core characteristic is few large buyers.

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be "difficult" (WTO Secretariat, 2020a). Biotechnology actors expressed criticism

of the UN High-level Panel on Access to Medicines (2016), arguing that IP tends to be overemphasized in debates over access to medicines, ignoring the wider context of what impedes such access (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, developed countries and biotech associations concur in identifying weak funding of health care and lack of manufacturing capacity as constituting the core of the problem of access (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), as well as regulatory inefficiencies, trade policies and inadequate health insurance (ICBA, 2016).

While there are no international treaties that explicitly specify rights and obligations in the context of global public goods (Maskus & Reichman, 2005), the global dimensions of IP and access gained more prominence in the aftermath of TRIPS (Drahos & Mayne, 2002; Matthews, 2002). Moreover, antologies and monographies have analyzed the relationships between human rights and IP (Geiger, 2015; Grosheide, 2010; Grosse Ruse-Khan, 2016; Helfer & Austin, 2011; Hestermeyer, 2007; Torremans, 2020). Human rights constitute primarily a proaccess and prodevelopment approach (Yu, 2020). Human rights in the context of medicines and vaccines are regulated in two provisions of the International Covenant on Economic, Social and Cultural Rights (ICESCR). First Article 12(2)(c) encompasses state measures for the "prevention, treatment and control of of epidemic … diseases." Second, Article 15(1)(b) recognizes the right to "benefits of scientific progress and its applications." As will be shown in Section 5.2, there is also a provision on authors' rights in the ICESCR, Article 15(1)(c), whose expansive interpretation has been criticized (Koopman, 2008, pp. 578–582). Moreover, the fact that the human right to property can justify IP claims has given rise to notions of "paradox" (Grosheide, 2010; Plomer, 2013).

It is important to acknowledge that the encounter between human rights and IP is an encounter between two regimes with different implementing institutions. The human rights regime has few specific prohibitions and more emphasis on taking the right measure, while the IP regime has more specific provisions and stronger mechanisms for enforcement. After identifying the core of the relevant human rights and TRIPS flexibilities, not elaborating on the corresponding obligations in great depth, the article will turn to soft-law documents. While proposals for an access to knowledge (A2K; Shaver, 2009) treaty has not progressed further—with the exception of the 2013 Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled (Helfer et al., 2017)—such access has been emphasized in the context of the sustainable development goals (SDG) and science and technology for innovation (STI).

The article will proceed as follows: Section 2 elaborates on the theoretical framework of power and space-claiming, and principled pragmatism, which will be applied in explaining both opposing and re-approaching views over IP. Section 3 presents the institutional framwork for vaccine development, approval, and dissemination. Section 4 identifies the TRIPS flexibilities and how these are applied. Section 5 reviews the 20 years of efforts to enhance access to medicines and vaccines within a human rights framework. Section 6 identifies initiatives and proposals in the millennium development goals (MDG) era practices for enhanced access to medicines and vaccines, particularly for states with limited purchasing capacity. Section 7 has a similar discussion for the SDG era, termed Agenda 2030. Section 8 provides a critical assessment of the role of IP in the context of STI. Section 9 is a concluding discussion, linking up to the rationales for the global public goods as identified above.

India will be central in the analysis as a core country in term of its pharmaceutical manufacturing capacity—being a producer of 70% of all vaccines globally (Upadhyay, 2020, referring to the Director-General of International Vaccine Institute)—its extensive use of TRIPS flexibilities—as reflected in both laws and court rulings—and its proactive role in the Council for TRIPS.

The research question this article seeks to answer is: How has the UN framed its efforts to enhance accessibility to medicines and vaccines, and has the framing of the COVID-19 medicines and vaccines in a global equity context—representing global public good and being crucial for human rights fulfillment—had any impact on the position of the most pro-TRIPS WTO member states?

2 | INSTITUTIONAL AND THEORETICAL EMBEDDING: POWER ASYMMETRIES AND SPACE-CLAIMING, AND PRINCIPLED PRAGMATISM

Unequal control over both technology and decision-making give rise to power asymmetries. Power that comes with controlling technologies, including patents and other IP, seems relatively obvious. The power dimensions inherent in the structure and functioning of the WTO, particularly TRIPS, as well as the theory of principles pragmatism must be explained. The section will introduce and embed the theories in the context of WTO, TRIPS, and the UN Guiding Principles on Business and Human Rights, and aspects of WTO decision-making will also be included in Section 2.2.

2.1 | Decision-making in the WTO

In the WTO, decision-making is neither based on financial contribution—as in the World Bank—nor on one state, one vote—as in the UN. The decision-making principle that applies in the WTO is that of consensus. There are examples of Ministerial Conferences that have not been able to come to agreement because of opposition expressed by merely one state, like India at the Cancun Ministerial Conference in 2003.

For some decisions, for instance determining on a waiver, applying to one—or a few—member state(s), there is a requirement of a three-fourths majority, as specified in the WTO Agreement, Article IX.3. Note 4 to the Agreement Establishing the WTO (hereafter: WTO Agreement) specifies that if a member state requests extension of its transition period—with less obligations imposed—the decision must be taken by consensus.

The meeting in the Council for TRIPS October 15 and 16, 2020 had before it a proposal by India and South Africa to adopt a waiver on the enforcement of IP—patents, industrial designs, trade secrets and copyrights—in relation to prevention, containment or treatment of COVID-19 (India and South Africa, 2020, para. 12). The term containment must be understood as encompassing vaccines. The duration of the waiver was specified to last "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity" (India and South Africa, 2020, para. 13). Not surprisingly, the debate was fierce, and concerns were expressed that the waiver proposal risks to "undermine the collaborative efforts to fight the pandemic" (WTO Secretariat, 2020a). A proposal for a "Trade And Health" Initiative was subsequently proposed (Australia et al., 2020). Three developing countries joined this proposal: Brazil, Chile, and Kenya.

The WTO requires all waiver requests to be considered within 90 days and then brought before the General Council; see WTO Agreement Article IX.3(b). The proposal by India and South Africa (2020) is specified as applying to all WTO member states. The WTO General Council instructed in December 2020 the Council for TRIPS to work further with the waiver proposal (WTO, 2020).

Hence, it is reasonable to state that the WTO system is characterized by certain asymmetries, but it must also be acknowledged that interests of economically poorer states might prevail over interests of economically more powerful states, at least in specific decisions.

2.2 | Power theories

A comprehensive model that builds on Lukes' theory on *forms* of power, distinguishing between visible (influence others), hidden (influencing what is and what is not on the agenda) and invisible (influencing overall perceptions) (Lukes, 1974) is the power cube (Gaventa, 2009). The power cube adds two dimensions: *levels* (global, national, and local) and *spaces* (closed, invited, and claimed/created). The realm of WTO is obviously on a global level. Hence, there is no need for a further elaboration on the dimension of levels, except from reminding of the fact that there are various traditions and legal frameworks for openness and transparency as regard IP and trade policies at the

domestic level. Moreover, asymmetrical power relations might be exercised more directly in bilateral relations as compared to multilateral relations where alliances can be built. A characterization of the degree of openness in the WTO will be given below.

As regards the *forms* of power, it is obvious that the WTO system has a relatively rigid monitoring and enforcement system, able to influence the conduct of the member states. Hence, visible power is obviously relevant. First, there are regular reviewing of each member state's legal framework in accordance with the Trade Policy Review Mechanism, Annex 3 to the WTO Agreement. Second, the Dispute Settlement Understanding (DSU), Annex 2 to the WTO Agreement. The DSU outlines procedures for how to solve any dispute arising under any of the WTO agreements, specifying in Article 22.1 that two forms of measures can be determined—by the Dispute Settlement Body—in cases of noncompliance with a given recommendation and ruling: compensation and suspension of concessions.

To what extent is there also hidden power at play in the WTO particularly in the context of TRIPS? TRIPS has established a minimum level of IP protection with certain flexibilities, as will be shown below. Several bilateral and trade and investment treaties have introduced higher levels of IP protection, with less flexibility, termed TRIPS+. The Council for TRIPS has not always served to uphold the TRIPS flexibilities in its oral and written communication, as will be shown when discussing TRIPS flexibilities below. Hence, there can be no doubt that agenda-setting power is exercised by the WTO and the Council for TRIPS.

Are the WTO and TRIPS processes also characterized by invisible power, which is about influencing overall perceptions? The overall perception that high levels of IP protection are an absolute requirement for private investors' willingness to invest, might ignore the fact that there are several other elements that must be in place in a given country (BIO, 2016; ICBA, 2016). Nevertheless, IP is important for enhancing predictability, particularly in the important phase from invention to a marketable innovation. What about perceptions about TRIPS flexibilities, specified in both the 2001 Doha Declarations (WTO, 2001a, para 17; 2001b) and in the Trilateral Cooperation on Public Health, IP and Trade (WHO, World Intellectual Property Organization [WIPO], and WTO, 2020a; 2013)? We will come back to these in Section 4.1. The G20 Statement emphasizing "effective IP protection" (G20, 2020b) might sum up these overall perceptions. TRIPS has introduced high overall protection levels and rigorous enforcement requirements globally.

As regards the *spaces* of power, particularly applying to TRIPS, it is reasonable to state that while the TRIPS negotiations in 1986–1994 can be characterized as closed, there has gradually been more space for civil society in the overall WTO system, and accreditation procedures allow civil society organizations to be "invited." Many of the IP negotiations within regional and bilateral trade and investment treaties are still relatively closed and asymmetrical. Civil society actors have tried to influence by various campaigns, advocacy efforts, and demonstrations, claiming a space for influencing decisions.

Tensions regarding IP between developed and developing countries are also evidenced in other forums, most notably WIPO, a UN specialized agency. An organizational review of WIPO found "an acute polarization between various groups of delegations…" (UN Joint Inspection Unit, 2014, p. 10). It is therefore reasonable to state that it is IP on a broader term, and not TRIPS specifically, that explains IP tensions globally.

2.3 | Theory on public–private cooperation

Additionally, a theory that is believed to capture the enhanced cooperation between public and private for-profit actors is the theory of principled pragmatism, being embedded in human rights and identifying "what works best in creating change where it matters most…" (UN Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, 2006, para. 81). The Special Representative 2005–2011 was John Ruggie, one of the world's leading social constructivist scholars within international relations studies. His efforts resulted in the UN Guiding Principles on Business and Human Rights ("UN

Guiding Principles," UN Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, 2011; see also UN Human Rights Council, 2011a, para. 1). The UN Guiding Principles consist of three pillars for the promotion of human rights: state duties to protect, corporate responsibility to respect, and access to remedies.

3 | THE GLOBAL INSTITUTIONAL FRAMEWORK FOR THE COVID-19 RESPONSE

Unicef and Gavi are already mentioned above, and there are other actors in the global response to COVID-19. According to its Constitution (WHO, 2006 [1946]), its objective is the "attainment by all peoples of the highest possible level of health." While WHO has adopted various tools to fight epidemic and endemic diseases—most notably the International Health Regulations, first adopted in 1969 (WHO, 2005)—WHO's overall inadequacies have been highligthed (France and Germany, 2020). Three distinct efforts by the WHO in 2020 are reviewed.

3.1 | WHO's coordination of vaccines testing and aprovals

WHO keeps a record of vaccines developments globally, currently being updated twice a week. On November 3, 2020 WHO published an overview of the various COVID-19 vaccines initiatives, identifying 10 to be in the Phase 3 (WHO, 2020b), implying that the vaccine is tested for efficacy and safety among several thousand persons (Robinson, 2016).

Within 3 weeks, 3 of 10 reported to have developed vaccines with 90%, 94.5%, and up to 90% efficacy, respectively (Moderna, 2020; Pfizer and BioNTech, 2020; 90% achieved in the smallest sample).[1] The first has challenging storing requirements (−70°C). Moderna has cooperated with the National Institute of Allergy and Infectious Diseases (NIAID), one of 27 institutes under the National Institute for Health (NIH, 2020). AstraZeneca has cooperated with the Jenner Institute and Oxford Vaccine Group at the University of Oxford.

Efficacy is measured during the testing phase, being the "protective effects of vaccination by the reduction in the infection risk of a vaccinated individual relative to that of a susceptible, unvaccinated individual" (Shim & Galvani, 2012, p. 6700). Effectiveness is measured in the context of the actual vaccination, being defined as "the reduction in the transmission rate for an average individual in a population with a vaccination program at a given level of coverage compared to an average individual in a comparable population with no vaccination program" (Shim & Galvani, 2012, p. 6700).

Together, the three first corporations indicate that approximately five billion vaccines can be produced by 2021 (AstraZeneca, 2020; Moderna, 2020; Pfizer & BioNTech, 2020). AstraZeneca seeks an Emergency Use Listing from the WHO to make vaccines available in low-income countries.

3.2 | WHO promoting access to COVID-19 tools in developing countries

WHO has launched the Solidarity Call to Action, highlighting three elements in the headings of the Call: public common good, equitable global access, and pooling of knowledge, IP and data (WHO, 2020c). Moreover the term response used in the Call must be understood to encompass both diagnosis, treatment, and vaccines, as well as broader measures to strengthen health systems. To facilitate pledges of commitments to the Solidarity Call to Action, the COVID-19 Technology Access Pool (C-TAP) has been established (WHO, 2020d). The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), having 12 corporations—including AstraZeneca—and 12 national associations as full members (IFPMA, 2020a), criticizes C-TAP:

> By urging licenses or non-enforcement declarations for COVID-19 treatments and vaccines to be granted on a non-exclusive global basis, the Solidarity Call to Action promotes a one-size-fits all model that disregards the specific circumstances of each situation, each product and each country (IFPMA, 2020b).

This must be understood as a form of assertion by the biotech corporations that they know best when to engage in voluntary licensing and nonenforcement of patent.

Other pledges have been launched by other actors, most notably the Open COVID Pledge, whose call is to "organizations around the world to make their patents and copyrights freely available in the fight against the COVID-19 pandemic" (Open COVID Pledge, 2020). Having support from main technology corporations, including Microsoft, IBM, and Facebook, as well as Amazon, the project is led and stewarded by Creative Commons.

3.3 | WHO's overall promotion and facilitation of joint efforts in the context of COVID-19

WHO has been instrumental in setting up the Access to COVID-19 Tools Accelerator (ACT-A), launched in April 2020 (WHO, 2020e). ACT-A coordinates efforts by nine global health organizations, as well as governments, scientists, businesses, civil society, and philanthropists. The highest body of the ACT-A is the Facilitation Council.

An overview of the nine organizations which are behind ACT-A—and how they interrelate to each other—is helpful in identifying the global landscape for COVID-19 responses (year of founding in paranthesis). First, the Bill & Melinda Gates Foundation (BMGF, 2000) is the largest foundation in the world, and is a cofounder (with Norway, Germany, India, Japan and Wellcome Trust; see below) of the second organization, the Coalition for Epidemic Preparedness Innovations (CEPI, 2016). The third organization is Foundation for Innovative New Diagnostics (FIND, 2003), having six of the nine organizations in ACT-A as donors (FIND, 2020), and the Memorandum of Understanding (MoU) entered between WHO and FIND February 10, 2020 refers to COVID-19 (WHO, 2020f). Fourth, Gavi, whose main funder continues to be BMGF. Fifth, The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund, 2002). Sixth, Unitaid (2006), established by France and Brazil to transfer innovative sources of financing—like air ticket levies—to innovative health projects, acknowledged as a partner by the WHO (2020g), and BMGF is also listed among the main donors (Unitaid, 2020). Seventh, Wellcome Trust (1936), listing its cooperation with CEPI and Unitaid in the context of COVID-19 efforts (Wellcome Trust, 2020). Eight, the WHO (1946), Ninth, the World Bank (1944).

ACT-A works within four pillars: diagnostics, treatments, vaccines, and health system strengthening. The Global Fund and FIND are the coconvenors of the Diagnostics Partnership. Unitaid and Wellcome are the coconvenors of the Therapeutics Partnership. The vaccines partnership is termed COVAX, with Gavi, CEPI and WHO as the coconvenors, operating through a mechanism called COVAX Facility (Berkley, 2020). The Global Fund and the World Bank are the coconvenors of the health system strengthening pillar. It is also relevant that Unicef has both facilities and experience in vaccine programmes—cooperating with WHO, CEPI and Gavi—and Unicef will be involved in the actual vaccination.

In addition to these organizations, the other categories: governments, scientists, businesses and civil society—supported by philanthropists—are working strenuously to provide vaccines and other medical technology, including tools for treatment and accurate diagnosis. Hence, the global institutional system for fighting COVID-19 by all means is complex and committed to find a solution to the COVID-19 pandemic as soon as possible.

4 | TRIPS FLEXIBILITIES AND THEIR APPLICATION

A full review of all the TRIPS flexibilities is neither possible nor necessary. In addition to the possibilities to adopt waivers under Article IX.3 of the WTO Agreement, as shown above, at least five provisions of TRIPS must be mentioned: Articles 6, 30, 31, 32, and 39. It is also relevant to emphasize that TRIPS Article 40 regulates anticompetitive practices, as will be seen in Section 6.2.

Moreover, TRIPS Article 7 (Objectives) and Article 8 (Principles) are important for "integrating and accommodating competing concerns within IP protection…" (Grosse Ruse-Khan, 2020; p. 206; see also 2016, pp. 439–481). While finding that these provisions were not frequently applied by the WTO dispute settlement system (Grosse Ruse-Khan, 2011; Rochel, 2020, p. 34), Grosse Ruse-Khan (2020) endorses the Panel's report in Australia—Plain Packaging which emphasized that each provision of the TRIPS Agreement is to be interpreted in light of these two provisions (WTO, 2018, para. 7.2410; see also WTO, 2001b, para. 5a). The panel emphasized that the 2001 Declaration on the TRIPS Agreement and public health is not an authoritative interpretation under Article IX:2 of the WTO Agreement, but a "subsequent agreement" in the words of the Vienna Convention on the Law of Treaties Article 31(3)(a), that is to be taken into account in the interpretation (WTO, 2018, para.7.2409).

It is also relevant to emphasize each state is able to determine its own standards of what is eligible for patentability, in accordance with TRIPS Article 27, but this is not further elaborated upon.

4.1 | Five flexibility provisions in TRIPS

TRIPS Article 6 establishes each country's freedom to establish its own regime of IP exhaustion. In 2001 it was specified that this must be done "without challenge…" (WTO, 2001b, para. 5d). Hence, provided that a country has chosen international exhaustion in its domestic legislation (WIPO Secretariat, 2010, pp. 32–42), a product legally placed in the market of one state can be subject to parallel importation. This might reduce the potential for monopoly tendencies and inadequate supply in the importing countries. EEA states and Switzerland practice regional exhaustion; India practices international exhaustion (WIPO Secretariat, 2010, p. 36).

TRIPS Article 30 applies the term "limited exceptions" provision, specifies that national legislation must comply with the TRIPS Agreement while "taking account of the legitimate interests of third parties." This phrase can be read to permit states to enact "innocent infringer" provisions, but not to allow stockpiling of generic medicines (WTO, 2000). Generic medicines must be distinguished from what is in normal language referred to as counterfeit products, whose new term is "substandard and falsified (SF) medical products" (WHO, WIPO, and WTO, 2020a, p. 214).

TRIPS Article 31 specifies the conditions for compulsory licenses. This provision underwent a long process of formal amendment, ending in 2017 and incorporating a new Article 31*bis* and Annex. This provision specifies that the general requirement that compulsory licenses shall be for the supply of the domestic market (TRIPS Article 31(f)) does not apply in certain situations. Such situations are specified in Article 31*bis* and in the Annex, including that the country in question has "insufficient or no manufacturing capacities in the pharmaceutical sector…" (TRIPS, Annex, Article 2(a)(ii)). Moreover, it is relevant to note that TRIPS Article 31(b) permits compulsory licenses for public noncommercial use, specifying that in such situations, "the right holder shall be informed promptly." WIPO has published an overview of compulsory license provisions—country by country—demonstrating that almost all countries include in their patent legislation provisions allowing for either compulsory licenses for public interest use or government use (WIPO Secretariat, 2010, pp. 1–31). India has provisions for all six categories of compulsory licenses (WIPO Secretariat, 2010, p. 11).

TRIPS Article 32 ("Revocation/Forfeiture") is rarely understood as an exceptions provision, and its wording is simply "An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available." Procedures for revocation are also specified in four other provisions of TRIPS: Articles 41.2, 41.3, 62.4, and Article

62.5. The Paris Convention for the Protection of Industrial Property regulates forfeiture and revocation of patents in even greater detail (Article 5A(3) and 5A(4)), and TRIPS Article 2.1 specifies that the Paris Agreement must be complied with. Because TRIPS Article 32 specifies no requirements for when revocation or forfeiture can be decided, specifying only the availability of judicial review, TRIPS does not prohibit states from authorizing patent revocation or forfeiture to protect prevailing public interests (Haugen, 2014, p. 205). India's Patent Act, Act No. 39 of 1970, is an example of a national legislation that authorizes revocation, if the patent is exercised in a manner that is "mischievous to the State or generally prejudicial to the public…" (Article 66), or in cases of nonworking of the patent (Article 85). The WIPO Secretariat (2012, pp. 52–56) lists other examples of domestic revocation provisions.

TRIPS Article 39 is on protection of undisclosed information; also termed trade secrets. Article 39.3 regulates protection of test data for pharmaceuticals or agricultural chemical products. It requires such test data to be protected if the domestic legislation requires such test data for approving marketing of products. India is among those countries which do not require this, even if there has been attempts of introducing this requirement (Haugen, 2021). On this background, it is unfortunate that the Council for TRIPS Chair did not challenge, but rather affirmed Switzerland's criticism of India's lack of test data protection (WTO Council for TRIPS, 2015, para 6.5; see also para 4.42).

Most of these flexibilities—but not Article 32—are analyzed in two publications from the so-called Trilateral Cooperation, which include a correct understanding of TRIPS Article 39.3 (WHO, WIPO, and WTO, 2020a, p. 82; 2013, p. 65). In summary, flexibilities in the TRIPS Agreement are applied to various degrees by the member states. India's legislation allows for most flexibility in the implementation of TRIPS (WIPO Secretariat, 2010).

4.2 | More on licensing

TRIPS does not use the term voluntary licensing, unlike the G20 (2020a, para. 3; 2020b). According to IFPMA, a voluntary license is "an authorization given by the patent holder to a generic company, allowing it to produce the patented article …" (IFPMA, 2010). The agreement might include conditions for such authorization (Médecins Sans Frontières [MSF], 2020; South Africa, 2020). Voluntary licenses are, however *implicitly* addressed in TRIPS Article 31(b), specifying the conditions for when compulsory licencing is permitted; there are three situations; the two first are identified above, namely in situations of public noncommercial use, specifying that in such situations, "the right holder shall be informed promptly" and in the situation of production for countries lacking manufacturing capacities (TRIPS Article 31*bis* and Annex).

The third situation is specified as follows in TRIPS Article 31(b), stating that use without the right-holder's authorization

> may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

TRIPS Article 31(h) specifies that the right holder shall be paid adequate remuneration in situations of compulsory licenses, and the general principles in TRIPS Article 41, as interpreted in light of Article 7 and 8, will apply.

In reality, therefore, there are four situations of licensing by a right-holder: (i) voluntary licence, (ii) compulsory licence if negotiation efforts for a voluntary licence are not successful, (iii) compulsory licence for public noncommercial use, if the right-holder is adequtely informed, and (iv) compulsory licence for export to countries lacking manufacturing capacities. In all situations, the right-holder is to receive adequate remuneration for others'

use of the patented technology, but this can be exempted in situations of voluntary licensing. The main purpose of voluntary licensing agreements is to enhance production and distribution (Raju, 2017).

According to the Trilateral Cooperation, the system established by TRIPS Article 31*bis* and Annex, "does not apply to most procurement scenarios …" (WHO, WIPO, and WTO, 2020a, p. 242), listing three such situations: (i) the product is available from countries with no patent in force; (ii) product prices are sufficiently low; and (iii) voluntary licensing. I like to add: (iv) the product is legally placed in the market in countries practicing international exhaustion of patent rights, in accordance with TRIPS Article 6.

5 | TWENTY YEARS WITH HUMAN RIGHTS-EMBEDDED EXPLORATION OF IP—AND ITS RESULTS

A 1998 seminar convened by WIPO to celebrate the 50th anniversary of the Universal Declaration of Human Rights was the first comprehensive effort of specifying human rights in the context of IP (WIPO, 1999). Three human rights, to health, culture and scientific progress, recognized in Articles 12, 15(1)(a) and 15(1)(b) of the ICESCR, respectively, were highlighted. Three other presentations framed the IP-human rights debate, addressed IP and traditional knowledge, and elaborated on links between IP and nationality embedded in nondiscrimation. Before 2000 the number of scholarly publications on human rights and IP were few. The attention of the civil society towards IP grew rapidly, with various campaigns, the first focusing on so-called "biopiracy"—practices contrary to the Convention on Biological Diversity Articles 15 and 8(j)—and on medicines and pricing.

5.1 | Initial clarifications

Starting in 2000, various human rights bodies became very active in analyzing IP-human rights links. It started with the [then] Subcommission on the Protection and Promotion of Human Rights (UN Subcommission, 2000; 2001), inviting a broad range of actors—including the UN Secretary-General and the UN High Commissioner for Human Rights—to clarify the IP-human rights links,[2] highlighting the role of TRIPS specifically.

5.2 | More elaborate clarifications

Another actor that was challenged by the Subcommission was the UN Committee on Economic, Social, and Cultural Rights (UN CESCR). It responded initially by a Day of General Discussion (2000a), followed by a Statement (2001), and then by a General comment (2006; adopted in 2005), all of which seek to clarify the content of the Article 15(1)(c) of the ICESCR, on human rights arising from the moral and material interests of authors of scientific, literary or artistic production. With the exception of a clear distinction between this human rights and IP in the initial paragraphs—a distinction that is not practiced consistently (Haugen, 2012, pp. 37–53)—there are few explicit references to IP. One paragraph specifies, however (UN CESCR, 2006, para. 35, extracts):

> Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines … undermining the rights of large segments of the population to health…

In addition to medicines, plant seeds and schoolbooks and learning materials are referred to in this paragraph, and affordability of facilities, goods and services is specified as one of the essential elements of the right to health (UN CESCR, 2000b, para. 12(b)(iii)).

The most recent General comment is on science and economic, social, and cultural rights (UN CESCR, 2020a),[3] preceeded by a Day of General Discussion, with experts and written responses to an open call to respond to a Discussion Paper (UN CESCR, 2018). The core provision is ICESCR Article 15(1)(b) on the human right of everyone to enjoy the benefits of scientific progress and its applications, a provision that was analyzed in the Venice Statement (Haugen, 2012, pp. 30–34; Müller, 2010; UNESCO, 2009). Three forms of benefits are identified by the UN CESCR: material results, like vaccines; knowledge and information; and "the role of science in forming critical and responsible citizens …" (UN CESCR, 2020a, para. 8). As regards science and IP, the UN CESCR acknowledges that IP enhances science and technology by providing economic incentives for innovation, but IP can also distort research funding, restrict information sharing and impede physical and affordable access (UN CESCR, 2020a, paras. 60–61). Generics are seen as a way to overcome the affordability problem (UN CESCR, 2020a, paras. 69–70; see also UN High Commissioner for Human Rights, 2001).

At the same session, the CESCR adopted a Statement on COVID-19, emphasizing that if public measures adopted do limit the human rights recognized in the ICESCR, Article 4 on justified limitations should be applied. These Article 4 requirements were specified as "necessary to combat the public health crisis posed by COVID-19, and be reasonable and proportionate" (UN CESCR, 2020b, para. 11). Such considerations also apply when securing national supply, calling upon states to take other countries' urgent needs into account (UN CESCR, 2020b, para. 20).

5.3 | States' acknowledgment of access to medication in the context of human rights

The first resolution on access to medication was adopted by the [then] UN Commission on Human Rights (2001a); from 2006 replaced by the UN Human Rights Council. These resolutions have operationalised ICESCR Article 12(2)(c). This first resolution was adopted with 52 votes to none with 1 abstention: the USA (UN Commission on Human Rights, 2001b, p. 410). Its scope was narrow, focusing on HIV/AIDS, and its wording addressed only states. The emphasis was on the pharmaceutical corporations in the 2000 Millennium Declaration: "To encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries" (UN General Assembly, 2000, para. 20 [extract]). The first UN General Assembly access to medication resolution extended the scope from HIV/AIDS to tuberculosis and malaria (UN General Assembly, 2004; adopted 2003), in line with MDG indicators 6.9 and 6.6, respectively (UN Statistics Division, 2008).

A full review of all resolutions is not possible, and in the final section I will return to how vaccines were initially ignored in the resolutions. The Trilateral Cooperation refers to 20 UN resolutions and seven reports by Special Rapporteurs on the right to health, specifying that the "list does not imply any evaluation of importance" (WHO, WIPO, and WTO, 2020a, p. 294), as well as 35 resolutions from the World Health Assembly (WHO, WIPO, and WTO, 2020a, pp. 300–301). Three aspects of the political declaration from the 2019 high-level meeting on universal health coverage are interesting: (i) generics are explicitly acknowledged in a substantive paragraph on increased acccess, together with medicines, vaccines, diagnostics and health technologies (UN General Assembly, 2019a, para. 51); (ii) the 2001 Doha Declaration (WTO, 2001b) is explicitly reaffirmed (UN General Assembly, 2019a, para. 51); and (iii) the resolution was adopted without a vote (UN General Assembly, 2019b).

5.4 | More on the right to enjoy the benefits of scientific progress and its applications

The mandate of the Special Rapporteur in the field of cultural rights was in 2012 extended to encompass the right to enjoy the benefits of scientific progress and its applications (UN Human Rights Council, 2012, para. 9–11; adopted without a vote). This led—via experts seminars and broad consultations—to an initial report and two final

reports, one on patents and one on copyrights for the human right to science and culture (UN Special Rapporteur in the Field of Cultural Rights, 2012, 2014, 2015).

Most interesting is the assertion that "States have a human rights obligation not to support, adopt or accept … [TRIPS+, and] … reconciling patent protection with human rights" (UN Special Rapporteur in the field of cultural rights, 2015, para. 104). The term "obligation" is most interesting, as well as the acknowledgment that it is only by using TRIPS exclusions, exceptions and flexibilities that IP and human rights can be reconciled. Moreover, she recommends that pharmaceutical companies "should disclose information about the costs for developing drugs, the items included in such costs and the sums they reinvest in research and development" (UN Special Rapporteur in the field of cultural rights, 2015, para. 94); for an emphasis on transparency and accountability in the context of COVID-19, see UN Human Rights Experts (2020).

Unlike the UN High-level Panel on Access to Medicines (2016), which received strong criticism (BIO, 2016; ICBA, 2016), the 2015 report from the UN Special Rapporteur in the field of cultural rights did not receive much opposition. This might be because the report did not directly specify that IP are subordinate to human rights, as was done in another report (Commission on Intellectual Property, 2002, p. 6). A more realistic explanation is that it went under the radar of the pharmaceutical and biotech associations.

5.5 | What has been achieved?

In summary, an assessment of 20 years of human rights-embedded exploration of IP is that there is more insight regarding the IP-human rights interface in 2020 as compared to the situation in 2000, when the UN Subcommission identified "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights…" (UN Subcommission, 2000, preambular para. 11; see also UN Subcommission, 2001, preambular para. 11). Even if there have been mutual references between World Health Assembly resolutions and UN human rights resolutions, there is no evidence to indicate that the human rights resolutions have had a substantial impact on *domestic* legislative IP processes.

On the *international* level, Grosse Ruse-Khan argues that there has been an "attempted regime capture …" of the IP system by human rights actors (Grosse Ruse-Khan, 2016, p. 265; see also 2020; p. 206). However, the strategy has shifted from a confrontational to a more accomodating approach (Grosse Ruse-Khan, 2020, p. 204; see also p. 486) by promoting the maximum use of flexibilities provided by TRIPS to also comply with human rights. His own approach is to apply TRIPS Article 7 and 8(1), particularly when faced with broad and open legal concepts, terming Article 7 "the single most important element in the process of interpretation…" (Grosse Ruse-Khan, 2020, p. 235; *contra*: Pires de Carvalho, 2014), arguing also for IP ceilings to enhance the enjoyment of global public goods (Grosse Ruse-Khan, 2016, p. 492; Grosse Ruse-Khan, 2009).

The 2019 General Assembly Political declaration does, however, stand out from other UN resolutions, as noted above, inter alia by including generics (UN General Assembly, 2019a, para. 51). Neither this nor previous resolutions do, however, explicitly regard medicines and vaccines as a global public good, but this was emphasized one year later (UN Human Rights Council, 2020, para. 7).

Expert seminars on the right to benefit from science have brought up concepts like public assets and public knowledge (UN High Commissioner for Human Rights, 2014). In her initial report, the UN Special Rapporteur in the field of cultural rights proposed "the adoption of a public good approach to knowledge innovation and diffusion, and … a minimalist approach to IP protection" (UN Special Rapporteur in the Field of Cultural Rights, 2012, para. 65; see also 2015, para. 12; 2014, para 14). Hence, despite these references, it is fair to state that the global public good terminology has generally been absent from the UN human rights system.

6 | HAVE 20 YEARS WITH MDGS AND SDGS IMPROVED OVERALL ACCESS TO MEDICINES? THE MDG ERA

To capture the MDG era, it is relavant to identify positive efforts and inadequate results of making medicines more accessible, and a particular focus on developing countries is warranted.

6.1 | Positive efforts

Access to medicines was high on the international agenda in 2000–2001, and the Doha Declaration on TRIPS and Public Health (WTO, 2001b) was the culmination. As seen above, the Millennium Declaration included a paragraph on affordability of essential drugs for persons in developing countries, using the term "encourage" (UN General Assembly, 2000, para. 20). The ambitions, particularly for HIV/AIDS, were subsequently strengthened (UN General Assembly, 2005, para. 57(d)), resulting in a new target: 6.B: "Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it" (UN Statistics Division, 2008; also MDG targets 1.B, 5.B, and 7.B were added after 2005).

The 2010 deadline was not met. A Special Session of the UN General Assembly in 2011 specified that 15 million persons should receive antiretroviral treatment (ART) by 2015 (UN General Assembly, 2011, para. 66). The 2015 MDG Report specified that this was on track, as 13.4 million had such access in June 2014 (UN, 2015, p. 46).

In addition to MDG target 6.B on universal access to ART, there is one other MDG target that directly addresses IP in the context of medicines. This is 8.E, reading: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries," and it is specified in the indicator that such affordable access is on a sustainable basis (UN Statistics Division, 2008). Sustainable is in the context of affordable access understood as enduring, implying that there are mechanisms in place to ensure predictable delivery at affordable prices. In the General comment on the rights to health this is specified to encompass equity (UN CESCR, 2000b, para. 12(b)(iii)). If equity is operationalized as implying that household incomes are not decisive for one's access, there is still a long way to go. This does not imply, however, that there have not been considerable efforts by a wide range of actors to foster such affordable access.

Hence, two of 22 MDG targets (6.B and 8.E) highlighted IP, at least implicitly, in the context of affordable access to medicines, and the efforts to enhance such access for at least some medicines must be acknowledged. Therefore, at least as regards some types of medicines there *has* been improved overall access to medicines, as well as higher awareness among relevant actors. This positive acknowledgment must, however, be nuanced.

6.2 | Inadequate results

First, WHO's efforts of establishing a voluntary fund, proposed to be named Health Product Research and Development Fund, to finance neglected disease research, was not successful, due to lack of funding (WHO, WIPO, and WTO, 2020a, p. 161; WHO, 2017, p. 49). The proposal came from WHO's Special Programme for Research and Training in Tropical Diseases (WHO, 2016). In 2020, the World Health Assembly (WHA) adopted a new road map for neglected tropical diseases for the period 2021–2030 (WHO, 2020h; WHO, 2020i). It is relevant to mention that WHO was a cofounder of the Drugs for Neglected Diseases initiative (DNDi) in 2003 (DNDi undated).

Second, the prices for certain newly introduced medicines are still very high. A decision at the 2020 WHA called for further discussions on "promoting and monitoring transparency of medicines prices and actions to prevent shortages" (WHO, 2020j, para. 3). To enhance affordability in situations of too high prices, TRIPS Article 40(2) is relevant (extract):

> Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.

What price level that constitutes "abuse" has not been clarified by the WTO's Dispute Settlement Body or any other WTO organ, as seen in the WTO's Analytical index (WTO Secretariat, 2020b). Even powerful states might have to accept the price as determined by the pharmaceutical corporations. Depending on the specific priorities, states might nevertheless be able and willing to pay the excessive costs to enable affordable access, as few individuals are able to pay for particular treatment by their own. There are also examples of crowd-funding or philanthropic efforts—but these efforts are not addressing the structural problem of affordability.

6.3 | Diverse approaches for various countries

The date for least-developed countries' implementation of the TRIPS Agreement has been extended several times, for pharmaceutical products the extension is until 2033 (WTO, 2015). Extension for other products—also untill 2033—has been proposed to the Council for TRIPS (Chad, 2020). Hence, there are limited TRIPS obligations for least-developed countries, having a GNI/capita of $1018 or below, but there are no distinctions between other countries.

Beyond the actual diverse approach within the WTO, the most specific proposal for a diverse approach of IP protection was presented in the report from the UN Millennium Project (2005b). This Task Force was one of 13 Task Forces under the UN Millennium Project. Those five Task Force reports that addressed IP did so in a critical manner (Haugen, 2021), as reflected in the overall report, that called for "revisiting … the rules to examine … any additional flexibility required" (UN Millennium Project, 2005a, p. 219). The UN Task Force on Science, Technology, and Innovation proposed a "three-tier system," based on the level of GDP/capita, with less onerous obligations for states with less than 5000 USD in per capita income, and even less onerous obligations for states with less than 1000 USD (UN Millennium Project, 2005b, pp. 112–113). This proposal has not proceeded further, and it is not likely that TRIPS will be amended.

The UN Millennium Project reports' assessments of the IP system can be characterized as overall highly critical (UN Millennium Project, 2005a, 2005b) and the same applies to the Commission on Intellectual Property (2002).

More moderate proposals, not amending TRIPS, are proposed by the WHO-mandated Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) under the four headings discovery, development, delivery, and promote innovation (2006, pp. 175–185). When mandating the CIPIH, the report by the WHO Secretariat emphasized voluntary licensing (WHO, 2003a)—unlike the resolution (WHO, 2003b)—and the importance of voluntary licensing is addressed in the final report (CIPIH, 2006, pp. 121–123).

The CIPIH report refers to public goods once (CIPIH, 2006, p. 56), in the context of presenting the international agricultural research centers operating under the umbrella of the Consultative Group on International Agricultural Research (CGIAR), indentifying three previous studies promoting a CGIAR-like model as highly relevant in mobilizing resources for under-funded research (CIPIH, 2006, p. 187). It is relevant, however, that several of the actors identified above, like Gavi, The Global Alliance and Unitaid, are relevant responses to this underfunded research.

7 | HAVE 20 YEARS WITH MDGS AND SDGS IMPROVED OVERALL ACCESS TO MEDICINES? THE SDG ERA

Initially, it is relevant to observe that the processes for formulating the MDGs and the MDG targets—and indicators—differ substantively from the process for formulating the SDGs and SDG targets. The MDGs and MDG targets and indicators were formulated by the Interagency and Expert Group on the Millennium Development Goal

Indicators (IAEG-MDGs) *after* the adoption of the Millennium Declaration (UN General Assembly, 2000). The formulation of the 169 targets of the SDG were negotiated *before* the adoption (UN General Assembly, 2015a), but the efforts to formulate SDG indicators were left to a process under the auspices of the UN Statistics Division. The first list of the SDG indicators were adopted in 2016 (UN General Assembly, 2016), and are subject to annual refinement (UN Statistics Division, 2020).

7.1 | The SDGs targets

Among the 169 SDG targets, only two address IP in the context of medicines, one implicitly and one explicitly. Target 3.8 is on (extract) "access to safe, effective, quality and affordable essential medicines and vaccines for all." Target 3.B reads (extracts):

> Support the research and development of vaccines and medicines …, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration… [WTO, 2001b] which affirms the right of developing countries to use to the full the … [TRIPS] flexibilities to … provide access to medicines for all.

We see that both provisions refer to medicines and vaccines, while the MDG targets merely referred to medicines. There are also three SDG targets on technology under SDG 17, but these are are not in themselves adding much to the problem complex of access to medicines. It must be noted, however, that the SDG Multi-stakeholder Forum on science, technology, and innovation for the Sustainable Development Goals (STI Forum; UN General Assembly, 2015a, target 17.6) is a forum for addressing IP–STI–SDG relationships, as will be further analyzed in Section 8.1 below.

It is relevant to ask whether the SDG era or Agenda 2030 can be characterized by terms from the theory of principled pragmatism. As an initial illustration, the UN High-level Panel on Access to Medicines (2016)—which was met with criticism (BIO, 2016; ICBA, 2016)—was rather moderate at least if compared with the UN Millennium Project (2005a, 2005b; Haugen, 2021), as seen above. The UN High-level Panel on Access to Medicines called for utilizing TRIPS flexibilities provisions and interpreting TRIPS provisions in accordance with TRIPS Article 7 and 8(1) (The UN High-level Panel on Access to Medicines, 2016, p. 60; see also WTO, 2001b).

7.2 | Stronger emphasis on public–private cooperation

The UN Guiding Principles are inspired by principled pragmatism, and norms dissemination through distributed networks globally and domestically, being embedded in reflexive dynamics and process legitimacy (Ruggie, 2015). They imply greater acknowledgment of corporations' potential for doing good and their responsibilites to avoid doing harm. Doing harm can either happen by their own activities or because of their business relationships with corporations, where knowledge about harmful conduct is not acted upon. According to Jägers (2020, p. 147), the MDGs were viewed as having too little attention to the private sector, while the SDGs "recognize business as a key partner…"

It is on this background that we can understand this statement:

> The private sector and public-private partnerships can promote innovations aimed at sustainable development, appropriately protecting intellectual property rights while increasing access of developing countries to essential goods and technologies (UN, 2019, p. 37).

This is the most substantial statement on IP in the *Global Sustainable Development Report*, whose 2019 edition highlights science. This harmonious relationship between IP protection and increased access to essential goods is reflecting the SDG era, influenced by the UN Guiding Principles. Moreover, there have been several IP and access-related initiatives over the last two decades, in addition to the processes within TRIPS and the Trilateral Cooperation.

Hence, new forms of cooperation and funding, often with specified conditions for how the resulting products are to be made available, are gaining ground.

7.3 | IP acting as impediments in the fights against COVID-19?

Full freedom to operate, implying that for instance developers of new vaccines can progress without having to consider existing patents, is illusory. One example is the mNeonGreen, which is a green fluorescent protein, patented by Allele Biotechnology, based in San Diego (U.S. Patent No. 10,221,221). On October 5, 2020 Allele brought two lawsuits, one against Pfizer and BioNTech for patent infringement, for using the technology for their COVID-19 vaccine without a licence (Egbuonu, 2020).[4]

In this context it is relevant that the Public Readiness and Emergency ("PREP") Act, 42 U.S.C. §247d–6d, adopted in 2011 and applying if the Secretary for Health determines a "public health emergency" as specified in Section §247d–6d(b)(1) *might* constitute a legitimate defense to patent infringement (Alosh, 2020).

Moreover, it is relevant that the Pandemic Influenza Preparedness (PIP) Framework was adopted by the 2011 World Health Assembly (WHO, 2011). The PIP Framework specifies IP concerns in Article 6 of its Standard Material Transfer Agreement ("SMTA 1"). The SMTA 1 intends to enhance access to vaccines and other benefits between authorized laboratories and while Article 6.1 discourages IP, Article 6.3 emphasizes respect of IP (WHO, 2011, p. 31). Even if the PIP Framework was adopted in the MDG era, it will be applied in the SDG era.

While IP can act as an impediment, as legal proceedings might not be finalized on time, no actor will like to be seen by the international community as an obstacle for an effective COVID-19 response. Hence, it is likely that in this situation, solutions will be found.

7.4 | Overall assessment of the MDG and SDG era

To sum up, the overall context for development-related efforts over the last two decades have been the MDGs and more recently the SDGs, driven in large parts by the various UN specialized agencies, funds and programmes. Four trends can be identified within these two frameworks. First, the role of the business actors have been more acknowledged in the SDG era as compared to the MDG era. Second, while there has been shifting emphasis on the issue of voluntary licensing (CIPIH, 2006, pp. 121–123), it is reasonble to state that voluntary licensing is more recognized and practiced today than at least at the start of the MDG era. Third, vaccines are explicitly included, in addition to medicines, in the context of identifying TRIPS flexibilities. Fourth, there are new institutional mechanisms for promoting STI globally, to which we will now turn.

8 | THE ROLE OF IP IN PROMOTING STI FOR THE SDGS

The IP-STI-SDG relationships are complex, but I will highlight three distinct issues. These three issues are chosen because they are the most specific in the context of implementing an IP policy that seeks to promote enhanced access, and hence most interesting. First, if generic medicines and vaccines is acknowledged. Second, what role

voluntary licensing can play for enhanced access. Third, why not more countries follow the example of India and make use of the flexibilities that TRIPS provides.

8.1 | Acknowledgment of generic medicines and vaccines

Initially, as specified above, it is relevant that the 2015 General Assembly resolution adopting the 17 SDGs and the 169 SDG targets endorsed the multistakeholder Forum on science, technology, and innovation for the Sustainable Development Goals (UN STI Forum; UN General Assembly, 2015a, target 17.6). The STI Forum had already been established by the Third International Conference on Financing for Development (UN General Assembly, 2015b, para 123). It is the third component of the Technology Facilitation Mechanism (TFM); the others are UN inter-agency task team on STI for the SDGs (UN IATT) and the online platform on STI for the SDGs, titled 2030 Connect (UN Secretariat, 2020a).[5]

The two first meetings in the UN STI Forum addressed IP, summarized by the term "effective" protection (UN STI Forum, 2017, paras. 21 and 68; see also G20, 2020b), and seeing IP as an element of "robust legal environments…" (UN STI Forum, 2016, para. 21). Similar terminology was not included in the summaries from the three subsequent forums. While these are merely summaries of the issues discussed at the STI Forums, these terms have a different emphasis than found in other UN documents, like "balanced" (UN Secretary-General, 2014, para. 11) and "access" (UN General Assembly, 2020, para 7). Nothing on generics is specified in these reports.

The UN STI Forum reports to the annual UN High-level Forum on Sustainable Development, which so far has not addressed IP in great detail. Specific advice on IP could have been foreseen in the 2020 UN Guidebook for the Preparation of STI for SDGs Roadmaps, developed under the auspices of the UN IATT. The most specific paragraph on IP merely refers to internal UN processes, expecting these to overcome the previous "political gridlock over [IP] and technology transfer issues" (UN IATT's Sub-Working Group on STI Roadmaps coled by World Bank, DESA, UNCTAD and UNESCO, 2020, p. 68). While this escape from the "political gridlock" is positive, the new approaches, including potentials for generics, is not addressed.

Hence, during the 5 years since the adoption of the SDGs, the issue of generic medicines and vaccines has seemingly not proceeded, with the exception for the 2019 Political declaration (UN General Assembly, 2019a, para. 51).

8.2 | Voluntary licensing

Voluntary licensing is addressed in two various ways in the UN MDG Gap Task Force report (2015), produced through an interagency coordination. The main part of the report reads (UN MDG Gap Task Force, 2015, p. 62):

> Full incorporation and use of TRIPS flexibilities will thus continue to be important to encourage pharmaceutical companies to license their products to increase access while not discouraging innovation.

In this context, the TRIPS flexibilities per se are seen as important to foster enhanced licensing by the corporations. Even if no specification of such licensing is given, the context implies that it is *voluntary* licensing. Voluntary licensing is not explicitly regulated in TRIPS, as seen in Section 4.2 above. Nevertheless, the wording in the UN MDG Gap Task Force report implies a link between using TRIPS flexibilities and promoting voluntary licensing.

In the summary part of the report, voluntary license agreements are specified as "other means," in *addition* to public health flexibilities (UN MDG Gap Task Force, 2015, p. xv). This seems to be more in line with the realities:

The voluntary licensing is another means—beyond ultilizing TRIPS flexibilities—in enhancing access to medicines and vaccines. Extensive use of TRIPS flexibilities does not necessarily imply more licensing.

Hence, the summary is more precise as regards the "framing" of voluntary licensing, as compared to the main text. It is not certain that voluntary licensing will be the preferred option by pharmaceutical corporations in a situation where these corporations are pressed by the relevant legislation to enjoy less favorable IP protection, as is the situation in India.

Voluntary licensing has not been addressed within the STI Forum, but was emphasized in the 2020 study by the Trilateral Commission, sometimes together with voluntary pooling and generics (WHO, WIPO, and WTO, 2020a, pp. 20–21; WHO, 2020a, para. 8(2); on patent pools, see WIPO Secretariat, 2014). Moreover, the Trilateral Commission refers to Unitaid's Medicines Patent Pool (WHO, WIPO, and WTO, 2020a, p. 157).

8.3 | India's strategies

Why not more countries apply flexibilities as done by India is a question that will have many answers. The obvious answer is that India has a considerable generic medicines industry, as well as other relevant bioech industries and wants to protect their interests.

This explanation has to be supplemented by other explanations, and the theories on forms of power—visible, hidden, invisible (Lukes, 1974)—and spaces of power—closed, invited, claimed (Gaventa, 2009)—is relevant.

As regards forms of power, there is no doubt that India is powerful enough in itself to make several actors change their conduct. While all states have laws and court systems to regulate the conduct of corporate actors, the Indian parliamentary, executive, and judicial systems together represent a strength that can influence both WTO negotiations globally and biotech corporations domestically. As regards the hidden form of power, this also applies, as India can at least domestically determine what is not placed on the political agenda. This applies as long as there are no rulings from the WTO dispute settlement system that India has to comply with.

The (no-)agenda-setting power on the global level is obviously more restricted. The invisible power, being about perceptions, is also more difficult to identify, at least on the global level. The positive role of generics in the Political declaration (UN, 2019, para. 51) is, however, important to acknowledge. Moreover, WIPO' Standing Committee on Patents (SCP) has two on-going agenda items: Agenda item 5 on Exceptions and limitations to patent rights and Agenda item 7 on Patents and Health. Countries like South Africa and particularly Brazil are more active in the SCP than India (Argentina Brazil Canada and Switzerland, 2018, para. 1; acknowledging generics). It is noteworthy that Switzerland—being one of the strongest proponents of an IP system with high protection standards—is acknowledging generics. Brazil, together with Argentina, was also behind the proposal to establish the Development Agenda for WIPO (2004), leading to the establishment of the Committee on Development and Intellectual Property (CDIP). India, on the other hand, is one of the most proactive countries in the Council for TRIPS.

This brings us over to the spaces of power. India is obiously neither excluded from nor merely invited to the relevant global forums where IP is discussed. Rather India is able to claim a space for the broadening of issues which are relevant to discuss in an IP context. India is not alone in seeking to broaden the agenda, but India is a leading actor. When India justifies its IP policies (see also WIPO Secretariat, 2010), the former WIPO's Director-General, Francis Gurry (2008–2020), is quoted twice when reminding of "how IP can not only be about protecting investment, but also social benefit" (Thomas, 2013, p. 19; see also p. 4).

8.4 | Promoting innovation and access in a global context

In summary, the complex issues of how to ensure the optimal balance between innovation and access for meeting the SDGs has not been brought much forward by the STI mechanisms under the TFM. The Trilateral Cooperation

provides the richest source for measures that can overcome inadeaquate access, either because of quantity or because of too high prices. These measures include pricing agreements, based on negotiations, voluntary licensing, compulsory licensing, patent oppositions, and buyers' clubs (WHO, WIPO, and WTO, 2020a, pp. 224–225).

9 | CONCLUDING DISCUSSION

The last two decades have seen a shift from the very high tensions over patenting and accessibility in 2000–2001 to a broader acknowledgment of the need to find a better balance between protection of innovations and access to such innovations. While the most important actor on the global scene is the WHO, the so-called nonpaper by France and Germany (2020) identifies the need for changes in the WHO governance. The initial framing of widespread immunization against COVID-19 as a global public good was done by the World Health Assembly (WHO, 2020a, para. 6), with others repeating its core (UN Human Rights Council, 2020, para. 7; G20, 2020a, para. 3; G20, 2020b). The global public goods terminology has been most consistently applied in the three reports on science by the former UN Special Rapporteur in the Field of Cultural Rights (2012, para. 65, 2014, para 14, 2015, para. 12). As seen above, her reports were not met with opposition and her involvement of recognized IP scholars in the preparation of her two last reports must be acknowledged.

How much acknowledgment for the changes in the perceptions among political leaders should be given to the various UN human rights bodies that have been engaged? Most notably, the 2019 Political declaration must be seen as a culmination for the enhanced access, by the explicit acknowledgment of generic medicines (UN General Assembly, 2019a, para. 51). In this context it is relevant to note that in the draft resolution for the 2018 UN Special Session on Tuberculosis, nothing was said about TRIPS flexibilities (UN Intergovernmental Consultations for the High-level Meeting on the Fight Against Tuberculosis, 2018), but this came in the final resolution (UN General Assembly, 2018, para. 19). The mutual influence takes place between the UN human rights bodies and the WHO through the World Health Assembly, which in turn influences the WHO–WIPO–WTO Trilateral Cooperation.

The new mechanisms on STI within the SDGs have so far not contributed to alternative perspectives. However, the UN Millennium Project (2005a, 2005b; Haugen, 2021) and the UN MDG Gap Task Force (2015) did identify the need for changes in IP policies. Furthermore, SDG targets 3.8 and 3.B both refer to vaccines and medicines together, which was a progress as compared to the MDG era.

As regards the latter part of the research question formulated at the end of the first section on whether the global equity, global public goods and human rights framing has had any impact on the position of the most pro-TRIPS WTO member states, this is also complex. It is a too strong assertion to claim that the position of these states have been substantively modified, but I have found that there is an increased openness to discuss alternative approaches—within an IP framework.

A relevant question is if it is only in the case of a pandemic—defined by the WHO as the widespread human infection of a new disease in at least *three* countries in at least *two* different WHO regions (WHO, 2009)—that a global public goods approach to vaccines (and medicines) is relevant. In other words, if there is widespread human infection of a new disease in several countries in only one WHO region, this will not be declared a pandemic. As an example, Ebola was declared as a "public health emergency of international concern" (WHO, 2014).

Notwithstanding these distinctions, merely the risk of spread of infectious diseases to other WHO regions should allow the global public goods approach to vaccines and medicines to be applied also in situations which are not declared a pandemic.

The language of the UN resolutions on access to medicines has been strenghtened overall. The first UN resolution on access to medicines included neither of the terms equitable or fair (UN Commission on Human Rights, 2001a). In the access to medication resolution adopted at the peak of the swine flu pandemic (H1N1), neither the terms equitable or fair nor the term vaccines is applied (UN Human Rights Council, 2009). Moreover, the first time the term vaccines appeared in the access to medication resolutions, it was in the context of

recognizing innovative funding mechanisms (UN Human Rights Council, 2011b, para. 8). Only in 2016 was the term vaccines applied in a stricter manner, specified as to "ensure their sustained accessibility, affordability and availability and to ensure access to treatment for all those in need…" (UN Human Rights Council, 2016, para. 5). It is reasonable that the SDGs, which referred to vaccines and medicines together (UN General Assembly, 2015a, targets 3.B and 3.8) is an important explanation for this shift.

The terms equitable and fair are applied in the 2020 resolutions on COVID-19, which also calls for the "urgent removal of unjustified obstacles … in accorance with [TRIPS] … as confirmed by the Doha Declaration … [WTO, 2001b]" (World Health Assembly [WHO, 2020a], para. 4; UN Human Rights Council, 2020, para. 5).

The biannual resolutions on STI for sustainable development, which are adopted without a vote are, however much softer, by "encouraging access" within an "efficient, adequate, balanced and effective [IP] framework…" (UN General Assembly, 2020, para. 7). This is a resolution that is linked to UN's STI agenda for the SDGs, and hence not a "pure" human rights resolution.

Hence, the direct influence of the UN human rights resolutions on domestic legislative outcome is somewhat difficult to identify. As regards norms development globally, it seems reasonable that the elements identified by Ruggie as crucial in norms dissemination, taking place through distributed networks globally (Ruggie, 2015) explain the overall positive role that the UN human rights system has exercised in the context of medicines and vaccines. The debates within the WTO are of course also influenced by this development, as witnessed in the Trilateral Cooperation. The urgency of identifying the best possible responses to COVID-19 within the IP framework has made the Trilateral Cooperation publish an extract of its 2020 report that applies particularly to COVID-19 (WHO, WIPO, and WTO, 2020b). It is reasonable to state that among pro-TRIPS developed countries there is an acknowledgment of obstacles created by the IP system, some of which are identified by South Africa (2020)—and of the social functions of an IP system—but their overall position on the IP system has not changed.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ENDNOTES

[1]Sinovac's efficacy is only 50.4%; see BBC (2021); on efficacy of vaccines developed by Johnson & Johnson and Novavax, see Clinical Trials Arena (2021); Sputnik V is in phase 2 (January 2021).

[2]Two reports are compilations of responses by nongovernmental and international organizations, by the UN Secretary-General (see Haugen, 2012, p. 38 (no. 7)); one is a substantive analysis, by the UN High Commissioner for Human Rights (2001); identifying in para 43–49 measures like generic substitutes, differential pricing and price negotiations, and parallel importation.

[3]Space does not allow a full review of General Comment 25, but it is surprising that it contains no references to the two comprehensive report by the UN Special Rapporteur in the Field of Cultural Rights (2015, 2014), only to her initial report (UN Special Rapporteur in the Field of Cultural Rights, 2012). Between these two reports, there were three expert seminars, in Geneva in 2013 (UN High Commissioner for Human Rights, 2014) and in New York and Geneva in 2014 (UN Special Rapporteur in the Field of Cultural Rights, 2014, para. 5 and Annex).

[4]Allele's Licensing Director explains: "The purpose of these lawsuits is to maintain Allele's patent rights and to ensure that an agreement can be put in place to protect the rights of current and future licensees" (Egbuonu, 2020). Moverover, Allele's CEO asserts that "in no way does Allele want to prohibit, or slow down development of vaccines or therapeutics discovered using this technology" (Egbuonu, 2020).

[5]Three UN bodies were responsible for the first launch of the Connect 2030, on July 15, 2020: UNCTAD (UN Conference on Trade and Development), UN Department on Social and Economic Affairs, which has a Division for Sustainable Development Goals (DESA/DSDG), and UN Office of Information and Communications Technology (OICT) (UN Secretariat, 2020b). It is specified: "Materials provided on this Site are provided 'as is'…"; and: "The United Nations in collaboration with the UN and non-UN partners, periodically adds, changes, improves or updates the Materials on this Site without notice" (UN Secretariat, 2020c). As there is a login function, it seems that anyone who is registering as user can

place documents on the 2030 Connect. For one example of what was found by the search term "patents," see Sehgal (2020).

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How to cite this article: Haugen, H. M. (2021). Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good? *J World Intellect Prop*. 24, 195–220. https://doi.org/10.1111/jwip.12187