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ARTICLE

The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence

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Abstract

This article is a critical legal analysis of the proposed TRIPS waiver under World Trade Organization (WTO) law. It reviews the existing TRIPS flexibilities and the "August 2003 TRIPS waiver", highlighting the obstacles to achieving the goals of these legal instruments. It demonstrates that numerous critical TRIPS flexibilities, notably TRIPS Article 31*bis*, are ineffective, prompting some countries to submit a new waiver proposal to the WTO. It highlights several WTO rules that are also quite ambiguous. This paper argues that a WTO clarification might be an alternative to the new TRIPS waiver proposal if it is ultimately rejected due to a lack of consensus among WTO members. Finally, this article emphasises the importance of adopting a balanced approach that may simplify complicated TRIPS rules, decrease the risk of trade-based retaliation and improve collaboration in knowledge transfer and scaling up the manufacture of and access to lifesaving vaccines, pharmaceuticals and healthcare equipment.

Keywords: COVID-19; intellectual property rights; TRIPS waiver; WTO

I. Introduction

COVID-19 has had a devastating impact on human lives, livelihoods and economies all across the world, and there appears to be no immediate end in sight to this catastrophic pandemic. Global and national economies have been ravaged by the pandemic, which has also threatened public health systems and damaged the social fabric of the global economy. Curative vaccines have been developed at an enormous speed. However, the global distribution of COVID-19 vaccines, drugs, therapeutics and other medical technologies, such as diagnostic kits, medical masks, personal protective equipment and ventilators (henceforth "COVID-19 pharmaceuticals") has been asymmetric, resulting in the "vaccine divide"[1] and "vaccine nationalism",[2] which are now at the heart of global public health and national security concerns.

[1] C Quinn, "The Global Vaccine Divide Looms Large Ahead of G-7 Summit: While Most G-7 Nations Have Plenty of Vaccine Doses, Poorer Countries Still Go Without" (*Foreign Policy*, 9 June 2021) <https://foreignpolicy.com/2021/06/09/g7-vaccine-coronavirus-covid/> (last accessed 19 June 2021).

[2] C Kay and H Amin, "Vaccine Nationalism Threatens WHO's 2021 Goal of 2 Billion Doses" (*Bloomberg Quint*, 17 March 2021) <https://www.bloombergquint.com/coronavirus-outbreak/vaccine-nationalism-threatens-who-s-2021-goal-of-2-billion-doses> (last accessed 22 December 2021); Gavi, "The Vaccine Alliance, COVID-19 and the Cost of Vaccine Nationalism" (*Gavi*, 25 January 2021) <https://www.gavi.org/vaccineswork/covid-19-and-cost-vaccine-nationalism?gclid=CjwKCAjwuIWHBhBDEiwACXQYsRvE-G0hUyyteTOPoz5IeRiZ1vLhucLX53liEWiiovo8acwm8SGVdBoClB4QAvD_BwE> (last accessed 19 June 2021).

At the height of this global COVID-19 pandemic, several developing countries, led by India and South Africa, submitted a proposal to the World Trade Organization (WTO) in October 2020, requesting a temporary waiver of Sections 1, 4, 5 and 7 of Part II of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[3] relating to COVID-19 pharmaceuticals.[4] They appealed to the WTO membership to approve their proposal to relax these TRIPS rules in relation to "prevention, containment or treatment of COVID-19 ... until widespread vaccination is in place globally, and the majority of the world's population has developed immunity".[5] Subsequently, on 21 May 2021, a revised proposal was submitted to add more clarity to the proposal.[6] The revised text calls for the temporary suspension of copyrights, patent rights, industrial designs and the protection of undisclosed information related to COVID-19 pharmaceuticals for a period of three years from the date on which the decision is made, and this is subject to yearly review after that period.[7] It broadly refers to "health products and technologies ... for the prevention, containment, or treatment of COVID-19".[8] If such a waiver is granted, WTO members may decline to implement, apply and enforce copyrights, patent rights, industrial designs and the protection of undisclosed information pertaining to "diagnostics, therapeutics, vaccines, medical devices, personal protective equipment" used in relation to preventing, containing or treating COVID-19 – as well as "their materials or components, and their methods and means of manufacture".[9] It is worth noting that the revised text does not make any significant change to the original proposal. It is a simple explication of numerous categories of pharmaceutical products and the intellectual property rights (IPRs) linked to them. The sponsors of the waiver proposal claim that this TRIPS exemption is necessary to provide an efficient pandemic response and the rapid availability of COVID-19 pharmaceuticals across the globe.

Until recently, the majority of advanced economies have resisted the TRIPS waiver proposal at every TRIPS Council meeting. The proposal is vehemently opposed by the European Union (EU), Germany, the UK, Canada, Japan, Switzerland, Brazil and Singapore. They contended that existing tools such as voluntary licensing or the COVAX initiative, as well as existing TRIPS "flexibilities" such as compulsory licensing, are sufficient to solve the challenges, and that IPRs are not an obstacle to the increased production of medical requirements. Rather than IPRs protection, they highlighted obstacles such as export restrictions and the restricted availability of raw material, as well as a scarcity of manufacturing capacity, as having a more significant negative influence on the world's ability to boost vaccine production. They argued that even if and when such concerns were resolved, the sophisticated technological processes are not amenable to straightforward reproduction of pharmaceuticals and technologies without a significant amount of assistance from capable countries.

On 5 May 2021, however, the USA expressed its limited support for the TRIPS waiver proposal.[10] In an unanticipated statement, the Biden–Harris Administration stated that it

[3] WTO Agreement on Trade-Related Aspects Intellectual Property Rights (TRIPS), 15 April 1995, 33 I.L.M 81 (1994). The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 321 (1999), as amended on 23 January 2017.

[4] The 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 (2 October 2020).

[5] ibid, paras 12 and 13.

[6] Revised Waiver Proposal, WTO Doc. IP/C/W/669/Rev.1 (25 May 2021).

[7] ibid. Revised Proposal, paras 2 and 5.

[8] Operative Paragraph 1, Revised Waiver Proposal. IP/C/W/669/Rev.1.

[9] ibid, para 4.

[10] The original proposal includes all technologies for COVID-19 detection, prevention, treatment and response, but the US statement simply supports waiving IPRs in COVID-19 vaccines. See "Statement from Ambassador Katherine Tai on the COVID-19 TRIPS Waiver" (*USTR*, 5 May 2021), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> (last accessed 10 July 2021).

"supports the waiver of [intellectual property] protections for COVID-19 vaccines" and "will actively participate in text-based negotiations at the [WTO] needed to make that happen".[11] Since then, global perspectives on the waiver request have been rapidly changing. On 18 May 2021, China stated that it will support a TRIPS waiver to encourage affordable access to vaccines in developing countries.[12] Germany has explicitly stated its opposition to the TRIPS waiver, while the EU has stated its support for a "third-way" alternative[13] that includes "trade facilitation and disciplines on export restrictions", "support for production expansion" (including through voluntary licencing agreements) and "clarifying and simplifying the use of compulsory licences [under TRIPS] during crisis times".[14] The EU's plan is mainly based on compulsory licensing, and it promises to provide donations to developing countries via the World Health Organization (WHO) COVAX facility. The WTO membership is currently working on finding a consensus on the TRIPS waiver issue, which is very difficult to achieve.

In this context, it is critical to assess whether this new TRIPS waiver is essential from the perspective of WTO law. This paper examines the waiver proposal and evaluates the requirement of a new waiver from the standpoint of WTO law and practice. This study investigates and assesses the current TRIPS flexibility provisions that apply to pharmaceutical goods and undertakes a critical review to see how well the same provisions can be applied explicitly to COVID-19 pharmaceuticals. If the existing TRIPS flexibilities and waiver are sufficient, it is likely that this proposed waiver may not be required. If the current flexibilities are inadequate or existing waiver regulations and practices are not functional, the requested new waiver may be unavoidable. As the WTO is a consensus-based institution, a new TRIPS waiver is extremely unlikely to occur due to the requirement of a unanimous resolution at the WTO. In light of these circumstances, this article highlights the importance of striking a balance between the protection of IPRs and the preservation of global public health. It also suggests that a "WTO clarification" of some relevant but ambiguous provisions is essential, as this might persuade the WTO membership to make the existing TRIPS flexibilities and waiver more effective. Even if the proposed TRIPS waiver is not granted for a lack of consensus, the essence of maintaining the balance between IPRs and public health and eliminating ambiguities from the TRIPS flexibility provisions cannot be disregarded.

II. TRIPS waiver for pharmaceutical products: is it a new phenomenon at the WTO?

This idea to override TRIPS provisions is not new. This waiver proposal is reminiscent of heated deliberations at the WTO TRIPS Council in 2001 at the height of the HIV/AIDS crisis

[11] ibid, USTR statement.

[12] H Monicken, "Tai Talks TRIPS Waiver with Allies as China Gets Behind it, GOP Balks" (*Inside Health Policy*, 20 May 2021) <https://insidehealthpolicy.com/daily-news/tai-talks-trips-waiver-allies-china-gets-behind-it-gop-balks> (last accessed 10 July 2021).

[13] Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic (Communication from the European Union to the Council for TRIPS), WTO Doc IP/C/W/681 (18 June 2021).

[14] B Baschuk, "EU's Trade Response to Pandemic Stops Short of Vaccine IP Waiver" (*Bloomberg*, 3 June 2021) <https://www.bloomberg.com/news/articles/2021-06-03/eu-s-trade-response-to-pandemic-stops-short-of-vaccine-ip-waiver>; K Cullinan, "G20 Leaders Promise to Share More Vaccines While EU Digs in Against TRIPS Waiver" (*Health Policy Watch*, 21 May 2021) <https://healthpolicy-watch.news/g20-leaders-promise-to-share-more-vaccines-while-eu-digs-in-against-trips-waiver/>; European Commission, "Opening Statement by Executive Vice-President Valdis Dombrovskis at the European Parliament Plenary Debate on the Global COVID-19 Challenge" (*European Commission*, 19 May 2021) <https://ec.europa.eu/commission/commissioners/2019-2024/dombrovskis/announcements/opening-statement-executive-vice-president-valdis-dombrovskis-european-parliament-plenary-debate_en> (all last accessed 10 July 2021).

when Zimbabwe, as a representative of African countries, proposed to the WTO membership that the WTO could no longer ignore access to medicine as "an issue that was being actively debated outside the WTO, not within it".[15] Similarly to the current conflicting positions of WTO members, Zimbabwe's proposal to waive IPRs over patented HIV/AIDS medicines was at first rejected by most developed countries that claimed that such a measure would threaten the comprehensive patent protection system that is necessary to foster research and innovation. The EU proposed interpreting TRIPS flexibilities as narrowly as possible. It contended that TRIPS flexibilities contained in Article 31 may be invoked only in the event of a "national emergency and other situations of extreme urgency", as defined in Article 31(b).[16] Developing countries, on the other hand, claimed that Article 31 should be interpreted in a lenient way so that they could get the greatest advantage from compulsory licenses and parallel imports.[17] The developed and developing members thus presented two diametrically opposed views on the clarification of TRIPS Article 31, demonstrating the Doha Round's sharply pitched battle over TRIPS flexibilities.[18]

The outbreak of certain deadly diseases in Europe, North America and some parts of Asia at that time played a pivotal role in reaching a consensus and making TRIPS more flexible.[19] The outbreak of anthrax in the USA and Canada after the 9/11 attacks, the epidemic of foot-and-mouth disease in the UK and other parts of Europe and the threat of a global avian flu pandemic on the eve of the WTO's Hong Kong Ministerial meeting in late 2005 had attracted widespread public attention to the WTO rules regarding IPRs on pharmaceuticals. These incidents directly influenced WTO negotiations on intellectual property and played vital roles in shaping TRIPS's public health provisions. After lengthy and complex phases of negotiations, the Doha Ministerial Declaration finally stressed the necessity to address the implementation and interpretation of the TRIPS flexibility provisions addressing the calls of developing countries.[20] The debate ultimately led to the adoption of the Doha Declaration on TRIPS and Public Health (DDTPH) in November 2001.[21] On the basis of the DDTPH, a temporary waiver of TRIPS Article 31(f) was granted in August 2003. Finally, this temporary waiver became a permanent provision of TRIPS. The treaty was amended, and Article 31*bis* was incorporated permanently as an exception to Article 31(f). This amendment came into force in 2017.[22] The August 2003 waiver is now an essential part of TRIPS flexibilities within TRIPS Article 31*bis*.[23]

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

[16] D Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London, Sweet and Maxwell 2003) pp 32–43.

[17] ibid.

[18] ibid.

[19] For a brief history and background of the scenario, see SK Sell, "Intellectual Property and the Doha Development Agenda" in D Lee and R Wilkinson (eds), *WTO after Hong Kong: Progress in, and Prospects for, the Doha Development Agenda* (Abingdon-on-Thames, Routledge 2007) pp 57–61.

[20] Ministerial Declaration, WTO Doc WT/MIN(01)/DEC/1 (20 November 2001) (para 17) (Ministerial Conference, Fourth Session, Doha, 9–14 December 2001).

[21] Doha WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2, "Declaration on the TRIPS Agreement and Public Health (Adopted 14 November 2001)" (*WTO*, 20 November 2001) <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (last accessed 19 July 2021).

[22] WTO: 2017 News Item, "WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines" (*WTO*, 23 January 2017) <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> (last accessed 16 July 2021).

[23] W New, "It's Official: TRIPS Health Amendment In Effect, First Ever to a WTO Agreement" (*Intellectual Property Watch*, 23 January 2017) <https://www.ip-watch.org/2017/01/23/official-trips-health-amendment-effect-first-ever-wto-agreement/> (last accessed 12 July 2021).

III. Do the WTO members need another TRIPS waiver?

A simple answer to this question is a little more difficult to obtain because TRIPS waivers are contingent on the effectiveness of the current flexibilities. Whether or not a new TRIPS waiver is required is highly dependent on how WTO members treat the existing TRIPS flexibilities in their dealings with their global trading partners. If the current flexibilities continue to function appropriately in accordance with their primary objectives, a new waiver may not be required. TRIPS contains a number of flexibility provisions that are particularly important when it comes to IPRs pertaining to medicines, vaccines, diagnostics, therapeutics and other medical technologies, among other things. Most significantly, besides other flexibilities, it is important to determine whether the exception to TRIPS Article 31(f) or the Article 31*bis* waiver can satisfy the objectives of the proposed waiver call in the context of the COVID-19 pandemic. The relevance and effectiveness of these flexibilities in the current context are assessed in the following sections.

1. Transitional waiver flexibilities for least developed countries

TRIPS grants a transitional waiver to least developed countries (LDCs) to enable them to implement or enforce TRIPS rules while taking into account their unique needs and requirements, economic, budgetary and administrative restrictions and the need for flexibility to develop a sustainable technical base.[24] As per TRIPS Article 66 and paragraph 7 of the DDTPH, LDC members of the WTO are not required to comply with Articles 5 and 7 of Part II and paragraphs 8 and 9 of Article 70 of TRIPS, which relate to patents and the protection of undisclosed pharmaceutical test data, including any obligation to enforce rights arising from these provisions. In practice, this implies that until 1 January 2033, LDCs are not required to grant, implement, apply or enforce patents or test data protection on pharmaceutical goods.[25] As a result, LDCs have significantly more flexibility when it comes to the procurement of generic medicines and medical technologies.

2. Compulsory licensing and import–export flexibilities under TRIPS Article 31

Under TRIPS Article 31, the primary flexibilities related to IPRs over pharmaceutical products are mainly "compulsory license" and "government use for non-commercial purposes" (or any patent flexibility). Compulsory licensing is the process by which a national body grants a licence to a private party or government agency to exploit a patented innovation without the consent of the patent holder.[26] TRIPS Article 31 lays forth the conditions for these alternatives. All WTO members, irrespective of their economic status and level of socioeconomic development, can issue compulsory licences and avail other flexibilities within this category. Pharmaceutical products produced under compulsory licences and exporting them to third countries are the most contentious and pertinent issues in the context of the COVID-19 pandemic.

TRIPS Article 6 and paragraph 5(d) of the DDTPH provide the flexibility of "parallel import" of IPRs-protected pharmaceutical products. The term "parallel import" refers

[24] TRIPS, supra, note 3, Art 66.1.

[25] United Nations, "WTO Drugs Patent Waiver for LDCs Extended until 2033" (*United Nations*, 2021) <https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033/> (last accessed 20 July 2021).

[26] For multiple national and international perspectives on compulsory licensing, see, in general, RM Hilty and K-C Liu (eds), *Compulsory Licensing: Practical Experiences and Ways Forward* (Berlin, Springer-Verlag 2015); CM Correa, "Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents" (South Centre Research Paper No. 107) (April 2020).

to the fact that intellectual property owners in one country cannot legally prevent imports of their intellectual property-protected products offered for sale in another country. The underlying rationale for allowing parallel imports is that because the innovator has already been rewarded through the first sale of the product, its IPRs have been "exhausted", and thus there should not have any IPRs issues in subsequent resales. Parallel imports under Article 31*bis* enable WTO members that lack manufacturing capacity or have insufficient production capacity to import compulsory licence items from third countries at a very low price.[27] As per Articles 31(f) and 31*bis*, the authorisation of patent owners is not required for such imports.[28] WTO members may also waive compliance with national and international intellectual property law in the interests of research, innovation and national security.[29]

Some legal scholars believe that these existing TRIPS flexibilities, such as compulsory licencing, government use or authorisation for non-commercial use, research and national security exceptions, parallel imports and LDC waiver, are sufficient to ensure equal access to COVID-19 medical products globally, and therefore a new TRIPS waiver is unnecessary.[30] Their views and arguments apparently presume that existing TRIPS flexibilities are sufficient to facilitate the export, import or domestic manufacture of critical lifesaving pharmaceuticals. However, as the following scenarios demonstrate, invoking these flexibilities is inadequate and may not be a viable choice for the vast majority of low- and middle-income WTO members.

a. Scrutinising the TRIPS flexibilities in the context of COVID-19 pharmaceuticals

First and foremost, since the LDCs are not required to comply with the relevant TRIPS provisions until January 2033, the transitional waiver flexibility under TRIPS is entirely useless for LDCs in terms of the procurement and equitable access to COVID-19 pharmaceuticals. The relevant provisions of TRIPS are still not binding for them, and therefore the apprehensions about the infringement or overriding of IPRs do not apply to them. Apart from that, most LDCs do not have the capacity to manufacture COVID-19 pharmaceutical products, and therefore the flexibilities and regulations on compulsory licensing and security exclusions do not oblige them.

Second, with regard to compulsory licencing, highly industrialised nations with adequate scientific and infrastructural facilities to produce COVID-19 pharmaceuticals can conceivably invoke TRIPS Article 31 to issue compulsory licences to meet their domestic demands.[31] While most of these capable nations are not presently manufacturers or exporters of COVID-19 pharmaceuticals, they are capable of doing so via reverse engineering or other

[27] FM Abbot, "Parallel Trade in Pharmaceuticals: Trade Therapy for Market Distortions" in I Calboli and E Lee (eds), *Research Handbook on Intellectual Property Exhaustion and Parallel Imports* (Cheltenham, Edward Elgar 2016) pp 145–67.

[28] S Frankel and D Gervais, "International Intellectual Property Rules and Parallel Imports" in I Calboli and E Lee (eds), *Research Handbook on Intellectual Property Exhaustion and Parallel Imports* (Cheltenham, Edward Elgar 2016) pp 85–105.

[29] TRIPS, supra, note 3, Arts 31(b) and 73(b)(iii).

[30] J Bacchus, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines" (CATO Institute: Free Trade Bulletin Number 78, 16 December 2020); B Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review" (2021) 62 Virginia Journal of International Law Online 10–31.

[31] KEI, "COVID-19 Vaccine Manufacturing Capacity" (*Knowledge Ecology International*, 19 February 2021) <https://www.keionline.org/covid-19-vaccine-manufacturing-capacity> (last accessed 18 July 2021).

imitation technologies.[32] If and when they decide to proceed, these capable economies may also legally rely on or invoke another TRIPS flexibility under the Article 73(b)(iii) "national security defence" to undertake a broader range of measures, including involuntary licences that restrict IPRs.[33] The capacity to manufacture and reproduce COVID-19 pharmaceuticals is, therefore, the primary factor influencing the decision to invoke these flexibilities. From this perspective, the majority of LDCs and developing nations lack the necessary manufacturing capacity, and as a result they are unable to take advantage of the compulsory licencing provisions of TRIPS.[34] Due to their incapacity to manufacture pharmaceutical goods locally to combat COVID-19, TRIPS Articles 31(b) and 73(b)(iii) "national emergency" or "national security" flexibilities are worthless for them. In such a complex situation, only Article 31*bis* rules may benefit low- and middle-income countries by enabling them to import generic COVID-19 pharmaceuticals manufactured under compulsory licences.

Third, the imminent challenges surrounding the export of COVID-19 medicines manufactured under compulsory licences is another recurring problem under WTO law. WTO members encountered a similar challenge while exporting and importing HIV/AIDS medications to impoverished developing countries. TRIPS Article 31(f) was amended and Article 31*bis* was incorporated to alleviate the challenges experienced by developing countries that lacked pharmaceutical production capacity. The origins of this TRIPS amendment may be traced all the way back to paragraph 6 of the Doha Declaration on TRIPS and Public Health, which acknowledged that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement".[35] This statement also directed the WTO TRIPS Council to identify an expedited solution to this problem and to report to the WTO General Council by the end of 2002.[36] Finally, in 2003, the TRIPS Council passed a resolution entitled "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".[37] This decision introduced a temporary waiver mechanism for circumventing TRIPS Article 31(f), which generally prohibits exporting pharmaceuticals manufactured under compulsory licenses. In 2005, with the inclusion of Article 31*bis* into TRIPS, the temporary waiver mechanism became a permanent feature of the TRIPS Agreement. As a result of the effect of Article 31*bis*, generic pharmaceuticals manufactured under compulsory licences may now be exported to other developing countries with no or insufficient manufacturing capability. Nevertheless, the use of this waiver mechanism remains controversial due to its numerous complex and onerous

[32] L Winter, "Scientists Reverse Engineer mRNA Sequence of Moderna Vaccine" (*The Scientists*, 6 April 2021) <https://www.the-scientist.com/news-opinion/scientists-reverse-engineer-mrna-sequence-of-moderna-vaccine-68640>; Berthub, "Reverse Engineering the Source Code of the BioNTech/Pfizer SARS-CoV-2 Vaccine" (*Berthub*, 25 December 2020) <https://berthub.eu/articles/posts/reverse-engineering-source-code-of-the-biontech-pfizer-vaccine/>; D Jeong et al, "Assemblies of putative SARS-CoV2-spike-encoding mRNA sequences for vaccines BNT-162b2 and mRNA-1273" (*Github*, 14 April 2021) <https://github.com/NAalytics/Assemblies-of-putative-SARS-CoV2-spike-encoding-mRNA-sequences-for-vaccines-BNT-162b2-and-mRNA-1273/blob/main/Assemblies%20of%20putative%20SARS-CoV2-spike-encoding%20mRNA%20sequences%20for%20vaccines%20BNT-162b2%20and%20mRNA-1273.docx.pdf> (all last accessed 21 July 2021).

[33] F Abbott, "The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic", Global South Research Paper 116 (South Centre, August 2020), 22.

[34] UNCTAD, "COVID-19 Heightens Need for Pharmaceutical Production in Poor Countries" (*UNCTAD*, 27 May 2020) <https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries> (last accessed 16 March 2021).

[35] Doha Declaration on the TRIPS Agreement and Public Health, supra, note 21.

[36] ibid.

[37] WTO, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", WTO Doc. WT/L/540 (2 September 2003) (Decision of 30 August 2003).

criteria.[38] Due to the extreme complexity of the provision and the gratuitous non-cooperation of highly developed countries, Article 31*bis* flexibility has been used only once in the last eighteen years since it was granted in 2003.[39]

IV. The prospect of utilising TRIPS Article 31*bis* flexibility in COVID-19 cases

After a careful study of the current regulations and practices of Article 31*bis* in the context of the export and import of COVID-19 pharmaceuticals to low- and medium-income countries, the following observations can be made.

1. Stricter interpretation of the DDTPH

Article 1 of the DDTPH states that "[w]e recognise the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". By applying a strict literal interpretation of the DDTPH, it might be argued that COVID-19 pharmaceuticals may be excluded from the scope of Article 31*bis*. This is undesirable but not completely unexpected. Although an objective reading of the treaty may deliver a realistic meaning,[40] this sloppy interpretation by some members might be a nullification issue in any future WTO dispute. This tiny flaw can easily be fixed if the TRIPS Council releases a clarifying note on the matter. If "COVID-19" in the context of DDTPH becomes an issue in any future dispute, it should be considered holistically and applied to all contagious illnesses, both known and unknown to science. The USA pioneered this broad interpretation of TRIPS patent flexibilities when it initiated mass production of antibiotics to combat the anthrax crisis in the post-9/11 period. The USA and Canada threatened to invoke compulsory licences to manufacture generic medicines in order to provide a constant supply of affordable copies of the drug to the North American population. Bayer was the IPRs owner of ciprofloxacin, which was the primary medication used to treat anthrax. In the end, neither Canada nor the USA followed through on their threats, but both countries were able to negotiate substantial price reductions with Bayer.

WTO members should not spuriously interpret the scope of DDTPH by limiting its application to the treatment of infectious diseases specified explicitly in the DDTPH. It should be perceived as a whole and applied to all contagious diseases, both known and undiscovered. Furthermore, and perhaps more importantly, COVID-19 will almost definitely not be the last pandemic that the world will confront. The rise of factory farming practices, urbanisation and globalisation all enhance the likelihood that a novel virus or other microbes might leap from animals to humans and then spread swiftly around the world. The SARS, H1N1, MERS and Ebola epidemics occurred in the twenty-first century before the current pandemic. Everything we do and learn in the present crisis should be viewed through the lens of preparing for next time. Therefore, Article 1 of DDTPH must be interpreted to encompass all relevant drugs, vaccines, technical processes and equipment necessary to address public health crises caused not only by known diseases, but also by unknown potential diseases such as bird flu, anthrax, Ebola and COVID-19, which were

[38] United Nations, "Final Report, The United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies" (*United Nations*, 14 September 2016) <http://www.unsgaccessmeds.org/final-report> (last accessed 11 July 2021).

[39] Medicines Law and Policy, "TRIPS Flexibility Database" (16 February 2021) <http://tripsflexibilities.medicineslawandpolicy.org/> (last accessed 10 March 2021).

[40] As per Arts 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT), 1969 (23 May 1969) (Effective from 27 January 1980) United Nations, Treaty Series, vol 1155, p 331.

unknown on 20 November 2001, when it was accepted. In the absence of a broadly accepted directive, a WTO clarification could be helpful to avert potential disputes on the issue.

2. Past experience of using the "August 2003 TRIPS waiver"

The effectiveness and implementation of the August 2003 waiver had been a hotly debated issue among WTO members.[41] It took five years to utilise the "August 2003 TRIPS waiver" for the first time due to its inbuilt procedural and administrative complexities. Canada was the first country to take advantage of the waiver to export the first batch of HIV/AIDS generic drugs to Rwanda in 2008.[42] Apotex, the drug manufacturer involved in the Canadian export deal, said that it "will not go through the complicated and costly process again unless the regulations are amended".[43] This was never done. So far, this is the only application of the export flexibility provided by TRIPS Article 31*bis* since the WTO authorised it.[44]

Rwanda notified the WTO TRIPS Council in July 2007 of its intention to import 260,000 packs of TriAvir® from Apotex for HIV/AIDS treatment over a two-year period.[45] Based on this notification, Apotex applied for the compulsory licence in Canada in 2007, requesting permission to export 15,600,000 tablets, which was roughly equivalent to Rwanda's requirement for 260,000 packs.[46] The licence was granted, and in October 2007, Canada submitted its notification in accordance with the Canada Access to Medicines Regime (CAMR), which incorporated the paragraph 6 mechanism into national law.[47] The notification contained all of the information required by the Annex to Article 31*bis* paragraph 2(b), including the labelling and listing obligations.[48] Canada's first shipment of the drugs to Rwanda was delivered in October 2008, but the second shipment was not scheduled until the end of 2009.[49] It took nearly three years for Rwanda to receive the full shipment of drugs that it had requested under the 2003 TRIPS waiver framework established under Article 31*bis*. Many WTO members showed their extreme concerns about the August 2003 waiver's efficiency and effectiveness in the 2010 annual review of its implementation of Article 31*bis*.[50] When it comes to national emergencies or a global pandemic such as COVID-19, the time lost while waiting for drug deliveries will probably eliminate the option of using these pharmaceuticals in specific circumstances. This protracted process

[41] ICTSD, *TRIPS Council: Debate over Effectiveness of System for Access to Medicine* (Vol 14, No 38, 3 November 2010).

[42] Canada was the first country to export the first shipment of generic drugs to Rwanda in 2008. See ICTSD, "First Generic Drugs En Route to Africa under 5 Year Old WTO Deal" (2008) 12(31) Bridges Weekly Trade News Digest.

[43] ICTSD, "Lamy: Review Mechanism Can Improve Access to Medicine in Developing Countries" (2008) 12(42) Bridges Weekly Trade News Digest.

[44] Medicines Law and Policy, supra, note 39.

[45] Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO DOC. IP/N/9/RWA/1 (19 July 2007).

[46] WIPO, "Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade" (WTO, WIPO, 2020), 243 <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_628_2020.pdf> (last accessed 19 July 2020).

[47] ibid.

[48] Council for Trade-Related Aspects of Intellectual Property Rights, Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. IP/N/10/CAN/1 (8 October 2007).

[49] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Report to the General Council, WTO Doc. IP/C/53 (4 December 2009).

[50] Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Report to the General Council, WTO Doc. IP/C/57 (10 December 2010).

for exporting pharmaceutical products in global pandemic situations would be unacceptable and impractical. Due to the complex regulations and unexpectedly lengthy timing required to obtain the benefits of TRIPS Article 31*bis*, the system has not been used since, and its future as a functional and applicable component of TRIPS appears to be in doubt. This experience also demonstrates that exports of lifesaving generic pharmaceuticals made under TRIPS Article 31*bis* are practically ineffective. In such a situation, it is logical to assume that the sponsors of the current TRIPS waiver proposal might be motivated to resurrect this recurring issue due to the past lacklustre performance of generic drug export deals under Article 31*bis*.

As long as the same trend and trade practices continue, even if a new TRIPS waiver is adopted to facilitate faster and fair access to COVID-19 pharmaceuticals, it can be as fruitless as the August 2003 waiver. The old conundrum of poor peoples' access to lifesaving drugs may recur again and again in the WTO under various guises and disguises. The WTO membership should recognise and draw lessons from the ineffectiveness of the August 2003 TRIPS waiver. In certain cases, it may be preferable to reaffirm, guarantee, and clarify existing TRIPS flexibilities and exemptions rather than having a new but ineffective waiver mechanism. A fresh TRIPS waiver may not be essential if the WTO ensures guarantees through a clarification that for the sake of combating the current global pandemic, COVID-19 pharmaceuticals should not be treated in the same way as the generic drug exports in the past. Bolivia recently notified the WTO that it needed to import 15 million doses of a COVID-19 vaccine under TRIPS Article 31*bis*, or the August 2003 TRIPS waiver mechanism.[51] It remains to be seen how Bolivia's demand is addressed under current WTO rules.

3. Non-acceptance of Article 31bis by thirty-seven WTO members

The final resolution of the August 2003 waiver deal was also very complicated. While TRIPS Article 31(f) is just twenty words long, the amended provisions of Article 31*bis* are more than 2400 words in length, including all annexes and protocols, and they have been criticised for their complexity and arduous composition. One of the most contentious aspects of the accord was the definition of an "eligible importing member",[52] which enabled WTO members to declare themselves ineligible in some instances or in all cases. The implementation of Article 31*bis* became more complicated when thirty-seven WTO members, including the USA, Canada, Australia, Japan, the UK, Switzerland, the EU, France, Germany and Italy, deliberately opted out of the August 2003 waiver or TRIPS amendment that included Article 31*bis*.[53] They declared themselves "ineligible" to import pharmaceuticals manufactured in another country under compulsory licenses.[54]

By retaining their "opt-out" position, these highly developed countries are inflicting harm not only on themselves, but also on other countries that wish to benefit from compulsory licence incentives. Coronavirus has demonstrated that even the most industrialised and rich countries are unable to produce enough COVID-19 medicines to meet their own needs on a sustainable basis. If the only domestic production facility of an affluent country is located in a region that is under lockdown or if a huge proportion of its population is suddenly infected by the virus, the plant's supplies may be completely depleted. The invasive spread of the Delta variant and the resulting high mortality toll in India are

[51] WTO, "Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic" (*WTO*, 12 May 2021) <https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm> (last accessed 12 May 2021).

[52] Art 1(b), WTO Doc., Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Decision of 30 August 2003), WT/L/540 (2 September 2003).

[53] WTO, Paragraph 1(b) (footnote 3), Annex and Appendix to the TRIPS Agreement <https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm#fnt-3> (last accessed 10 June 2021).

[54] ibid.

stark evidence of this. A total export restriction on vaccines hardly saved the nation from the devastation of COVID-19.[55] The recent huge death tolls in the USA, UK, Germany, Italy and other EU countries are also eye-openers. In such a deadly pandemic situation, thirty-seven WTO members are constraining the market for COVID-19 vaccines, medications and diagnostics that can be manufactured in other countries via a compulsory licence. The "opt-out" choice may also prohibit industrialised nations from profiting from economies of scale, forcing them to raise prices or to discontinue manufacturing entirely. These "opt-out" nations should consider not just their own self-interest, but also the interests of their less affluent neighbours. Extending export and import facilitation for pharmaceutical items manufactured under compulsory licence may be the prudent course of action in this circumstance.

In a recent open letter to these thirty-seven countries, almost forty academic experts in health, law and international trade urged these developed countries to reconsider their decision to forgo compulsory licencing in order to expand access to COVID-19 pharmaceutical goods.[56] Until April 2021, the EU stuck to its original position.[57] Anthrax, foot-and-mouth disease, avian flu and post-9/11 realities had largely contributed to the adoption of the August 2003 waiver.[58] It remains to be seen how far the COVID-19 pandemic can persuade these nations to change their stance and embrace TRIPS Article 31*bis* rules.

4. TRIPS lacks clarification on two sets of national emergency defences

TRIPS Article 31(b) states that compulsory licenses are permitted "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". This provision is one of the main grounds of using "national emergency" as a defence to invoke the compulsory licensing mechanism.[59] Article 31*bis* expands the ambit of this mechanism by facilitating the export of the pharmaceutical products manufactured under such licences. While defining "eligible importing member" for the purpose of Article 31*bis*, TRIPS Annex states that "it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". This provision reaffirms the right to invoke national emergency and other defences contained in Article 31(b) while simultaneously emphasising the importance of using compulsory licencing measures to accomplish the purposes of Article 31*bis*.

TRIPS Article 73(b)(iii), on the other hand, permits the invocation of "national security" as a defence to utilise compulsory licences. It should be unequivocally admitted that the COVID-19 pandemic qualifies as an "emergency in international relations", and some experts have plainly analysed that WTO members may utilise this defence to issue compulsory licences to manufacture COVID-19 pharmaceuticals.[60] Through a literal and objective interpretation of the treaty,[61] it can be said that TRIPS Article 73(b)(iii) operates in close proximity to

[55] R Peters and D Prabhakar, "Export Restrictions Do Not Help Fight COVID-19" (*UNCTAD*, 11 June 2021) <https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19> (last accessed 14 June 2021).

[56] J Love, "Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured under Compulsory License in Another Country, under 31*bis* of TRIPS Agreement" (*Knowledge Ecology International*, 7 April 2020) <https://www.keionline.org/32707> (last accessed 26 December 2021).

[57] European Parliament, Answer given by Executive Vice-President Dombrovskis on behalf of the European Commission, Document No. E-000463/2021 (13 April 2021) <https://www.europarl.europa.eu/doceo/document/E-9-2021-000463-ASW_EN.pdf> (last accessed 14 May 2021).

[58] Sell, supra, note 19.

[59] TRIPS Art 73 also provides another ground to issue compulsory license.

[60] Abbott, supra, note 33.

[61] Arts 31 and 32, Vienna Convention on the Law of Treaties, 1969, supra, note 40.

the TRIPS Article 31(b) framework. Article 31(b) is complementary to Article 73(b)(iii), and therefore compulsory licences can be invoked in both cases. Nevertheless, it is critical to realise that it is still uncertain whether the vehicle or mechanism established by TRIPS Article 31*bis* can also be used to import COVID-19 pharmaceuticals manufactured under the TRIPS Article 73(b)(iii) defence. On this point, there exists a gap in WTO jurisprudence that demands clarification. The WTO Secretariat should respond to it.

WTO jurisprudence on the use of the "national security" defence and its nexus to international trade is still very narrow, like the measure itself. Nonetheless, it is gradually expanding. National security clauses in GATT Article XXI and TRIPS Article 73(b)(iii) have never been interpreted by the WTO dispute settlement bodies prior to the emergence of the "*Russia–Ukraine Traffic Transit*"[62] and "*Qatar–Saudi Arabia Protection of Intellectual Property Rights*"[63] disputes. In the *Russia–Ukraine* dispute, the panel's interpretation of Article XXI(b)(iii) established a methodological and analytical framework for determining the grounds for legitimate invocation of the TRIPS Article 73(b)(iii) defence.[64] This guideline was followed in the *Qatar–Saudi Arabia* dispute. According to the interpretation given by the panels in these two disputes, the measures implemented by a country under Article 73(b)(iii) must not be so "remote from, or unrelated to" the "emergency" that it is implausible that the country implemented the measures for the protection of its own "essential security interests arising out of the emergency".[65] In other words, it is unclear whether an exporting country can invoke Article 73(b)(iii) to justify the nullification of IPRs on its own territory in order to safeguard the essential security interests of the importing country (which lacks manufacturing capacity) through the export of generic pharmaceuticals to the latter. WTO law is not clear enough on whether Article 31*bis* permits WTO members to "mix and match" the mechanisms (eg when an exporting country invokes Article 31 and an ineligible importing country invokes Article 73, or vice versa) or whether both exporting and importing members would have to invoke compulsory licences on a common "national security" ground. It is currently unknown whether both exporting and importing countries should invoke compulsory licences concurrently on the same grounds or whether they can have different grounds. In addition, although they are believed to have a complementary relationship, there is no clearly established WTO jurisprudence on the interrelation between TRIPS Articles 73(b) and 31(b). This is another vital issue that deserves clarification from the WTO.

V. A balanced approach can create a more effective IPRs regime

There are numerous hurdles in the way of the approval of a fresh TRIPS waiver. The first immediate obstacle is the requirement to achieve the unanimous consent of 164 WTO members. Germany (together with Japan, Switzerland and others) still strongly opposes any waiver proposal. Even though the USA has expressed its support, it is only for a waiver with a considerably smaller scope than the sponsors' current plan. The USA has shifted its position and now intends to support a TRIPS waiver solely for "COVID-19 vaccines", not for other pharmaceuticals or medical technologies. The EU's "third-way" option, which avoids the need for a TRIPS waiver, is still on the table.[66]

[62] Russia – Measures Concerning Traffic in Transit, Panel Report (5 April 2019), WTO Doc. WT/DS512/R, paras 7.27–7.149.

[63] Saudi Arabia – Measures Concerning the Protection of Intellectual Property Right, Panel Report (16 June 2020) WTO Doc. WT/DS567/R.

[64] Saudi Arabia–Qatar IPRs dispute, paras 7.241–7.243.

[65] ibid, paras 7.242, 7.252, 7.271, 7.285 and 7.293.

[66] Supra, notes 13 and 14; E 't Hoen, "The Elephant in the Room at the WHO Executive Board" (*Medicine Law and Policy*, 22 January 2021) <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> (last accessed 10 February 2021).

Second, it can be predicted that, similar to the August 2003 waiver, even if a new TRIPS waiver of some degree were to be authorised by the WTO through text-based negotiations, major obstacles (eg payment of fair compensation for compulsory licenses, production capacity of mRNA vaccines) would still stand in the way of its effective implementation.[67] A handful countries with the potential to manufacture sophisticated pharmaceutical products currently have the technological capability to produce mRNA and adenovirus vaccines to international standards. This is due to the extremely centralised structure of the global pharmaceutical sector, which has made it difficult to transfer manufacturing technology to other countries, apart from to a small number of exceptions. One of the main obstacles to this transfer of technologies is the continued reluctance of profit-driven pharmaceutical companies to share their technological expertise more broadly with capable partners. Governments in high-income countries also support these non-sharing strategies. Pharmaceutical companies (and their supporters) argue that the wider distribution and production of mRNA vaccines are prohibitively difficult due to the complex and relatively new technology involved.[68] This is partially true. The virus's genetic sequence is now publicly available. Unquestionably, the safe transfer of this sequence to human bodies via mRNA or an inactivated adenovirus is a complicated and sophisticated process. Pharmaceutical corporations claim that this procedure should be handled only by capable hands. They assert that they are the only ones with this capability, and as a result they have acquired and continue to acquire enormous public funding[69] and windfall profits.[70] Nevertheless, none of them is willing to share their knowledge and, in particular, technologies that they consider to be trade secrets for wider public use, which would significantly expand the manufacturing and distribution capabilities beyond the borders of wealthy countries.

Given the enormous public funding already invested, the windfall profits already realised and the substantial public interest at stake, we can and should do more than simply support an intellectual property waiver to facilitate capacity building in low-income countries for pharmaceutical manufacturing and distribution. Vaccine manufacturers are essentially profiting as government contractors, and it is in the interests of the governments of developed countries for the pandemic to end globally, not just in their own countries. This will only be possible if low-income countries are able to manufacture and distribute vaccines.

There are instances of COVID-19 pharmaceuticals being manufactured outside of the Western world. The Serum Institute of India has been producing a significant amount of the AstraZeneca vaccine that is shipped to Europe on a regular basis. There is no reason why the Serum Institute and other manufacturers with emerging scientific and technological capacity could not produce significantly more for the developing world. The WHO's Coronavirus Treatment Acceleration Program (C-TAP) planned such an approach.[71]

[67] E Bonadio and F Fontanelli, "Push for COVID-19 Vaccine Patent Waiver Isn't a Panacea: But It Could Nudge Companies to Share" (*The Conversation*, 13 May 2021) <https://theconversation.com/push-for-covid-19-vaccine-patent-waiver-isnt-a-panacea-but-it-could-nudge-companies-to-share-160802> (last accessed 12 October 2021).

[68] KHN, "Can Pfizer and Moderna End the Pandemic by Sharing Their Vaccine Designs? It's Not that Simple" (*KHN*, 15 February 2021) <https://khn.org/news/article/can-pfizer-and-moderna-end-the-pandemic-by-sharing-their-vaccine-designs-its-not-that-simple/> (last accessed 30 November 2021).

[69] Scientific American, "For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork" (Scientific American, 18 November 2020) <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/> (last accessed 30 November 2021).

[70] J Kollewe, "From Pfizer to Moderna: Who's Making Billions from Covid-19 Vaccines?" (*The Guardian*, 6 March 2021) <https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines> (last accessed 30 November 2021).

[71] WHO, "How WHO C-TAP Works?" (*WHO*, 27 October 2020) <https://www.who.int/initiatives/covid-19-technology-access-pool/what-is-c-tap> (last accessed 30 November 2021).

Pfizer and Moderna, with the support of the Trump administration, resisted it.[72] Nevertheless, the latest outbreaks of the Delta and Omicron variants of the COVID-19 virus remind us again that COVID-19 is a global threat. It will not be eliminated locally until it is extinct globally. Therefore, the international community should provide incentives, expertise and assistance to low-income countries through transfer of technologies in order for them to radically increase their production capacity.

Third, since TRIPS ensures a minimum standard of intellectual property protection for WTO members, a TRIPS waiver would not change the higher level of IPRs protection. Each WTO member would be responsible for determining whether and how to amend their domestic intellectual property laws within the boundaries permitted by the TRIPS waiver, which would be done through their own national legislative processes. Certain countries may still choose to opt out of the new waiver in the same way they dejected the August 2003 waiver and Article 31*bis*. Due to the vast discretion granted under TRIPS and the discrepancies between different countries' intellectual property protection systems, it is doubtful that the new TRIPS waiver will be implemented effectively unless it is addressed with openness and considerable compassion. This complexity can be resolved through adopting a balanced approach, as mandated by TRIPS Articles 7 and 8.

TRIPS Article 7 states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and the balance of rights and obligations". Apart from that, Article 8 of the Agreement also states that WTO members "may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health ... provided that such measures are consistent with the provisions of this Agreement". Maintaining the balance between IPRs and public health was the main driving force behind granting the August 2003 TRIPS waiver. This waiver was an effort to recalibrate some imbalances in TRIPS. However, the functional ineffectiveness of the 2003 waiver (or perhaps the loopholes in the waiver mechanism) has motivated some countries to sponsor a new TRIPS waiver request in the context of the COVID-19 pandemic. The time has come once again to touch base and further recalibrate the balance[73] that is proclaimed in TRIPS Articles 7 and 8. These two provisions could reopen the door to a wide variety of policy options, such as authorising an effective TRIPS waiver and implementing health measures in the event of a global emergency like the COVID-19 pandemic. The WTO decision in the *Canada–Pharmaceuticals* dispute also supports maintaining a healthy balance between IPRs and public health and the recalibration of that equilibrium.[74]

To end the pandemic, WTO members require a variety of strategies that will allow them to share the advantages of existing COVID-19 vaccines, treatments and diagnostics as well as to facilitate more innovations in different regions of the world. Developed countries

[72] Los Angeles Times, "Vaccine Companies and the U.S. Government Snubbed WHO Initiative to Scale Up Global Manufacturing" (*Los Angeles Times*, 30 April, 2021) <https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing> (last accessed 1 December 2021).

[73] GB Dinwoodie and RC Dreyfuss, "Designing a Global Intellectual Property System Responsive to Change: The WTO, WIPO and Beyond" NYU School of Law, Public Law Research Paper No. 09-63 (2009); H Ullrich, J Drexl, M Lamping and RM Hilty (eds), *TRIPS Plus 20: From Trade Rules to Market Principles* (Berlin, Springer-Verlag 2016) p 302.

[74] Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R, adopted 7 April 2000, paras 7.23–7.26; Appellate Body Reports, Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WT/DS435 - 441/AB/R, adopted on 29 June 2020, paras 6.625, 6.626 and 6.658. If such a balance is maintained, it will not undermine the "research, development and innovation" as claimed by some authors (eg Mercurio, supra, note 30, pp 16, 17).

should stop or at least minimise the practice of vaccine nationalism. All export restrictions on COVID-19 products and technologies should be lifted to boost manufacturing and to facilitate the voluntary transfer of technologies. The transfer of technologies through voluntary licencing across developed and developing nations may play a critical role in reducing the risk of invoking compulsory licences or other coercive methods of circumventing IPRs.[75] Nevertheless, voluntary license agreements may or may not entail the transfer of manufacturing knowhow. IPRs owners often refuse to grant voluntary licenses unless in extremely restricted circumstances, and then only with rigorous criteria about the market supply and other restraints, which invariably exclude a large number of emerging developing economies.[76] A major challenge is that the voluntary licensing contracts are secret. Any nocturnal or clandestine approach to voluntary licenses must be deterred. The practice of a fair, transparent and balanced voluntary license can contribute to building a stronger IPRs regime.

The proposed waiver has the potential to have a greater impact and to provide more effectiveness to the current flexibilities. The adoption of a new TRIPS waiver or the creation of any such indirect pressure of overriding other IPRs regulations (ie invoking compulsory licences or other TRIPS flexibilities) also has the effect of reducing the freight of IPRs monopolies. For example, after the final approval of the August 2003 TRIPS waiver, some leading pharmaceutical companies such as Merck, Roche, Abbot Laboratories and Gilead negotiated with the Brazilian government and reduced their prices for AIDS drugs significantly.[77] The proposed waiver can therefore act like a catalyst that may categorically help in the structural rebalance of TRIPS. Millions of people in the world's poorest nations would benefit from the waiver because it would accelerate a fundamental rebalancing of monopolistic power on the part of Big Pharma, allowing the people from these nations to purchase and access essential health medications and vaccines.

It can be anticipated that the potential of a waiver would encourage efforts to convince pharmaceutical companies to engage in more voluntary arrangements and non-exclusive license agreements under flexible terms and conditions.[78] This will undoubtedly allow for the transfer of technology in a regulated and transparent manner. Companies from all around the world may benefit from such common knowledge without having to negotiate country-by-country and product-by-product license agreements. This would also diversify production locations.

VI. Conclusion

This study shows that if the WTO membership follows a constructive and balanced approach consistent with Articles 7 and 8 of TRIPS, then this may contribute to rebalancing TRIPS against monopolistic use of IPRs in this COVID-19 pandemic. It is understandable that, as a consensus-based organisation, reaching a consensus at the WTO on any issue is exceedingly difficult. Adopting a fresh TRIPS waiver is unquestionably a more challenging task than that of adopting the August 2003 TRIPS waiver. Amidst this difficult situation, if a new TRIPS waiver is approved, it could create a more balanced approach

[75] T Amin, "Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?" (*Oxfam*, 8 February 2007) <https://www.i-mak.org/wp-content/uploads/2017/10/Oxfam-VoluntaryLicensingResearchIMAKWebsite.pdf> (last accessed 15 January 2021).

[76] J Lexchin, "As U.S. Buys Up Remdesivir, 'Vaccine National-ism' Threatens Access to COVID-19 Treatments" (*The Conversation*, 5 July 2020) <https://theconversation.com/as-u-s-buys-up-remdesivir-vaccine-nationalism-threatens-access-to-covid-19-treatments-141952> (last accessed 5 July 2021).

[77] C Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford, Oxford University Press 2009) pp 303–20.

[78] Bonadio and Fontanelli, supra, note 67.

towards serving the interests of both IPRs owners and their consumers all over the world. A balanced approach could simplify complicated rules, reduce the risk of trade-based retaliation and litigation and pave the way for better collaboration in technology transfer and in scaling up the manufacturing of lifesaving vaccines, pharmaceuticals and healthcare products, especially in the world's poorest countries.

This article outlines some challenges that hinder the goals of existing TRIPS flexibilities and how these obstacles can be overcome. The past experience regarding the implementation of the August 2003 TRIPS waiver, the "opting out" of thirty-seven high-income countries from TRIPS Article 31*bis* implementation and the existing ambiguity regarding the export of COVID-19 pharmaceuticals produced under compulsory licences are the legal difficulties in ensuring fair access to COVID-19 pharmaceuticals.

If the existing TRIPS flexibilities and August 2003 TRIPS waiver are applied holistically to all known and unknown contagious diseases, the demand for a new TRIPS waiver may be significantly reduced. The August 2003 TRIPS waiver, the TRIPS amendment in Article 31*bis* and other flexibilities must cover the relevant drugs, vaccines, technical processes and equipment required to address public health crises caused not only by known diseases, but also by unknown potential diseases such as bird flu, anthrax, Ebola and COVID-19, which were unknown on 20 November 2001 when the DDTPH was accepted. It is expected that a WTO clarification of these points will surely help in alleviating any concerns.

Last but not least, it is evident that there is also no clear WTO jurisprudence on the interlinkage between the TRIPS Articles 31(b), 31*bis* and 73(b)(iii) national security defences. The use of the "national security" defence under TRIPS Article 73 to issue compulsory licenses and to export pharmaceuticals manufactured under such licenses in conformance with TRIPS Article 31*bis* is a new phenomenon. This complex situation has never occurred before, and it is also not expressly addressed within the current compulsory licensing regulations under the TRIPS–WTO regime. A precise "WTO legal explanation" or "WTO Explanatory Note" on these issues is therefore essential if the WTO membership is finally unable to reach a consensus on the proposed TRIPS waiver. The WTO clarification of these concerns might also support the WTO membership in avoiding the arduous road to consensus and adopting a fresh TRIPS waiver, be it temporary or permanent. It would undoubtedly mitigate the risk of future TRIPS-related disputes at the WTO.

Competing interests. The author declares none.

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