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NOTES AND COMMENTS

The TRIPS Waiver Decision at the World Trade Organization: Too Little Too Late!

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Abstract

The recently adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver decision at the World Trade Organization is a grossly inadequate and insincere response to the COVID-19 pandemic. This paper criticizes the TRIPS waiver for being faulty on several fronts such as: excluding COVID-19 diagnostics and therapeutics from its fold and focusing only on COVID-19 vaccines; restricting its coverage to only patents and leaving out other intellectual property rights; excluding developed countries that possess manufacturing and technological capability from being eligible exporters of COVID-19 vaccines; and its perplexing silence on the transfer of technology. It will have negligible impact on fighting the pandemic, sets an enfeebled example for the future, and is a classic case of "too little too late".

Keywords: TRIPS; WTO; Covid; Public Health; Waiver

Ever since the Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement, came into force as part of the World Trade Organization (WTO) package of agreements, the debate on its impact on peoples' right to health across the globe has been raging.[1] The TRIPS Agreement prescribes for application, protection, and enforcement of intellectual property (IP) and imposes an obligation on WTO member countries to ensure that their relevant laws adhere to its standards. On the one hand, since IP (intellectual property) protection acts as an incentive for spurring innovation,[2] it is justified to protect it through a network of national and international laws such as the TRIPS Agreement. On the other hand, it is argued that IP rights, especially patents, hinder the introduction of affordable vaccines and drugs in developing countries,[3] thus adversely affecting the right to health.

This inherent tension between protecting IP rights and ensuring accessibility of vaccines and drugs at affordable prices to people resurfaced as the world grappled with

[1] Sarah JOSEPH, *Blame it on the WTO: A Human Rights Critique*, 1st ed. (Oxford: Oxford University Press, 2011) at 241.

[2] Sunil KANWAR and Robert EVENSON, "Does Intellectual Property Protection Spur Technological Change" (2003) 55(2) Oxford Economic Papers 235.

[3] Joseph, *supra* note 1 at 217; Médecins Sans Frontières, "A Fair Shot for Vaccine Affordability" (September 2017), online: MSF <https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>.

the Coronavirus disease 2019 (COVID-19) – the worst pandemic in this century. The conviction that IP rights may become impediments to ratcheting up the production and supply of COVID-19 medical products led India and South Africa, in October 2020, to demand a comprehensive temporary waiver against certain provisions of the TRIPS Agreement on COVID-19 vaccines, drugs, and other therapeutics:[4] in short, COVID-19 medical products.[5] This demand was supported by large sections of civil society[6] and the academic community.[7] Proponents of the TRIPS waiver argue that patents may block access to drugs, the process of producing them, and copyrights, and industrial design may impinge on access to items like gloves, masks, or blueprints of ventilators,[8] and that protecting trade secrets and clinical trial data may hamper the development of vaccines and other medicines.[9]

After twenty months of intense negotiations at the WTO, a TRIPS waiver was adopted at the 12th ministerial meeting of the WTO in Geneva in June 2022,[10] as part of what is known as the "Geneva Package".[11] However, as this paper argues, the TRIPS waiver, which will remain in force for five years unless the WTO's General Council extends it,[12] is too shallow and miserably fails to remove the IP barriers to augment the production and supply of COVID-19 medical products.

We criticize the 2022 TRIPS waiver on the following counts. In Part I of this paper, we examine how the waiver decision is restricted to a temporary waiver of patent rights but

[4] Council for Trade-Related Aspects of Intellectual Property Rights, "Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Communication from India and South Africa (IP/C/W/669)" (2 October 2020), online: WTO <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>.

[5] *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 U.N.T.S. 3 (entered into force 1 January 1995) [WTO Agreement], arts. IX.3 and IX.4. Articles IX.3 and IX.4 establishing the WTO allow for waiving an obligation imposed on a WTO member country by the WTO Agreement or any other multilateral trade agreement given in Annexes 1A, 1B, or 1C in "exceptional circumstances", subject to the terms and conditions that shall govern the working of the waiver.

[6] Electronic Information for Libraries, "Statement on Copyright and Proposal of a Waiver from Certain Provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the Prevention, Containment and Treatment of COVID-19 (IP/C/W/669)" (22 March 2021), online: EFIL <https://www.eifl.net/system/files/resources/202103/civil-society-statement-on-copyright-and-proposed-trips-waiver.pdf>.

[7] The London School of Economics and Political Science, "Waive Intellectual Property Protection for COVID vaccines and related technologies urge over 100 IP academic experts" (13 July 2021), online: LSE <https://www.lse.ac.uk/News/Latest-news-from-LSE/2021/g-July-21/Waive-intellectual-property-protection-for-COVID-vaccines> (the first author is one of the signatories to the letter). See also Siva THAMBISETTY, Aisling MCMAHON, Luke MCDONAGH, Hyo Yoon KANG, and Graham DUTFIELD, "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic" *LSE Legal Studies Working Paper No. 06/2021* (2021), Online: SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737#>; Prabhash RANJAN, "The Case for Waiving Intellectual Property Protection for COVID-19 Vaccines" *ORF Issue Brief No. 456* (2021), online: ORF <https://www.orfonline.org/wp-content/uploads/2021/04/ORF_IssueBrief_456_TripsWaiver.pdf>. However, some contend that waiving the agreement is needless because countries can rely on the existing TRIPS flexibilities such as compulsory licensing and parallel importation to augment the supply of COVID-19 medical products. See Bryan MERCURIO, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review" (2021) 62 Virginia Journal of International Law Online 9.

[8] Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 4.

[9] David LEVINE, "COVID-19 should spark a Re-examination of Trade Secrets' Stranglehold on Information" *The Centre for Internet and Society* (10 July 2020), online: Stanford Law School, Centre for Internet and Society <http://cyberlaw.stanford.edu/publications/COVID-19-should-spark-reexamination-trade-secrets%E2%80%99-stranglehold-information>.

[10] *Ministerial Decision on The TRIPS Agreement*, WT/L/1141 (2022) [the TRIPS waiver].

[11] "MC12 outcomes" *World Trade Organization* (2022), online: WTO <https://www.wto.org/english/thewto_e/minist_e/mc12_e/mc12_e.htm#outcomes.

[12] The TRIPS waiver, *supra* note 10, para. 6.

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not other IP rights. Additionally, the patent waiver applies only to vaccines. It does not cover therapeutics and diagnostics. The waiver decision, as discussed in Part II of this paper, reiterates an already known flexibility given in Article 31 of the TRIPS Agreement to impose limitations on the patent holder's rights; namely, the issuance of compulsory licenses. This raises the question of whether the waiver decision can even be called a waiver.[13] Part II also discusses the decision's only genuine waivers from the requirements imposed by Articles 31(f) and (h). Apart from limiting patents, in Part III we discuss what the waiver says on other flexibilities such as the issue of trade secrets. In Part IV, we discuss the extremely narrow definition of eligible Members for this waiver, which excludes from its scope developed countries that have the manufacturing and technological capability to produce COVID-19 vaccines. Finally, in Part V we highlight how the decision is silent on technology transfer, thus making it very difficult for most developing countries to manufacture COVID-19 vaccines. Part VI offers concluding remarks.

I. The Waiver is Restricted to Limiting Patent Rights Under Article 28.1

Article 28.1 of the TRIPS agreement confers upon the patentee the right to exclude any third party from unauthorized product or process patent use without the former's consent. This unauthorized use can be in form of making, using, offering to sell, selling, or importing the patented product or product derived from a patented process. It also prohibits unauthorized direct use of the patented process.[14]

The waiver allows an eligible member country to impose limitations on the rights conferred by Article 28.1 of the TRIPS Agreement. Paragraph 1 of the TRIPS waiver provides:

> Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic ...

Thus, an eligible Member may restrict a patentee's rights under Article 28.1 of the TRIPS Agreement by authorizing the non-consensual use of a process or product patent required for the production and supply of COVID-19 vaccines (hereinafter "COVID-19 vaccine patents") to the extent necessary to address the pandemic.[15] Unlike the original TRIPS waiver proposal, made by India and South Africa in October 2020,[16] which talked of covering all the COVID-19 medical products including diagnostics and therapeutics, the 2022 waiver has a product restriction. It includes only COVID-19 vaccines and does not cover

[13] See also Bryan MERCURIO and Pratyush Nath UPRETI, "From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for COVID-19 Vaccines and Treatments" (2022) World Trade Review (First View).

[14] *Agreement on Trade Related Aspects of Intellectual Property Rights*, 15 April 1994, online: WTO <http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm> [TRIPS], art. 28.1, which provides: "A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing6 for these purposes that product; This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6. (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing".

[15] The TRIPS Waiver, *supra* note 10, para. 1.

[16] Council for Trade-Related Aspects of Intellectual Property Rights, *supra* note 4.

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diagnostics, therapeutics, and other COVID-19 medical products. This is a major handicap because vaccines, though important, are not the only tool to fight the virus. Medicines play an equally important role. For instance, the World Health Organization (WHO) has recommended a drug called baricitinib for treating severe or critical COVID-19 cases.[17] However, the generic version of baricitinib is not available in several countries because it is patented.[18]

Going forward, there is a possibility of the waiver being extended to therapeutics and diagnostics. Paragraph 8 of the 2022 waiver states, "no later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics". However, considering that it took this waiver almost two years to come into being, it does not inspire confidence in the fate of its application on other items, apart from vaccines. Moreover, the waiver also has an IP restriction; namely, it is restricted to waiving only patent rights whereas the original proposal was to address the challenges in accessing the COVID-19 medical products arising out of different IP rights such as copyright and industrial designs, etc., not just patents.

After discussing that the waiver is restricted to limiting patent rights for vaccines only, this paper now discusses the waiver's explanation of the exceptions to patent rights given in Article 31 of the TRIPS agreement.

II. Use of Article 31 of the Trips Agreement: Reiterating an Existing Flexibility

Article 31 of the TRIPS Agreement allows for other uses of the patent "without authorization of the right holder". In other words, Article 31 allows for non-consensual authorization for the use of the patent right such as the issuance of a compulsory license.[19] This is further supplemented by paragraph 5(b) of the Doha Declaration on TRIPS and Public Health, which states that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted". The grounds to issue a compulsory license fall under the bracket of either the "local working requirement"[20] or the "public interest". Of the two, public interest is a broader ground for claiming compulsory licenses as it includes grounds which are (but are not limited to): government use,[21] dependent or "blocking patents",[22] anti-competitive

[17] World Health Organization, "WHO recommends two new drugs to treat COVID-19" (14 January 2022), online: WHO <https://www.who.int/news/item/14-01-2022-who-recommends-two-new-drugs-to-treat-COVID-19#:~:text=The%20first%20drug%2C%20baricitinib%2C%20is,it%20is%20given%20with%20corticosteroids>.

[18] Médecins Sans Frontières, "MSF responds to latest WHO recommendation for a COVID-19 therapeutic, baricitinib" (14 January 2022), online: Reliefweb <https://reliefweb.int/report/world/msf-responds-latest-who-recommendation-COVID-19-therapeutic-baricitinib>.

[19] A compulsory license is an authorization given by the Member to a third party for the exploitation, i.e. production, importation, sale, or use of the patent product, without the consent of the patent owner to attain certain public policy objectives. See Carlos M CORREA and World Health Organization, "Guide for the Granting of Compulsory licenses and Government Use of Pharmaceutical Patents" *World Health Organization* (2009), online: WHO <https://apps.who.int/iris/handle/10665/70096> at 13.

[20] As per art. 5(A) of the Paris Convention, if a patentee does not "make" the patented invention in the territory of the country where it enjoys patent protection within three years of getting patent protection, then a compulsory license can be issued against it. Provisions of the Paris Convention have been incorporated into the TRIPS Agreement by art. 2(1).

[21] To permit the government or its contractors to make noncommercial public use of the patents without the consent of the right holders. See Wael ARMOUTI, "Grounds for Compulsory license with Selected Cases Granted for Pharmaceuticals" (2018) 26 Tulane Journal of International and Comparative Law 381 at 392.

[22] When the license is issued for use of subsequent patents without infringing an earlier patent. See Joseph A. YOSICK, "Compulsory Patent Licensing for Efficient Use of Inventions" (2001) 5 University of Illinois Law Review 1275 at 1293–4.

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practices,[23] demands to lower the drug prices,[24] and working requirements.[25] Thus, countries have ample regulatory leeway to decide on the issuance of compulsory licenses.

Normally, a proposed user who wishes to manufacture drugs under Article 31 will approach its government with a request for a compulsory license. After assessing each of such requests individually,[26] the government will issue the license. The 2022 TRIPS waiver recognizes the role of Article 31 to restrict the rights that a patent holder enjoys under Article 28.1. Paragraph 2 of the waiver provides:

> For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.

In other words, the TRIPS waiver states that the non-consensual use of the COVID-19 vaccine patent shall be in accordance with provisions of Article 31 of the TRIPS Agreement. But this is not a waiver. It is merely a reiteration of existing flexibility; namely, the compulsory license mechanism enshrined in Article 31. If recourse to Article 31 would have been sufficient to increase the accessibility of COVID-19 medical products, there would not have been a need to ask for a new and comprehensive TRIPS waiver.

An important characteristic of paragraph 2 of the TRIPS waiver is that it broadens the mode by which countries can make use of Article 31. It states that countries can allow non-consensual authorization of the COVID-19 vaccine patents by issuing an executive or administrative order, a judicial order, or an emergency decree, etc. It is not necessary to enact a legislative framework to implement the waiver. However, if an eligible Member wishes to implement the waiver by amending its existing patent laws or enacting a new patent law, the concerned country would be able to do so.

Article 31 lays down the conditions that a country has to comply with while issuing a compulsory license. One of the prerequisites is given in Article 31(b) whereby the proposed user must have made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions, and that such efforts had been unsuccessful within a reasonable time.[27] However, Article 31(b) also recognizes that, in case of a national emergency or other circumstances of extreme urgency (such as a pandemic of the scale of COVID-19) or in case of public non-commercial use, the requirement of seeking prior authorization may be waived.

Paragraph 3(a) of the 2022 TRIPS waiver provides that "an eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain

[23] Armouti, *supra* note 21 at 388.

[24] See generally Hilary WONG, "The Case for Compulsory Licensing during COVID-19" (2020) 10 (1) Journal of Global Health 1.

[25] Yosick, *supra* note 22 at 390.

[26] TRIPS, art. 31(a).

[27] Some other requirements given in art. 31 of the TRIPS Agreement for the issuance of compulsory licenses are: the scope and duration of the license must be limited only to the purpose for which they were authorized (art. 31(c)); these licenses should be non-exclusive (art. 31(d)); the licenses should be non-assignable (art. 31(e)); and if the patent owner is aggrieved then the decision of grant and remuneration governed by art. 31(h) is subjected to judicial review (art. 31(i)).

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an authorization from the right holder as set out in Article 31(b)". Again, this is not a waiver but a mere reiteration of the existing flexibility given in Article 31(b) of the TRIPS Agreement. As discussed, in a situation of national emergency, Article 31(b) does not mandate the requirement to negotiate with the patent holder and seek his/her authorization.

We now discuss two specific provisions in Article 31 that are mentioned in the 2022 TRIPS waiver. First, Article 31(f), which provides that the issuance of the compulsory license is predominantly for the supply of the domestic market. Second, Article 31(h), which states that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. Both these provisions lay down important requirements for the issuance of a compulsory license.

A. Article 31(f)

The quintessential part of the waiver is paragraph 3, which waives the obligation imposed by Article 31(f). Article 31(f) of the TRIPS Agreement, another important condition for the issuance of compulsory licenses, requires that any authorization for the issuance of compulsory licenses shall "predominantly" be for the domestic market of the country giving such authorization. Although the meaning of the word "predominantly" is not defined, it is largely understood that medicines produced under a compulsory license cannot be exported. It is important to bear in mind that the flexibility of compulsory license is useful only for those countries that possess manufacturing capability. Countries that lack manufacturing capability cannot make effective use of the compulsory license flexibility. This problem was recognized by the WTO in 2001, as evident in paragraph 6 of the Doha declaration on TRIPS and Public Health.[28] Paragraph 6 of the declaration states:

> we recognize 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. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Further to this, on 30 August 2003, the WTO's General Council adopted a decision that waived the obligations imposed by Articles 31(f) and 31(h) to allow countries to export drugs manufactured under a compulsory license to countries that lacked the manufacturing ability.[29] Finally, in 2005, the TRIPS agreement was amended, which took effect on 23 January 2017,[30] to include Article 31*bis*, thereby making the 2003 decision permanent.

However, Article 31*bis* has not solved the problem of countries with insufficient manufacturing ability to access drugs at affordable prices due to the cumbersome process that countries need to follow to import and export such medicines.[31] For instance, if a country issues a compulsory license to export drugs to a country that lacks manufacturing capability, the exporting country has to ensure that the medicines so manufactured are exported to that nation only; the medicines should be easily identifiable through different colours,

[28] *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (14 November 2001).

[29] *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1 (30 August 2003) [2003 August decision].

[30] Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), online: WTO <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm>.

[31] Oxfam International, "Patents versus Patients, Five years after the Doha Declaration" (November 2006), online: Oxfam <https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114562/bp95-patents-versus-patients-doha-q-and-a-141106-en.pdf?sequence=8&isAllowed=y>.

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or shape; and only the amount necessary to meet the requirements of the eligible importing country are manufactured; etc.[32] These procedural requirements act as deterrents for generic pharmaceutical manufacturers to produce medicines under a compulsory license for export because it disables the manufacturers from reaping the economies of scale.[33] This problem clearly surfaced when this system was put to use involving Rwanda and Canada[34] – the only instance of using this arrangement in the last nineteen years.

The TRIPS waiver attempts to overcome the problem posed by Article 31*bis*. The cardinal aspect of the TRIPS waiver is paragraph 3(b), which waives the condition imposed by Article 31(f). Paragraph 3(b) provides:

> an eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members...

Thus, the waiver allows an eligible Member to export any proportion of vaccines manufactured under a compulsory license to another eligible country. However, waiving the obligation imposed by Article 31(f) is subject to other requirements, which dent its efficacy. First, eligible Members are obligated by anti-diversion requirements, i.e. they are under an obligation to take all reasonable efforts to prevent the re-exportation of COVID-19 vaccines that they have imported.[35] Footnote 3 of the TRIPS waiver provides that only in exceptional circumstances, such as for humanitarian and not-for-profit purposes, an eligible country may re-export COVID-19 vaccines. Second, eligible Members who issued compulsory licenses to export COVID-19 vaccine patents under the TRIPS waiver should ensure the availability of effective legal means to proscribe the importation of COVID-19 vaccine patents back into their territories.[36] Third, paragraph 5 of the TRIPS waiver requires that eligible countries who issue a compulsory license for COVID-19 vaccines have to notify the WTO about the entity that has been authorized to produce the product, the quantities permitted, the duration, and the list of countries to which the vaccines are being exported.

In sum, all these procedural requirements will increase transaction costs and may deter countries from using the system. Moreover, it is difficult to fathom why restrictions have been imposed on the re-exportation of the COVID-19 vaccines when the very purpose of having the waiver is to increase the accessibility of COVID-19 vaccines.

B. Article 31(h)

As mentioned, an important requirement for the issuance of a compulsory license is the payment of adequate remuneration to the patent holder. In the case of the COVID-19 pandemic, if we look at the profits that the vaccine manufacturers have already reaped in the

[32] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health,* WT/L/540 and Corr.1 (2003).

[33] See Holger P. HESTERMEYER, "Canadian-Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" *American Society of International Law* (10 December 2007), online: American Society of International Law <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>; Carlos M CORREA, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?" (2019), online: South Centre <https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf>.

[34] Hestermeyer, *supra* note 33. See also Correa, *supra* note 33.

[35] The TRIPS waiver, *supra* note 10 at para. 3(c).

[36] *Ibid*.

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form of pre-purchase agreements[37] and limited spending in Research and Development (R&D), which was, instead, covered by grants from different governments,[38] remuneration to the vaccine manufacturer should not have been an issue at all. Nonetheless, it remains a sticky issue and thus the TRIPS waiver clarifies the principles governing the country's obligation to fix remuneration for the patentee while allowing unauthorized use of the patent.

As a background, voluntary licensing entails negotiations between a patentee and an interested party whereby they decide on the royalty that the patentee shall receive as compensation to share its patent with the latter. However, in times of crisis and subject to the conditions of Article 31, a country fixes remuneration under Article 31(h), which is paid to the patentee and takes into account the economic value of each authorization of the compulsory license.

However, as pointed out by Cynthia M. Ho, the TRIPS Agreement does not provide any further criteria to determine remuneration under Article 31(h), thus leaving it to the countries to decide the level of "adequate remuneration" at their own discretion.[39] Pragmatically speaking, full use of this discretion is a rare occurrence as developing countries may avoid aggressive compulsory licensing manoeuvres to remain in the "good books" of international corporations and avoid unilateral retaliation.[40] The TRIPS waiver under paragraph 3(d) comes to the aid of these countries because it provides clarification to the ambiguous Article 31(h) by stating that the determination of adequate remuneration under Article 31(h) may take into account the humanitarian and not-for-profit purpose of specific COVID-19 vaccine distribution programme and may take into consideration existing good practices.[41] In effect, this provision thus allows countries to use the flexibility under Article 31(h) a little more flexibly in the context of the COVID-19 vaccines. Apart from limiting patent rights, the TRIPS waiver also offers some other flexibilities, which we will discuss next.

III. Other Flexibilities

A noteworthy feature of the TRIPS waiver is that it clarifies Article 39.3 of the TRIPS Agreement, which obligates a country to protect undisclosed information such as clinical trial data and other know-how, and shall not impinge rapid approval for use of the COVID-19 vaccines.[42] Again, this is not a waiver but clarifies a safeguard that exists within Article 39.3.[43] Nonetheless, this clarification is important because the IP behind a drug is

[37] "New Study Shows Rich Country Shopping Spree for COVID-19 Vaccines Could Mean Fewer Vaccinations for Billions in Low-Income Countries" *Duke Global Health Innovation Centre* (2 November 2020), online: Duke Global Health Innovation Centre <https://dukeghic.org/wp-content/uploads/sites/20/2020/11/COVID19-Vax-Press-Release__28Oct2020-1.pdf>.

[38] Oliver J. WOUTERS, Kenneth C SHADLEN, Maximilian SALCHER-KONRAD, Andrew J POLLARD, Heidi J LARSON, Yot TEERAWATTANANON, and Mark JIT, "Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment" (2021) 397 (10278) The Lancet 1023 at 1025.

[39] Cynthia M. HO "Patent Breaking or Balancing: Separating Strands of Fact from Fiction Under TRIPS" (2009) 34 North Carolina Journal of International Law 371 at 407 and 409

[40] David SHORE, "Divergence and Convergence of Royalty Determinations between Compulsory Licensing under the TRIPS Agreement and Ongoing Royalties as an Equitable Remedy" (2020) 46(1) American Journal of Law and Medicine 56 at 69. See also Suerie MOON and Wolfgang HEIN, *Informal Norms in Global Governance* (Routledge, 2013) at 113–14 and 132–3.

[41] The TRIPS waiver, *supra* note 10 at para. 3(d). Instances of existing good practices cited in the Decision are WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020), and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO.

[42] *Ibid*., at para. 4.

[43] Mercurio and Upreti, *supra* note 13 at 7.

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not just limited to patents, it includes two other sets of information, making it a combined stack of three.[44] These three stacks are as follows. First, the disclosure made by the inventor before the Patent Office in a "clear and complete" manner indicating the best mode for carrying the invention on which patent is sought.[45] The intent behind this disclosure is to gain exclusive rights to sell and manufacture the drug resulting from the relevant product or process patent and, ultimately, cut competition, remove the risk of imitation, and recuperate the R&D costs, etc.[46] Second, clinical and pre-clinical trial data submitted by the manufacturer of the drug in the process of obtaining market approval before the drug regulatory authority.[47] Third, the sum of trade secrets and know-how. Specific undisclosed information such as formulae, which enjoys a commercial value, is referred to as a trade secret.[48] On the other hand, know-how refers to the less well-defined but commercially valuable ideas such as technical designs, instruction manuals, process control, quality control process, and technical training working practices.[49] Know-how is the broader term of the two, which includes trade secrets within its ambit but not the other way round.

IV. A Deeply Narrow Definition of Eligible Members

Another defining characteristic of the TRIPS waiver is the definition of an eligible Member, i.e. identifying which countries can make use of the waiver. Footnote 1 of the waiver states that all developing countries are eligible Members for the purpose of the waiver. Therefore, the Members who have declared themselves as developing countries under the WTO[50] are eligible to authorize the use of COVID-19 vaccine patents without the consent of their respective patentees.

However, this definition comes with an "opt-out" mechanism; the footnote further states that developing countries with the existing capacity to manufacture COVID-19 vaccines are "encouraged" to make a binding commitment not to avail themselves of the provisions of the waiver. This binding commitment could be statements made before the General Council, such as the statement made by China on 10 May 2022, declaring that it will not use the provisions of the agreed text.[51] With China's exit from the arrangement,

[44] Christopher GARRISON, "What is the 'know-how gap' problem and how might it impact scaling up production of COVID-19 related diagnostics, therapies and vaccines?" *Medicines Law and Policy* (16 December 2020), online: Medicines Law and Policy <https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-COVID-19-related-diagnostics-therapies-and-vaccines/>.

[45] TRIPS, art. 29.1.

[46] Richard POSNER and William LANDES, *The Economic Structure of Intellectual Property Law*, 1st ed. (Harvard University Press, 2003) at 294.

[47] "The information content of test data can be viewed (and regulated) at several levels: (i) as empirical information about the physical properties of chemical substances; (ii) as information that test data establish a substance as safe, acceptably non-toxic, sufficiently efficacious, etc.; (iii) as information that the substance is approved for use by a certain regulator on the basis of test data submitted." See Antony TAUBMAN, "The International Patent System and Biomedical Research: Reconciling Aspiration, Policy and Practice" (2008) 10(4) American Association of Pharmaceutical Scientists Journal 526.

[48] A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. See Michael RISCH, "Why do we have trade secrets?" (2007) 11 Marquette Intellectual Property Law Review 1 at 6.

[49] Garrison, *supra* note 44.

[50] "Who are the developing countries in the WTO?" *World Trade Organization* online: WTO <https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm>.

[51] "Members welcome Quad document as basis for text-based negotiations on pandemic IP response" *World Trade Organization* (10 May 2022), online: WTO <https://www.wto.org/english/news_e/news22_e/gc_10may22_e.htm>.

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the success of the waiver largely depends on a few other developing countries such as India, Iran, and Cuba who produce approved COVID-19 vaccines.[52] So far, there are no indications of India making use of this waiver. Despite pushing for a comprehensive waiver, India appears reluctant to enact administrative or legislative measures to do so.[53] Moreover, encouraging developing countries like India, which possesses COVID-19 vaccine manufacturing capacity, to opt out of the system is perplexing because it defeats the very purpose of increasing the production of COVID-19 vaccines needed to fight the pandemic in the countries that lack such capacity.[54]

Another major flaw in the definition of an eligible Member is that developed countries are excluded from the waiver, even for manufacturing COVID-19 vaccines and exporting them to developing countries. This is so even though developed countries have the manufacturing capability and technical prowess to produce COVID-19 vaccines. Thus, if the objective of the waiver is to increase the accessibility of COVID-19 vaccines, then both developed and developing countries should have been included as eligible exporters – even though the pool of eligible importers could have been restricted to only developing countries or countries that lack manufacturing capability.

The current arrangement of eligible Members in the TRIPS waiver is different from the waiver that was adopted in 2003, where the selection criteria was limited to eligible importing countries, i.e. countries that lacked the manufacturing capability.[55] However, upon request, any country developed or developing, was allowed to export medicines manufactured under a compulsory license. The same approach should have been followed in the 2022 waiver as well.

It is not just the restricted definition of eligible Members but also the silence on the transfer of technology that impedes the efficacy of the waiver decision – a point that we discuss next.

V. Silence on Technology Transfer

One of the justifications to have a TRIPS waiver in place was the uneven capacity of Members to manufacture sophisticated biologics. In the context of vaccines, it was once reported that some 80% of vaccines are manufactured by five pharmaceutical companies in the United States and Europe.[56] In light of this disparity, the need of the hour was to promote and incorporate sincere technology transfer provisions from the industry leaders to the ones in dire need of the same.

TRIPS, under Article 66.2, does prescribe for a voluntary technology transfer obligation, which the developed country Members have towards the Least Developed Countries (LDC) Members. The provision states that the Developed Members shall provide incentives to their enterprises and institutions for promoting and encouraging technology transfer to LDC Members. However, past practices show that this provision has rarely been utilized. The global shortage of vaccines during the pandemic further evidenced the imbalance

[52] Jeff CRAVEN, "COVID-19 Vaccine Tracker" *Regulatory Focus* (24 June 2022), online: Regulatory Focus <<https://www.raps.org/news-and-articles/news-articles/2020/3/COVID-19-vaccine-tracker>.

[53] Prabhash RANJAN and Praharsh GOUR, "Amend the Patents Act to execute TRIPS waiver" *Hindustan Times* (26 June 2022) online: Hindustan times <https://www.hindustantimes.com/opinion/amend-the-patents-act-to-execute-trips-waiver-101656255517110.html>.

[54] See also Mercurio and Upreti, *supra* note 13 at 14.

[55] 2003 August decision, *supra* note 29 at para. 2(a)(ii).

[56] Tara Kirk SELL, Daniel GASTFRIEND, Matthew WATSON, Crystal WATSON, Lauren RICHARDSON, Anita CICERO, Tom INGLESBY, and Nancy CONNELL, "Building the global vaccine manufacturing capacity needed to respond to pandemics" (2021) 39(12) Elsevier Public Health Emergency Collection 19.

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between vaccine suppliers and demanders.[57] Therefore, it was expected that once the TRIPS Waiver came into play it would address this imbalance and, perhaps, make an arrangement for some sort of mandatory technology transfer. However, the decision is starkly silent on it.

One way to look at the provisions of the waiver *vis-à-vis* technology transfer is that it inadvertently gives the eligible Member the prerogative to make erstwhile protected information concerning vaccines public by actively sharing the disclosure of the patentee with the interested parties and assisting them in increasing the output of the products. However, this benefit is surmised upon the assumption that the eligible Members with manufacturing capabilities will share the erstwhile protected information and the necessary know-how to manufacture COVID-19 vaccines with other eligible Members. Considering that only a handful of countries, such as India, have the requisite prowess to manufacture the COVID-19 vaccine, the whole burden of technology transfer that originally lay on the shoulders of the developed countries now lies upon these few eligible Members, i.e. the developing countries.

VI. Conclusion

The TRIPS waiver is a classic case of too little too late. It will be of negligible assistance to developing countries and to the LDCs in the fight against the worst pandemic in the last 100 years for the following reasons. First, the waiver is restricted to only limiting patent rights, not other IP rights such as trademarks and industrial designs. Consequently, it does not address the challenges posed by the IP regime as a whole in ensuring global access to COVID-19 medical products.

Second, the waiver covers only COVID-19 vaccines. It does not cover diagnostics and therapeutics. Due to the failure to include medicines that may be useful in treating COVID-19, the waiver does not go the full distance in being an effective response to the pandemic. Even in terms of waiving patent rights, the waiver is like old wine in a new bottle, it largely clarifies the existing flexibilities in the TRIPS Agreement.

Third, the waiver excludes developed countries from being eligible manufacturers and exporters of COVID-19 vaccines. Thus, the entire burden of providing COVID-19 vaccines falls on a few developing countries such as India, which, in turn, are encouraged to opt out of the system. Arguably the TRIPS waiver has been designed to help developing countries build their manufacturing, technological, and industrial capacity to produce COVID-19 vaccines by relieving them of the obligation to enforce patent rights for a temporary period.[58] However, this will be a time-consuming process. Moreover, the purpose of the TRIPS waiver is to provide an immediate and robust public health response to the pandemic, not to have long-term goals such as building the industrial capability of developing countries.

Fourth, the waiver does precious little in terms of the transfer of technology for vaccine production to countries that need it the most. In sum, the waiver is a huge letdown. The WTO has failed to respond effectively to the pandemic, thus strengthening the perception that corporate profits are more important than the public health of humanity.

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[57] See Victoria PILKINGTON, Sarai Mirjam KEESTRA and Andrew HILL, "Global COVID-19 Vaccine Inequity: Failures in the First Year of Distribution and Potential Solutions for the Future" Frontiers (7 March 2022), online: Frontiers <https://www.frontiersin.org/articles/10.3389/fpubh.2022.821117/full>.

[58] See James LOVE, "The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement" *Knowledge Ecology International online* (17 June 2022), online: KEI Online <www.keionline.org/37830>.

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