ACCESS TO ESSENTIAL MEDICINES AND INTERNATIONAL HEALTH LAW: TOWARDS A NEW PARADIGM?

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ABSTRACT

Newly independent countries always expressed the need for an equal access to essential medicines based on international human rights treaties. The right to access essential medicines was officially expressed in 2001 during the World Trade Organization's (hereinafter "WTO") Doha Conference. However, is it possible to consider that the World Health Organization (hereinafter "WHO") has today the prerogatives to coordinate an international response to a pandemic, facilitate research and development of vaccines and above all allow fair and equitable access to new treatments? The recent tensions between the United States and China for instance demonstrate the structural inertia of both the WHO and the WTO, and this is all the truer as these key international organizations have binding rules for States Parties: the International Health Regulations (2005) adopted by WHO members and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) adopted by WTO members. The devastating effects of the COVID-19 pandemic must encourage the international community to a change of paradigm by adopting a legally binding arsenal aimed at facilitating access to essential medicines. Cooperation with the WHO must be in full conformity with the purposes and the principles of the Charter of the United Nations

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which provides that States Parties have a general obligation of cooperation, including health matters. It is, therefore, essential to provide the WHO with coercive legal means to ensure compliance with international treaties and the International Health Regulations.

KEYWORDS: *essential medicines, vaccines, WHO, pandemic, right to health, international cooperation, global public goods*

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I. INTRODUCTION

Globalization and health are intrinsically linked; greater international cooperation through legally binding rules and codification is necessary,[1] especially in times of global public health crisis. International health law is indeed a vital area with ramifications in a wide range of fields such as human rights, scientific research, trade and customs law. The concept of global public goods[2] with regard to access[3] to essential medicines as part of the right to health[4] must be applied in international law throughout a series of legally binding instruments under the supervision of the World Health Organization (hereinafter "WHO") for health regulations on the one hand; and the World Trade Organization (hereinafter "WTO") for intellectual property rights and commercial regulations on the other hand.[5] Indeed, international health law must serve to guarantee and improve public health around the world.[6] Sustainable development is only possible if the vaccines developed in times of pandemic are accessible to all, it must, therefore, be considered as an essential medicine and international health law should enable an equal access to COVID-19 vaccines.[7] The purpose of this article is to demonstrate that vaccines are necessarily essential medicines especially in times of global pandemics, and that both WHO and WTO have to tackle the issues related to their commercialization and accessibility in developing countries. Some authors believe, indeed, that COVID-19 vaccines should be considered as essential medicines even though they have been deployed and

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[1] *See generally* Allyn L. Taylor, *Global Governance, International Health Law and WHO: Looking Towards the Future*, 80(12) BULL. WORLD HEALTH ORG. [hereinafter WHO] 975 (2002), https://www.who.int/bulletin/archives/80(12)975.pdf.

[2] *See generally* Anne Mills, *Technology and Science as Global Public Goods: Tackling Priority Diseases of Poor Countries*, 10(1-2) REVUE D'ÉCONOMIE DU DÉVELOPPEMENT 117.

[3] *Access to COVID-19 Vaccines: Global Approaches in a Global Crisis*, OECD (Mar. 18, 2021), https://www.oecd.org/coronavirus/policy-responses/access-to-covid-19-vaccines-global-approaches-in-a-global-crisis-c6a18370/.

[4] Comm. on Econ., Soc. & Cultural Rts. [CESCR], Rep. on the Twenty-Second, Twenty-Third and Twenty-Forth Session, annex IV, at 131, U.N. Doc. E/2001/22, E/C.12/2000/21 (2001).

[5] *See* Joint Report elaborated by the WHO and the World Trade Organization [hereinafter WTO] in 2002 following the Doha Conference, WTO & WHO, WTO AGREEMENTS & PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT 22 (2002), https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf:

> The Doha Declaration on the TRIPS Agreements and Public Health and paragraph 6 of the Doha Ministerial Declaration made clear that WTO rules and health policies can go hand in hand, that public health considerations are important in implementing WTO rules, and that trade and health policies can be made mutually supportive.

[6] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

[7] Alexandra L. Phelan et al., *Legal Agreements: Barriers and Enablers to Global Equitable COVID-19 Vaccine Access*, 396 LANCET 800, 800-02 (2020).

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authorized following emergency procedures.[8] From the beginnings of decolonization, developing countries expressed the need for an equal access to essential medicines based on international human rights treaties. The right to access essential medicines was officially expressed in 2001 during the WTO's Doha Conference.[9] However, is it possible to affirm that the WHO has today the prerogatives to coordinate a coordinated international response to a pandemic, facilitate research and development of vaccines and above all, allow fair and equitable access to new treatments? The task promises to be difficult as the interests at stake diverge massively from developed countries trying to protect their pharmaceutical companies and developing countries claiming that access to essential medicines and vaccines are indivisible and interdependent. The recent commercial and political tensions between the United States and China, for instance, demonstrate the structural inertia of both the WHO and the WTO, and this is all the truer as these key international organizations have binding rules for States Parties: the International Health Regulations (hereinafter "IHR") were adopted by the WHO in 1951 and entered into force for all States Parties in their current form on 11 July 2016.[10] The devastating effects of the COVID-19 pandemic must incite the international community to a change of paradigm by adopting a binding legal arsenal aimed at facilitating access to essential medicines and vaccines during pandemics (Section II). A legally binding arsenal will facilitate the economic recovery and limit the spread of the disease. Cooperation with the WHO must be in full conformity with the purposes and the principles of the Charter of the United Nations (hereinafter "UN") which provides that States Parties have a general obligation of "cooperation,"[11] including health matters (Section III). Research has also investigated this field of international law and shows that progress is very limited. It has been described as a "mixed patchwork of achievements and missteps in

[8] Maxwell J. Smith et al., *Should COVID-19 Vaccines Authorized for Emergency Use Be Considered "Essential" Medicines?*, 23(1) HEALTH & HUM. RTS. J. 145, 149 (2021), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/2469/2021/06/Smith.pdf:

> Yet, in the context of a pandemic and large-scale vaccination programs rolled out under EUAs (or similar regulatory mechanisms), it may be imprudent to require that COVID-19 vaccines wait to receive licensure before they can be considered as essential medicines. We therefore argue that COVID-19 vaccines authorized for emergency use should not necessarily be precluded from being considered as essential medicines candidates, but rather be considered for essential medicine status only if they have undergone a systematic, consistent, transparent, and coordinated process for being assessed and listed for emergency use.

[9] WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (2001).

[10] WHO, INTERNATIONAL HEALTH REGULATIONS (2005) 1-2 (3d ed. 2016).

[11] Michaela S. Halpern, *State Obligations Under Public International Law During Pandemics*, 35 EMORY INT'L L. REV. RECENT DEVS. 1, 1 (2020).

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responding to COVID-19 [that] show powerful nations are not living up to their commitment to solidarity and equity."[12] It is, therefore, essential to provide the WHO with coercive legal means to ensure compliance with international treaties and the IHRs (Section IV). As witnessed today with the world economy struggling to recover and the emergence of new COVID-19 variants, the current legal framework is limited and a change of paradigm is a necessity (Section V).

II. NEW PARADIGM: THE ADOPTION OF A LEGALLY BINDING ARSENAL AIMED AT FACILITATING ACCESS TO ESSENTIAL MEDICINES AND VACCINES

The COVID-19 pandemic has highlighted the limitations of international law when it comes to access to essential medicines and vaccines. Indeed, developing countries have great difficulty in accessing vaccines recently developed by pharmaceutical companies. Some research suggests that COVID-19 vaccines will only reach poor countries in 2023.[13] Today, developing countries cannot access vaccines for their populations and pressure is increasing on pharmaceutical companies to allow access to their vaccines.[14] As of 8 September 2021, less than 1% of people in low-income countries are fully vaccinated, and just 10% are in lower-middle-income countries, compared with more than half in high-income countries.[15] Despite all the efforts made by the WHO since the outbreak of the pandemic, few countries in the Global South have wide access to vaccines. Some authors consider that it complied with its obligations and that states have been informed of the risks of a pandemic very early. Bump et al. note that:

> WHO is a manifestation of the advantages of cooperation and collaboration, and it consistently leads member states in ways that uphold its mission to advance the highest standard of health for all. In the pandemic, WHO has shown leadership in sharing information and in co-launching the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to accelerate development and equitable access to diagnostic tests, treatments, and vaccines.[16]

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[12] Jesse B. Bump et al., *International Collaboration and Covid-19: What Are We Doing and Where Are We Going?*, THE BMJ (Jan. 29, 2021), https://www.bmj.com/content/372/bmj.n180.
[13] T. V. Padma, *COVID Vaccines to Reach Poorest Countries in 2023—Despite Recent Pledges*, NATURE (July 9, 2021), https://www.nature.com/articles/d41586-021-01762-w.
[14] Amy Maxmen, *The Fight to Manufacture COVID Vaccine in Lower-income Countries*, NATURE (Sept. 16, 2021), https://www.nature.com/articles/d41586-021-02383-z.
[15] *Id.*
[16] Bump et al., *supra* note 12.

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Access to COVID-19 vaccines and essential medicines necessarily impacts the economic recovery and the way out of this public health crisis for the international community. Increased protectionism and isolationism in these times of pandemic and a notable "vaccine nationalism" have been witnessed.[17] Many countries have, thus, limited exports of vaccines to third countries and have given priority to their populations. Health emergencies have impacted both national and international trade policies. Observers and researchers believe that the pandemic of COVID-19 may kill globalization as it is known today.[18] How can the international community combat COVID-19 vaccine nationalism? Couldn't states consider the COVID-19 vaccines developed recently as essential medicines? What can the WHO do to guarantee equal access to vaccines for developing countries? All these questions will determine whether the international community will be able to turn the page of the pandemic and its repercussions on public health and international trade. According to the WHO, "[e]quitable access to health products is a global priority, and the availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target 3.8."[19] Access to essential medicines has always been a crucial issue for the international community, especially for developing countries, but the current legal regime applicable to essential medicines does not favor developing countries and states are reluctant to cooperate and encourage technology transfers to both low-income and low-middle-income countries.[20] Licensing deals and technology transfers continue to limit the global response to the pandemic. As acknowledged, access to essential medicines depends on supportive national policies but a greater proactive role of the WHO is also needed. Including COVID-19 vaccines in the list of essential medicines will help the international community to combat the spread of the disease. Some authors note that: "[v]oluntary licensing, through mechanisms such as the Medicines Patent Pool (MPP), can allow generic companies in [lower and middle-income countries (LMICs)] to produce and sell essential medicines still under patent for a fraction of the cost of branded versions."[21] Moreover, "[w]hen voluntary licensing cannot be obtained, countries must be encouraged to use existing legal flexibilities in international intellectual

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[17] *See generally* Matthew Rimmer, *The People's Vaccine: Intellectual Property, Access to Essential Medicines, and COVID-19*, 5(1) J. INTELL. PROP. STUD. 1 (2022).

[18] Nina Boberg-Fazlic et al., *Pandemics and Protectionism: Evidence from the "Spanish" Flu*, 8 HUMANS. & SOC. SCIS. COMMC'NS 1, 2 (2021).

[19] WHO, *Access to Medicines and Vaccines: Report by the Director-General*, at 4, WHO Doc. A72/17 (Apr. 4, 2019), https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf.

[20] Johnathan H. Duff et al., *A Global Public Health Convention for the 21st Century*, 6 LANCET PUB. HEALTH e428, e428 (2021).

[21] Adrianna Murphy et al., Commentary, *Can We Do for Other Essential Medicines What We Are Doing for the COVID-19 Vaccine?* 6(2) BMJ GLOB. HEALTH 1, 2 (2021), http://dx.doi.org/10.1136/bmjgh-2021-005158.

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property laws to overcome patent barriers that stand in the way of public health." The IHR (2005) could be used by States Parties to the WHO to improve the degree of response to the pandemic and increase interstate cooperation. A further negotiation to modify these rules does not seem to be an insurmountable obstacle. One of the limitations here is that bilateral and multilateral cooperation are only encouraged. Some states criticized the WHO for its inertia and lack of information during the pandemic but it seems that the WHO notified promptly Member States on 4 January 2020 regarding the risks associated with the new disease. Also, the WHO regularly "advocated for global financial solidarity by establishing the COVID-19 Solidarity Response Fund in April 2020 and the external independent WHO Foundation in May 2020."[22] Thus, the international community has to adopt a new legally binding agreement or, at least, modify the IHR (2005) to recognize that during pandemics vaccines will be made available for all, especially for developing countries. Indeed, the COVID-19 pandemic created an unprecedented situation in interstate relations since the end of the World War II in 1945. The paralysis of international trade and transportation provoked a massive recession in many states and led to new questions relating to the future of globalization in its current form. The international community can only acknowledge that a new paradigm is an absolute necessity in order to reshape international health law and international cooperation to efficiently combat such global public health crises.[23] This new paradigm is the adoption of a global answer throughout the implementation of new international rules by states to facilitate cooperation and access to essential medicines and vaccines, especially by developing countries. On the one hand, the WTO shall modify the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS Agreement") and authorize waivers and suspension of IP rights. On the other hand, WHO members shall revise the WHO IHR in order to take into consideration global public health crises such as the COVID-19 pandemic. Additionally, WHO members shall provide a comprehensive set of mandatory rules to facilitate interstate cooperation and involve the private sector in these efforts. Some efforts have been made but existing initiatives—COVID-19 Vaccines Global Access (hereinafter "COVAX") among others—suffer numerous limitations as they essentially rely on the goodwill of states. Coordinated responses through mandatory rules will allow the world to recover and turn the page of the COVID-19 pandemic. It is conceivable that the necessity to cooperate under the UN Charter in times of global pandemics is a fundamental obligation for all states. The UN International Law

[22] Bump et al., *supra* note 12.

[23] *See generally* Pepita Barlow et al., *COVID-19 and the Collapse of Global Trade: Building an Effective Public Health Response*, 5(2) LANCET PLANETARY HEALTH e102 (2021), https://doi.org/10.1016/S2542-5196(20)30291-6.

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Commission listed the obligation to cooperate among peremptory norms of *jus cogens*.[24] Can the obligation to cooperate in times of global public health crisis be considered as a mandatory obligation in international health law? The answer is positive: states do have an obligation to cooperate not only in the peaceful settlement of disputes but also in situations threatening millions of lives and international trade. The obligation to cooperate in times of pandemic can be assimilated to a rule of *jus cogens*.

The WHO may decide to declare a state of emergency due to a pandemic requesting States Parties to force pharmaceutical companies to give access to their vaccines throughout in an affordable manner or to suspend intellectual property rights for a certain period of time. It is also possible to imagine that technology transfers to developing countries will be facilitated as well as licensing deals at affordable terms and conditions for developing countries. Suspending intellectual property rights in times of pandemic is a source of debates and controversy within states. Some authors consider that waivers are essential for global vaccine equity.[25] Such a solution can be implemented through a legally binding instrument and regulated by the WHO which may decide whether or not intellectual property rights should be suspended for a limited period of time. For example, the global rate of vaccination can be taken into account to determine such suspension of intellectual property (hereinafter "IP") rights and their duration. Intellectual property rights should be waived until the world reaches a rate of 70% of vaccinated adults. It should be a temporary measure with strict conditions to be met in order to suspend IP rights. Indeed, without strong intellectual property rights, pharmaceutical companies will not be prompt to invest in research and development, and the international community will be facing a global health crisis or only developed countries will have access to vaccines. The pandemic will endure for years with economic and sanitary consequences especially for developing countries. In 2020, a research conducted by experts demonstrated that efforts should be made in order to combat the pandemic but states should also pursue their efforts for other diseases such as tuberculosis.[26] This can be a challenge for developing countries and without the support of the WHO and the international an insurmountable obstacle.

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[24] *See generally* Dire Tladi (Special Rapporteur), *Third Rep. on Peremptory Norms of General International Law (*jus cogens*)*, U.N. Doc. A/CN.4/714 (Feb. 12, 2018).

[25] Priti Krishtel & Rohit Malpani, *Suspend Intellectual Property Rights for Covid-19 Vaccines*, THE BMJ (May 8, 2021), https://doi.org/10.1136/bmj.n1344.

[26] *See generally* Ana María Autrán Gómez & Luciano A. Favorito, *The Social, Economic and Sanitary Impact of COVID-19 Pandemic*, 46 INT'L BRAZ. J. UROLOGY (SUPPLEMENT ISSUE 1) 3 (2020), https://doi.org/10.1590/S1677-5538.IBJU.2020.S1ED2. As pointed out by these authors, "[j]ust three months into lockdown, 10 months of discontinuation of Tuberculosis treatment in Third World countries will follow, equivalent to approximately 1,4000,000 deaths between 2020-2025." *Id.* at 3.

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Suspending intellectual property rights in times of pandemic will help developing countries to focus not only on their COVID-19 vaccination programs but also on diseases specific to African countries such as tuberculosis or malaria. The United States decided, for example, to support a temporary suspension of vaccine patents.[27] However, many states and international organizations are not willing to waive IP rights—even on a temporary basis—in order to combat the pandemic. They argue that suspending the IP rights of COVID-19 vaccines will dissuade pharmaceutical companies to pursue their efforts in terms of research and development. The European Union (hereinafter "EU"), Germany, Japan and Switzerland are examples of opponents to this idea.[28] Some authors also consider that suspending IP rights should not be encouraged, they believe that pharmaceutical companies are already cooperating and giving access to their vaccines.[29] Here, one can refer to compulsory licensing of pharmaceuticals under the TRIPS Agreement signed in Marrakech in 1994 following the Uruguay Round.[30] WTO Members may indeed allow pharmaceutical firms—located, for instance, in developing countries—to produce a patented product or process without the consent of the patent owner or otherwise using the patent-protected invention itself. Compulsory licensing of pharmaceuticals has been agreed on by WTO Members in 1994. This mechanism is explicitly specified in the TRIPS Agreement. Here, developed countries may adopt such compulsory licensing under the TRIPS Agreement as the generic copy of COVID-19 vaccines will be produced mainly for the domestic markets of developing countries and not for export. The Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licenses, and to determine what constitutes a national emergency. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory

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[27] Biden's administration decided to back this proposal to temporarily suspend the TRIPS Agreement, one of the WTO Covered Agreements. *See* Thomas Kaplan et al., *Taking 'Extraordinary Measures,' Biden Backs Suspending Patents on Vaccines*, N.Y. TIMES (May 5, 2021), https://www.nytimes.com/2021/05/05/us/politics/biden-covid-vaccine-patents.html.

[28] Rimmer, *supra* note 17, at 8.

[29] Rachel Silverman, *Featured Responses* to *Would Exempting COVID-19 Vaccines from Intellectual Property Rights Improve Global Access and Equity?*, CTR. GLOB. DEV., https://www.cgdev.org/debate/would-exempting-covid-19-vaccines-intellectual-property-rights-improve-global-access (last visited Feb. 19, 2022). See Q&A: Rachel Silverman, Research Associate at the CGD believes that there is no need to suspend intellectual property (IP) rights. This author cites the example of AstraZeneca which signed an agreement with CEPI, Gavi and the Serum Institute of India to "bring vaccine to low-and-middle income countries and beyond," 4 June 2020. *AstraZeneca Takes Next Steps Towards Broad and Equitable Access to Oxford University's Potential COVID-19 Vaccine*, ASTRAZENECA (June 4, 2020), https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html.

[30] *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Feb. 19, 2022).

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licensing. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licenses, and to determine what constitutes a national emergency. In the present time, the COVID-19 pandemic can be considered as a clear illustration of situations of national emergency. However, as pointed out by some authors the current legal framework of IP rights contained in the WTO Agreements is limited and needs to be improved. Indeed, some authors note that: "[t]he crisis further demonstrates the failure of high-income countries (HICs) to realize the promise they made at the time of the TRIPS negotiations in 1994, that by agreeing to the terms of TRIPS, lower and middle-income countries (LMICs) would benefit from technology transfer and the building of productive capacity."[31] When analyzing data, the total number of COVID-19 vaccine doses produced by developing countries is not significant. Only South Africa and India are listed among the countries producing COVID-19 vaccines.[32] As of March 2021, South Africa only produced 160,000 doses and India 42 million doses. However, Africa is undoubtedly underserved by COVID-19 vaccines. As noted by an author, "17.4[%] of the world population lives [in Africa], yet less than 3[%] of coronavirus vaccine doses have been given out in Africa."[33] By comparison, with a share of 5.7% of world population, Europe has a share of 8.5% of COVID-19 vaccine doses given in the world as of 25 October 2021.[34] This situation is particularly alarming and efforts have to be made by the international community: negotiations under the auspices of the WTO should be initiated and accelerated to create a legal obligation upon developed countries to be forced to grant licensing of pharmaceuticals to other members in times of pandemic. The adequate legal tools already exist: the TRIPS Agreement signed in 1994. WTO members can only agree that the COVID-19 global health crisis impacted massively the world economy.[35] Indeed, health and international trade are interconnected, the world economy will not recover if more than half of the world population cannot be vaccinated and protected.

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[31] Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic* 2 (London Sch. Econ. & Pol. Sci. L. Dep't, LSE L., Soc'y & Econ. Working Paper No. 06/2021, 2021).

[32] *See* chart elaborated by Statista: *The Countries Dominating Covid-19 Vaccine Production*, STATISTA (Mar. 23, 2021), https://www.statista.com/chart/24492/total-covid-19-vaccine-production-by-country/.

[33] Katharina Buchholz, *The Global Vaccine Imbalance*, STATISTA (Oct. 26, 2021), https://www.statista.com/chart/26055/share-of-vaccine-doses-covid-19-share-of-world-population/.

[34] *Id.*

[35] M. Szmigiera, *Impact of the Coronavirus Pandemic on the Global Economy - Statistics & Facts*, STATISTA (Feb. 21, 2022), https://www.statista.com/topics/6139/covid-19-impact-on-the-global-economy/#dossierKeyfigures. According to economists, "most major economies will lose at least 2.9[%] of their gross domestic product (GDP) over 2020."

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III. THE GENERAL OBLIGATION OF COOPERATION WITH THE WHO UNDER THE UN CHARTER REGARDING HEALTH MATTERS

Under the UN Charter, Members have a legally binding obligation to cooperate in matters representing a threat to international peace and security but also to the development of peaceful interstate relations, especially in the field of economic and social matters.[36] This duty of cooperation is at the core of international law. Some authors argue that such obligation can be assimilated to a hard law principle of international law.[37] Cooperation in the field of global health crisis such as the COVID-19 pandemic is a clear illustration. Therefore, the international community has an obligation to cooperate under the auspices of the UN, the WHO or the WTO. Research and development of medicines and vaccines, support to developing countries through compulsory licensing of pharmaceuticals, and technology transfers should become mechanisms to be implemented automatically by Member States of the WHO and WTO. Traditionally, the general duty to cooperate under the UN Charter applies in all situations that may threaten international peace and security. Our postulation is that such a duty to cooperate should necessarily be transposed into the field of international health law and be implemented in situations of global public health crisis such as the COVID-19 pandemic. Coordinated actions between the General Assembly of the UN and both WTO and WHO could easily be implemented in order to conduct a global answer through what is a hard law principle, namely the duty to cooperate. Here, both WTO and WHO will guide and ensure that states members do comply with their obligations such as implementing waivers and suspension of IP rights and give access to essential medicines and vaccines to developing countries. To this effect, the UN General Assembly may adopt a new Resolution and refer to the general duty to cooperate in health matters and especially global public health crisis and call for a coordinated answer that will be led by the WHO. Efforts to modify the TRIPS Agreements and the WHO IHR shall continue as they will create new obligations for states and create a truly global response.

To support such position, research and traditional concepts demonstrate that the obligation to cooperate is hard law in international water law.[38] This

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[36] *United Nations Charter, Chapter IX: International Economic and Social Cooperation*, UNITED NATIONS, https://www.un.org/en/about-us/un-charter/chapter-9 (last visited Feb. 25, 2022). (Article 56: "All Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55.")

[37] *See generally* Jost Delbrück, *Coexistence, Cooperation and Solidarity in International Law. The International Obligation to Cooperate–An Empty Shell or a Hard Law Principle of International Law?–A Critical Look at a Much Debated Paradigm of Modern International Law*, *in* COEXISTENCE, COOPERATION AND SOLIDARITY: LIBER AMICORUM RÜDIGER WOLFRUM 1 (Holger P. Hestermeyer et al. eds., 2012).

[38] Nkechinyelu Patricia Oranye & Abimbola W. Aremu, *The Duty to Cooperate in State Interactions*

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obligation of cooperation can be transposed to health and economic matters. States shall cooperate actively in times of pandemic and allow an equitable and fair access to medicines developed such as COVID-19 vaccines. Moreover, vaccines and medicines developed to combat pandemics have to be classified as essential medicines by the WHO. The WTO will also supervise that States Parties to the TRIPS Agreement are actively cooperating. As witnessed today, the TRIPS Agreement in its current form does not create legally binding obligations and States Parties can interpret the provisions relating to compulsory licensing of pharmaceuticals and technology transfers to firms located in developing countries, for instance, in a way that dilutes their legal effects. The existing international legal framework allows us to consider that both the WTO and the WHO can monitor the implementation of this general obligation of cooperation. Task forces and Public-Private Partnerships (hereinafter "PPPs") have been created to tackle the pandemic of COVID-19, what is needed now is a greater compliance with the general obligation to cooperate by states. In the present time, it is agreed that the end of the pandemic will only be possible if states cooperate on a larger scale.[39]

Different formal mechanisms of international cooperation have been created but they all failed due to a lack of effective cooperation. These initiatives were ambitious as they gathered more than two-thirds of states. A few mechanisms implemented by the WHO to combat the pandemic failed: COVAX[40] and Gavi, the Vaccine Alliance.[41] COVAX has been initially launched in April 2020 in order to supply COVID-19 vaccines equally among states, especially developing countries. Coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, COVAX was supposed to achieve its mission to provide vaccines to all states by acting as a platform that will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing. But COVAX failed to meet its expectations. As noted by an author, "[t]he original notion of a global vaccine hub more or less collapsed, and COVAX ended up using a traditional aid-financed approach, which has left lower-income countries wholly at the mercy of wealthy nations and profit-driven companies."[42]

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for the Sustainable Use of International Watercourses, SPRINGER LINK (Oct. 20, 2021), https://link.springer.com/article/10.1007/s43621-021-00055-6.

[39] *See generally* José Guimón & Rajneesh Narula, *Ending the COVID-19 Pandemic Requires More International Collaboration*, 63(5) RSCH.-TECH. MGMT. 38 (2020).

[40] *COVAX*, WHO, https://www.who.int/initiatives/act-accelerator/covax (last visited Feb. 18, 2022).

[41] *Covax*, GAVI, https://www.gavi.org/covax-facility (last visited Feb. 18, 2022).

[42] Ann Danaiya Usher, *A Beautiful Idea: How COVAX Has Fallen Short*, 397 LANCET 2322, 2325 (2021).

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Another example of the lack of interstate cooperation is illustrated by the COVID-19 Technology Access Pool (hereinafter "C-TAP").[43] The C-TAP was launched by WHO, in partnership with the Government of Costa Rica, under a global Solidarity Call to Action endorsed by nearly forty Member States. WHO C-TAP implementing partners include the Medicines Patent Pool (hereinafter "MPP"),[44] Open COVID Pledge, UN Technology Bank and Unitaid. This mechanism, too, suffered limitations owing to the interstate cooperation hinging on the goodwill of Member States. The first agreements have been signed very recently in October and November 2021. In October, MPP and MSD—the tradename of Merck & Co., Inc. Kenilworth NJ USA—signed a voluntary licensing agreement to facilitate affordable access to molnupiravir in 105 low-and middle-income countries.[45] On the 16th of November 2021, Pfizer and MPP announced the signing of a Licensing Agreement for a COVID-19 oral antiviral treatment candidate have expanded access across low- and middle-income countries.[46] Another licensing agreement was signed a few days later on the 23rd of November 2021 by the WHO COVID-19 Technology Access Pool.[47] These recent

[43] *WHO COVID-19 Technology Access Pool*, WHO, https://www.who.int/initiatives/covid-19-technology-access-pool (last visited Feb. 18, 2022).

[44] The Medicines Patent Pool [hereinafter MPP] is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low-and middle-income countries. *See* MPP, https://medicinespatentpool.org/ (last visited Feb. 25, 2022).

[45] *See* press release of the MPP: *The Medicines Patent Pool (MPP) and MSD Enter into License Agreement for Molnupiravir, an Investigational Oral Antiviral COVID-19 Medicine, to Increase Broad Access in Low- and Middle-Income Countries*, MPP (Oct. 27, 2021), https://medicinespatentpool.org/news-publications-post/mpp-msd-new-licence-announcement-molnupiravir. According to the MPP:

> Under the terms of the agreement, MPP, through the license granted by MSD, will be permitted to further license non-exclusive sublicences to manufacturers ("MPP Licence") and diversify the manufacturing base for the supply of quality-assured or WHO-prequalified molnupiravir to countries covered by the MPP Licence, subject to local regulatory authorization. MSD, Ridgeback Biotherapeutics and Emory University will not receive royalties for sales of molnupiravir under this agreement for as long as COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

[46] *See* press release of the MPP, *Pfizer and the Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low-and Middle-Income Countries*, MPP (Nov. 16, 2021), https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries.

[47] The WHO's COVID-19 Technology Access Pool (C-TAP) and MPP signed a licensing agreement with the Spanish National Research Council (CSIC). *See* WHO's press release, 23 November 2021: *WHO and MPP Announce the First Transparent, Global, Non-exclusive License for a COVID-19 Technology*, WHO (Nov. 23, 2021), https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology. According to the WHO:

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agreements demonstrate that formal and informal mechanisms of interstate cooperation can work efficiently but as we explained nothing will replace a legally binding instrument. The TRIPS Agreement could be the starting point for new international rules that may apply in times of global health crisis, moreover, temporary derogations are acceptable as the purpose here is to rely on pharmaceuticals firms and their expertise to provide medicines and vaccines—essential medicines—for low-and middle-income countries.

PPPs can also be key players in times of global pandemic. When used on a global scale by states and international organizations such as the WHO, PPPs will improve national healthcare systems and help public authorities to combat the spread of the COVID-19 and all its variants[48] by relying on the private sector's expertise and technologies. It is essential to involve the private sector as many states do not have the adequate financial, technical and human resources. As noted by Krijger et al., "[i]n early 2020, most countries were completely unprepared to carry out the massive systematic testing of symptomatic and asymptomatic individuals necessary to monitor and control spread of a virus undergoing community transmission."[49] These authors presented the creation of a PPP in the Netherlands that designed and developed in a timely manner a diagnostic platform for the COVID-19. Here, the Netherlands was able to conduct testing on a "massive scale."[50] This example demonstrates that the international community can cooperate efficiently but only through legally binding instruments in order to reach such achievements on a global scale.

Task forces have also been created at the international level regarding the development and deployment of vaccines. The most prevalent example is the Task Force on COVID-19 Vaccines, Therapeutics and Diagnostics for Developing Countries, established on the 30th of June 2021 by the heads of the International Monetary Fund, World Bank Group, WHO and the WTO. The goals and purposes are to accelerate access to COVID-19 vaccines, therapeutics and diagnostics by leveraging multilateral finance and trade solutions, particularly for low and middle-income countries.[51] All these

> The aim of the license is to facilitate the rapid manufacture and commercialization of CSIC's COVID-19 serological test worldwide. The agreement covers all related patents and the biological material necessary for manufacture of the test. CSIC will provide all know-how to MPP [Medicines Patent Pool] and/or to prospective licensees as well as training. The license will be royalty-free for low- and middle-income countries and will remain valid until the date the last patent expires.

[48] On 26 November 2021, WHO classified Omicron (B.1.1.529) as a SARS-CoV-2 Variant of Concern. See WHO press release: *Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern*, WHO (Nov. 26, 2021), https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern.

[49] Peter H. L. Krijger et al., *A Public-Private Partnership Model for COVID-19 Diagnostics*, 39 NATURE BIOTECHNOLOGY 1182, 1182 (2021).

[50] *Id.*

[51] See institutional website of the Covid-19 Task Force: *Multilateral Leaders Task Force on Covid-*

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initiatives are laudable but they rely on states' goodwill to participate in such mechanisms. Indeed, the COVID-19 Task Force is simply "calling on countries to share at least 1 billion vaccine doses with developing countries during 2021."[52]

Some authors also studied the theory of global public goods and how it could be applied to COVID-19 vaccines to develop further international cooperation.[53] Indeed, the doctrine traditionally used to consider public health as a global public good, "with a particular emphasis on the control of infectious diseases."[54] Global public goods—essential medicines such as COVID-19 vaccines and materials—could be implemented in a legally binding treaty signed under the auspices of WHO. State members will have obligations to cooperate and assist each other in times of pandemic as the ultimate goal is to prevent any further global health crisis and to allow the world economy to recover.

IV. THE NECESSITY TO PROVIDE THE WHO WITH COERCIVE LEGAL MEANS TO ENSURE COMPLIANCE WITH INTERNATIONAL TREATIES AND THE INTERNATIONAL HEALTH REGULATIONS

Today, the WHO has no enforcement powers[55] and its inability to regulate this health crisis reflects the shortcomings of international law. Obviously, legal tools exist and written rules akin to codes of conduct allow states with gaps in their health regulations to adopt a number of international standards. However, this is only a mitigative measure subject to the goodwill of states. The limitations of the WHO have been addressed by researchers.[56] Moreover, the WHO has been criticized by commentators for its "rather restrained role in creating new norms under its Constitution."[57] Despite the fact that the WHO has a recognized expertise and a constitutional mandate to tackle pandemics and global health crises, it only provides soft rules such as guidelines and recommendations to state members. As noted by Gostin et

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19 Vaccines, Therapeutics, and Diagnostics, TASK FORCE ON COVID-19 VACCINES, https://www.covid19taskforce.com/en/programs/task-force-on-covid-19-vaccines (last visited Feb. 18, 2022).

[52] *Id.*

[53] *See generally* Gordon Brown & Daniel Susskind, *International Cooperation During the COVID-19 Pandemic*, 36 OXFORD REV. ECON. POL'Y (SUPPLEMENT ISSUE 1) S64 (2020).

[54] *Id.* at S65-66. International cooperation should allow states to facilitate research and development of new medicines and their equal access.

[55] Armin von Bogdandy & Pedro A. Villarreal, *International Law on Pandemic Response: A First Stocktaking in Light of the Coronavirus Crisis* 4-5 (Max Planck Inst. for Compar. Pub. L. & Int'l L., MPIL Research Paper Series No. 2020-07, 2020).

[56] *See generally* Youfa Wang et al., *Limitations of the Current World Health Organization Growth References for Children and Adolescents*, 27(4) FOOD & NUTRITION BULL. (SUPPLEMENT ISSUE) S175 (2006).

[57] von Bogdandy & Villarreal, *supra* note 55, at 6.

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al., "[t]he WHO's most salient normative activity has been to create 'soft' standards underpinned by science, ethics, and human rights. Although not binding, soft norms are influential, particularly at the national level where they can be incorporated into legislation, regulation, or guidelines."[58] In international law, soft rules are necessary as they allow the international community to reach a consensus on certain matters, and they simplify the adoption of a formal treaty, for example. However, strong answers are necessary in times of pandemic as many state members may decide not to actively cooperate with other members or international organizations. As discussed, vaccine nationalism and commercial tensions have increased such March 2020. This applies to both the WHO and the WTO. Consequently, the WHO should be granted a real normative power throughout a set of legally binding rules. The IHRs have been considered as a fundamental development in international law.[59] These regulations are an existing legal tool that can provide the WHO outstanding attributions in times of pandemic. The current version of the WHO IHR entered into force on 15 June 2007.[60] Article 2 WHO IHR, which is related to purposes and scope of the WHO—one of the most important provisions—states that "the purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."[61] It is also worth referring to Part II of the WHO IHR related to Information and Public Health Response, especially Articles 12[62] and 13.[63] These provisions give important powers to the WHO but there are no enforcement powers in

[58] Lawrence O. Gostin et al., *The Normative Authority of the World Health Organization*, 129(7) PUB. HEALTH 854, 855 (2015).

[59] *See generally* David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34(1) J.L. MED. & ETHICS 85 (2006).

[60] WHO, INTERNATIONAL HEALTH REGULATIONS (2005) (2d ed. 2008).

[61] WHO, *supra* note 10, at 1.

[62] *Id.* at 14. Article 12 *Determination of a public health emergency of international concern* states that: "1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations."

[63] *Id.* at 15. Article 13 *Public health response* states that:

> 1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.

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situations where WHO members refuse to cooperate nor coercive measures that can be taken against such states.

The same applies to the WTO and the TRIPS Agreement for which a revision is possible. As mentioned previously, the TRIPS Agreement should be amended and revised to take into consideration pandemics and allow waivers of IP rights for developing countries. In October 2020, India and South Africa co-authored a proposal[64] requesting that certain obligations in the TRIPS Agreement be waived with respect to the prevention, containment or treatment of COVID-19. Developed countries such as the United States, Japan or Australia refused at that time to engage in discussions but in May 2021, the United States President, Joseph Biden, accepted to initiate discussions on this matter.[65] A few weeks later, on 21 May 2021, a few WTO members—including India and South Africa—issued a new proposal requesting that certain obligations in the TRIPS Agreement "be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19."[66]

WTO members would not be obligated to provide IP protections relating to copyright, industrial designs, patents and protections of undisclosed information with respect to any of the listed health products and technology for an initial period of three years. The proposed waiver would give developing countries the ability to domestically produce these products where they have the capacity to do so. It would also not be possible for WTO members to challenge decisions of other members through the WTO's dispute settlement system in situations where such decisions are in accordance with the proposed waiver. The proposed waiver faces strong resistance from developed countries. Some of them argue that developing countries will not be able to produce COVID-19 vaccines as they do not have the necessary facilities. Such argument is invalid since a few developing countries are handling the pandemic in efficient ways. For instance,

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[64] *See* Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa*, WTO Doc. IP/C/W/669 (Oct. 2, 2020).

[65] *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, U.S. TRADE REPRESENTATIVE (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases /2021/may/statement-ambassado r-katherine-tai-covid-19-trips-waiver.

[66] *See* Council for Trade-Related Aspects of Intell. Prop. Rts., *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text, Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the Ldc Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe*, at 3, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

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Morocco[67] and Egypt[68] concluded agreements with Chinese pharmaceutical companies to manufacture COVID-19 vaccines.[69]

In response to the proposed waiver submitted by developing countries on 25 May 2021, the EU submitted to the WTO General Council a communication on "Urgent trade policy responses to the COVID-19 crisis," [70] which called for limiting export restrictions, supporting the expansion of vaccine production, and facilitating the use of current compulsory licensing provisions in the TRIPS Agreement. The EU also submitted a communication[71] to the TRIPS Council which focused on the use of the compulsory licensing provisions, including a proposal to clarify that the requirement to negotiate with the right holder of the vaccine patent does not apply in urgent situations such as a pandemic. On 18 June 2021, the EU has also drafted a declaration on the "TRIPS Agreement and public health in the circumstances of a pandemic."[72] This declaration is to be adopted by the WTO General Council. The EU tried to address the effects of the pandemic in order to facilitate access to COVID-19 vaccines for instance but EU members refuse to allow manufacturers in other countries to breach IP rights in order to domestically produce vaccines. Developed countries want to protect their pharmaceutical industries but in the long term this position is not sustainable as the world economic recovery seems to be hampered with the appearance of new variants.

The TRIPS Council is still discussing different versions of proposals to the TRIPS Agreement as the positions differ largely regarding the waivers to

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[67] On 8 July 2021, the Organization of Islamic Cooperation (OIC) General Secretariat welcomed the launching of Morocco's Anti-COVID-19 Vaccine Manufacturing Project. *OIC General Secretariat Welcomes Launching of Morocco's Anti-COVID-19 Vaccine Manufacturing Project*, ORG. ISLAMIC COOP. (July 8, 2021), https://www.oic-oci.org/topic/?t_id=29279&t_ref=18442&lan=en.

[68] Abdel Latif Wahba, *Egypt to Begin Vaccine Supply to African Nations Within 2 Months*, BLOOMBERG (Sept. 23, 2021, 6: 29 PM), https://www.bloomberg.com/news/articles/2021-09-23/egypt-to-begin-vaccine-supply-to-african-nations-within-2-months.

[69] *Less Than 10% of African Countries to Hit Key COVID-19 Vaccination Goal*, WHO AFR. (Oct. 28, 2021), https://www.afro.who.int/news/less-10-african-countries-hit-key-covid-19-vaccination-goal, which states that:

> Just five African countries, less than 10% of Africa's 54 nations, are projected to hit the year-end target of fully vaccinating 40% of their people, unless efforts to accelerate the pace take off. This comes as the Region grapples to meet rising demand for essential vaccination commodities, such as syringes. Three African countries, Seychelles, Mauritius and Morocco, have already met the goal that was set in May by the World Health Assembly, the world's highest health policy-setting body.

[70] General Council, *Urgent Trade Policy Responses to the COVID-19 Crisis*, WTO Doc. WT/GC/231 (June 4, 2021).

[71] Council for Trade-Related Aspects of Intell. Prop. Rts., *Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property*, WTO Doc. IP/C/W/680 (June 4, 2021).

[72] Council for Trade-Related Aspects of Intell. Prop. Rts., *Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstance of a Pandemic*, WTO Doc. IP/C/W/681 (June 18, 2021).

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be implemented. At a meeting of the Council for TRIPS on 20 July 2021, WTO members agreed to continue consideration of the proposal for a temporary waiver of certain TRIPS obligations in response to COVID-19 and other related proposals. WTO members approved a status report which they tasked the chair to deliver at the General Council during its meeting held on 27-28 July 2021.[73] As mentioned, efforts should be made to modify the WHO IHR and adopt the temporary waiver to the TRIPS Agreements. Here, it is worthy to note that negotiations already started although this process will be difficult and may take time to reach a consensus within the WTO. However, this option should be encouraged and supported by all WTO members and key international organizations such as the UN and the WHO. Adopting the temporary waiver to the TRIPS Agreements will create a precedent in international law to implement global responses in times of pandemic. The international community has to realize that the COVID-19 pandemic is an unprecedented situation since the adoption of the UN Charter. Globalization also created a fundamental obligation for states to cooperate not only in situations threatening international peace and security but also international health. The international community acknowledged that there is a correlation between international economic law and development since decades.[74] The same should apply to international health law: economic and sustainable development cannot be achieved without a fair access to essential medicines and vaccines in times of pandemics. The duty to cooperate in health matters can be considered as a principle of international law and a fundamental component of the new international economic order. As discussions are still in progress, a vote is unlikely to take place in a near future unless WTO members realize that the current legal framework—the TRIPS Agreement and the WHO IHR—needs substantial amendments.

V. CONCLUSION

The pandemic showed us the limitations of international law, especially the role played by both the WHO and the WTO. These international organizations have been designed as key players in the regulation of public health—including global health crisis—and international trade with legal tools negotiated for decades. However, the international community has to acknowledge that a new paradigm is necessary in times of global pandemics. The WHO shall have the adequate coercive and normative powers to tackle issues related to an equal access to COVID-19 vaccines and all types of

[73] *TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19*, WTO (July 20, 2021), https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm.

[74] U.N. Conference on the Human Environment, *Declaration on the United Nations Conference on the Human Environment*, at 3-5, U.N. Doc. A/CONF.48/14/Rev.1 (June 5-16, 1972), https://documentsddsny.un.org/doc/UNDOC/GEN/NL7/300/05/IMG/NL730005.pdf?OpenElement.

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materials needed by developing countries. Moreover, WTO members have to recognize that temporary waivers on IP rights are a sustainable solution that will help the world economy to recover. Efforts have to be made and divergent interests can be surmounted. As stated by the WHO, "[b]lanket booster programmes are likely to prolong the pandemic, rather than ending it, by diverting supply to countries that already have high levels of vaccination coverage, giving the virus more opportunity to spread and mutate."[75] Therefore, isolated national health policies will only exacerbate vaccine inequity.

[75] *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 -22 December 2021*, WHO (Dec. 22, 2021), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---22-december-2021.

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