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Waive IP Rights & Save Lives

By Srividhya Ragavan¹

In October of 2020, when India and South Africa proposed a waiver from certain provisions of the TRIPS agreement, it was meant to increase local manufacturing capacity in these countries. The waiver was proposed as a tool to kick-start prevention, containment and treatment of COVID-19. While there is an imminent need to meet a growing supply-demand gap for all medical products, COVID-19 related products are urgently required in poorer nations to contain the pandemic. The waiver has an additional role to play in the larger trade schema. In enabling vaccination of populations across the globe, the waiver would be critical to normalize global trade. The paper below captures the benefits of the waiver and compares it with the existing flexibilities under the trade regime, being compulsory licensing.

Introduction

COVID-19 has been a disruptive leveler. In gist, before the onset of COVID-19, trade dictated public health. Efforts to protect public health were considered a barrier to trade unless the necessity of the public health measure could be established “without unduly impacting trade interests”, which was a high-bar. The onset of COVID highlighted the bottom line that stable public health is important for trade; the idea of a globe fueled by trade can come to a screeching halt unless we tackle the public health conundrum effectively.

In October of 2020, when India and South Africa proposed a waiver from certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), it was meant to increase local manufacturing capacity in these countries while the waiver, in enabling vaccination of populations across the globe, would be critical to normalize global trade. The waiver was proposed as a tool to kick-start prevention, containment and treatment of COVID-19. While there is an imminent need to meet a growing supply-demand gap for all medical products,

¹ Srividhya Ragavan, Professor of Law & Director of India Programs, Texas A&M University School of Law. A version of this paper was presented at the European Parliament Webinar Series on the Measures Needed to Boost Global Availability of COVID-19 Vaccines (8 Sept. 2021) by MEP Antoni COMIN I OLIVERES. It was also part of the WTO Public Forum Webinar on Making the TRIPS Agreement Work for Public Health, organized by the Institute for Studies in Industrial Development (ISID) (1 Oct. 2021). The author thanks Professor Peter Yu, Regents Professor of Law, Texas A&M School of Law, for his comments on the draft.

COVID-19 related products are urgently required in poorer nations to contain the pandemic. The waiver will be critical to remove barriers and help scale-up global production such that a vaccinated globe can be back to business as before. The proposal seeks a limited waiver of sections 1, 4, 5, and 7 of Part II of the TRIPS agreement which are different intellectual property provisions that can broadly impact vaccine production, distribution, therapeutics and diagnostics albeit for a limited duration with a possible termination period set at no more than three years. At the time of writing this note, the United States (US) as well as the European Union (EU) have expressed support for the general idea of enabling access to vaccines, although the EU has made an alternative proposal in favour of the existing flexibilities in TRIPS and reservations in different forms to the waiver. The following note hopes to capture some of the benefits of the waiver.

Legal Basis

The request for a waiver has a legal basis in Article IX(3) of the Agreement Establishing the World Trade Organization which allows Member Countries the ability to seek a waiver from certain provisions of the World Trade Organization (WTO) agreement. The decision by consensus rule requires that any request for a waiver be submitted to the Ministerial Conference for review within 90 days with a minimum of 3/4 majority approving the request. A request for a waiver from the TRIPS Agreement, as mandated under Article IX(3), shall be submitted to the Council for TRIPS which shall within 90 days submit a report for the review of the Ministerial Conference, or to the General Council when the Ministerial Conference is not in session. Decisions granting a waiver are required, under Article IX(4), to state the exceptional circumstances along with the terms and conditions governing the waiver including the date of termination. The Ministerial Conference shall review waivers on a yearly basis until termination to determine if the exceptional circumstances that justified it continue to exist to warrant an extension, modification or, alternately termination. Alternately, waivers will terminate if the underlying provision is amended through the established procedure.² Waivers are well-couched in WTO precedent. For example, the first amendment to the TRIPS Agreement, the Doha Declaration for public health, which celebrates its 20th anniversary in 2021, operated effectively as a “waiver” until ratified by two-thirds of WTO Members. In the current case, organizations like Health Gap, for example, have asserted that the urgency warrants simultaneous review by the WTO General Council for its independent consideration and at the TRIPS Council.³

Waiver v. Compulsory Licenses

The waiver embodies the following benefits when compared with other options, particularly compulsory licensing.

a. More efficient:

The alternative to the waiver is the existing exceptions under the TRIPS agreement under Article 30 and Article 31. Article 30 permits limited exceptions to the monopoly rights of the patent holder (as opposed to exclusions from patenting in Article 27),

² Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round, vol. 1, 33 I.L.M. 181 (1994).

³ Brook Baker, “Recognition and Enforcement of Intellectual Property Rights for COVID-19 Medical Technologies Deserves Universal Support, But Countries Also Have to Take Domestic Measures”, *Health Gap*, 10 October 2020. Available from <https://healthgap.org/south-africa-and-indias-proposal-to-waive-recognition-and-enforcement-of-intellectual-property-rights-for-covid-19-medical-technologies-deserves-universal-support-but-countries-also-have-to/>.

provided the patent is exploited *without affecting the legitimate interests* of the owner.⁴ Basically, where public interest demands overweigh the private monopoly incentives, governments will interfere with patents by compulsorily licensing the patent. Under the Indian statute, for instance, patented inventions that were either not reasonably priced or were not worked to satisfy the reasonable requirements of the public could be subject to compulsory licensing.⁵

The procedure to compulsorily license a patent should be statutorily established in every Member Country which would be cumbersome and time consuming. That the United States could not do it even during the anthrax crisis of 2001 should give an indication of the difficulties in just one country whose support is needed now to pass a waiver at a global level. The waiver minimizes the cumbersome nature of establishing and/or individually using a national compulsory licensing regime at several Member States. It is worth noting that Professor Yu, for instance, asserts that while this limited benefit will exist for WTO obligations and notifications, national action will be warranted in jurisdictions where the treaty is not self-executing such as India, for instance. He adds that the impact of a WTO waiver on free trade agreements and bilateral agreements remains unclear.⁶ Nevertheless, national action to execute a WTO waiver is bound to be more simple and less contentious than compulsory licenses.

b. Minimizes USTR Special 301 and EU Counterfeit Commission suffrage:

Compulsory licenses are most effective if they can serve as a vehicle for providing local manufacturing of the inventions. One of the objectives of the waiver is to facilitate local manufacturing. At a general level, historically, both the EU and the US have pushed back against the use of compulsory license; the United States Trade Representative (USTR)'s yearly Special 301 Report and the EU Commission's Counterfeit and Piracy Watch List have targeted countries using compulsory licensing. This factum alone makes the mechanism of compulsory licensing difficult to use to achieve the objective of scaling up global production of vaccines in many countries.

Moreover, the US has specifically discredited the Bayer judgment of India by Justice Prabha Sridevan for even mentioning local manufacturing.⁷ India's compulsory license over Nexavar, Colombia's frustrated compulsory license over Glivec which caused the US to threaten to stop funding for Pax-Colombia at that time and the US reaction to compulsory licensing in South Africa and Thailand during the AIDS crisis are all examples. It is also hypocritical for EU to now support an option that they have historically refused to accept as viable for enabling access to medication.

Even during COVID-19, big pharmaceutical companies lobbied against the use of compulsory licensing for COVID-19 treatment. At the initial stages of COVID-19, Gilead sued the Russian government for issuing a compulsory license on Remdesivir. The

⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [TRIPS Agreement].

⁵ Indian Patent Act, 2005, at § 84.

⁶ See on this issue Carlos M. Correa, Nirmalya Syam and Daniel Uribe, *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements*, Research Paper, No. 135 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP135_Implementation-of-a-TRIPS-Waiver-for-Health-Technologies-and-Products-for-COVID-19_EN-1.pdf.

⁷ *Bayer v. Union of India*, OA/35/2012/PT/MUM, 04.03.2013.

Russian Supreme Court ruled against Gilead.⁸ PhRMA lobbied against the Hungarian compulsory license on remdesivir,⁹ and that became part of the much criticized USTR Special Report for 2020.¹⁰ Similarly, the USTR, which seemingly supports the waiver, continued to feature countries such as India for under protecting intellectual property for pharmaceuticals during COVID-19.

A study recently conducted by Michael Palmedo showed that from 2009 until 2018, only middle-income countries have been cited in the USTR Special Report for compulsory licensing.¹¹ The same study showed that over a 12 year average, 75% of countries listed by USTR were criticized every year for either including the provisions in national laws or, alternately for the use of TRIPS flexibilities such as compulsory licenses. Similarly, citations for compulsory licensing have increased over the years. For example, in 2019, 37.5% of the countries that the US singled out (because Big Pharma wanted them to be) were because of compulsory licensing. These countries singled out together make more than half of the world's population, according to the Palmedo study.¹² The past failings and push-back by developed nations when compulsory licenses were issued by developing countries has contributed to the lack of enthusiasm of the rest of the world to use this mechanism. It is somehow surprising that in the Special 301 Report of 2021, the USTR has ceased to threaten countries on the basis of provisions on compulsory licenses.

c. Option to the waiver seems “meaningless”:

Recently, Ellen 't Hoen and Pascale Boulet wrote on Medicines Law and Policy that the “[t]he EU proposed Covid waivers of certain TRIPS rules are mostly meaningless” and I cannot agree more.¹³ They reflect the collective sentiment that EU's strong opposition against the waiver is unfortunate. A leaked document of October 2021 from the EU is disappointing at best in refusing to consider protection of undisclosed data and trade secrets and enforcement of intellectual property rights.¹⁴ The need for waiving these rights is discussed below.

In any case, historically, most of EU, such as Italy for instance, had worked around pharmaceutical patents until the 1970s. The development of Germany's chemical industry is credited to degrading patent protection. Their justification on the note that the TRIPS agreement already offers sufficient flexibility in the form of compulsory licenses is ill-founded and, indeed, factually incorrect. In fact, EU has tended to support the US

⁸ “Russian court rejects U.S firm's lawsuit over COVID-19 drug Remdesivir”, *Reuters*, 28 May 2020. Available from <https://reut.rs/3mSP8Vh>.

⁹ Thiru, “Hungarian compulsory license for remdesivir raises a stir with BIO, PhRMA and the US Chamber of Commerce”, *Knowledge Ecology International*, 8 March 2021. Available from <https://www.keionline.org/35558>.

¹⁰ See generally Office of the United States Trade Representative, *Special 301 reports*. Available from www.ustr.gov.

¹¹ Michael Palmedo, “United States: Unilateral Norm Setting Using Special 301”, in *Intellectual Property Law and Access to Medicine: TRIPS Agreement, Health, and Pharmaceuticals*, Srividhya Ragavan and Amaka Vanni, eds. (Routledge, 2021).

¹² *Ibid.*

¹³ Ellen 't Hoen and Pascale Boulet, “The EU proposed Covid waivers of certain TRIPS rules are mostly meaningless”, *Medicines Law and Policy*, 14 October 2021. Available from <https://medicineslawandpolicy.org/2021/10/the-eu-proposed-covid-waivers-of-certain-trips-rules-are-mostly-meaningless/>.

¹⁴ Daniel Marans, “New European Vaccine Proposal Offers Limited Help To Developing Countries”, *Huffpost*, 13 October 2021. Available from https://www.huffpost.com/entry/european-union-covid-vaccine-intellectual-property-proposal_n_61664498e4b0f26084edbbff.

adversarial position whenever a compulsory license was announced or issued to save lives in third countries. Further, not once during the existence of TRIPS and before the pandemic have developed countries agreed that there is a need for a life-saving medication in a third country and that the legitimate interest of the owner is unaffected, which is a pre-condition to issue a compulsory license. That said, currently, it is commendable to see the USTR supporting the developing countries' call for a waiver. Notably, the 2021 USTR report does not list compulsory licenses amongst the objected standards, which is a significant and commendable change for the USTR. On the question of the waiver, it would be good if the United States would lead to push for negotiations on a waiver text, delivering on this pledge of support. Otherwise, the fear is that the US support notwithstanding, EU can continue to object to the delay and detriment of a quick waiver.

d. Export of COVID vaccines:

The waiver does away with the cumbersome issues from Article 31(bis) of TRIPS. The Article exempts Members from the obligations under Article 31(f) of TRIPS, which requires that compulsory licensing be used predominantly to cater to the domestic market.¹⁵ Under Article 31(bis) the preconditions to facilitate importation of compulsorily licensed medication from countries that house manufacturing facilities such as India subjects both exporting and importing Members to specific conditions. The governments of exporting Members should compulsorily license the patent for the limited purpose of manufacturing for export and provide information on the terms of the license such as identity, country, quantity of product(s) and duration.¹⁶ Importing countries should submit information to the Council of TRIPS about insufficient manufacturing capacity, while quantities to be supplied, use of specific identification marks or colors that distinguish such products need also to be reported.¹⁷ Rwanda, for example, based on an evaluation of its public health needs, notified the TRIPS Council that it intended to import AIDS medication from Canada for two years.¹⁸ This was one of the two cases, the other, being Bolivia, in which the new system was used. Notwithstanding the above, some countries have unilaterally precluded themselves from the use of compulsory licensing under Article 31(bis).¹⁹

If the globe were to choose the option of compulsory licensing, vaccines will have to be exported using the WTO process. There have been issues in the past with Third World countries when drugs were exported. India's export of Losartan to Africa was held in the Netherlands for over 39 days, some of it was deported back and, of course, some of it went to Africa, necessitating the EU to specifically pass a regulation effectuating it which resulted in delays. Thus, poorer countries are justified in hesitating to go through the compulsory licensing and Article 31(bis) route.

¹⁵ TRIPS Agreement, Art. 31(bis).

¹⁶ World Trade Organization, "Notifications by Exporting WTO Members". Available from http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm.

¹⁷ World Trade Organization, "Notifications by Importing WTO Members". Available from http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm.

¹⁸ Rwanda notified the Council of its intention to import 260,000 packs of TriAvir. See Council for Trade-Related Aspects of Intellectual Property Rights, Notification under paragraph 2(a) of the Decision of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Rwanda, IP/N/9/RWA/1 (19/07/2007).

¹⁹ Mike Gumbel, "Is Article 31**bis** Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System", 22 *Temple Int'l & Comp. L.J.* 161, 171 (2008).

The point is, if a delay ensues from exporting, it is bound to be very long from having to clear export licensing in individual nations which will take time and training. Instead, an IP waiver will freeze some of these issues and make local manufacture and distribution easier, and enable local production of the vaccines which is more efficient and does away with distribution issues. Also, Africa received a \$2 billion fund in 2021 from the World Health Organization (WHO) for local production. Countries like Bangladesh are ready to produce. These countries will now go up the production chain, which is one of the major objectives of the TRIPS agreement under Article 7 and Article 8.

e. Waiver includes all applicable forms of intellectual property rights:

Unlike a compulsory license which tends to deal with patents alone, the waiver will include all applicable forms of intellectual property rights. While patents are the primary barrier, nevertheless, copyrights, trade secrets and industrial designs also continue to be barriers for local manufacturing and distribution of vaccines. The breadth of the waiver makes it better, although inclusion of some of these forms remains contentious.

The waiver has the benefit of enabling local production, but can also be used with other existing solutions such as differential pricing and price control in local markets. For example, in countries like India, differential pricing locally can mean that private hospitals pay a higher sum to get the vaccine. Alternately, vaccine prices can be priced differently in different jurisdictions subject to an agreement on parallel importation. Right now, the vaccine is free in rich countries like the US whereas it costs close to \$12 or Rs. 850 in India, a developing country. And in Africa, the vaccine is mostly unavailable.

In waiving IP rights, to enable local production, although currently contentious, countries hope to be able to access related and relevant technology such as trade secrets and copyrights. Even with that, as Professor Peter Yu notes, transfer of that technology may become a separate issue. Nevertheless, it is unfortunate that the EU does not seem to appreciate the importance of this paradigm. Compulsory licensing will *only* waive patent rights to increase competition by local producers. A waiver will enable access to copyrighted software that may be useful to make vaccine production more efficient. For example, artificial Intelligence (AI) or AI software is used for data mining, to run ventilators; medical equipment used to treat COVID are encrypted and protected using copyright law. Recently, a letter to President Biden from the [Electronic Frontier Foundation](#), the [Wikimedia Foundation](#), as well as [iFixit](#), pointed to specific examples of how copyright law impeded the treatment of and research about COVID-19. The letter pointed to examples of copyright covering algorithms used in mRNA vaccine technology, copyright covering repair documentation as well as software needed to repair [Medtronic](#)-brand ventilators, used to treat patients with COVID-19.²⁰

While Articles 13, 14 and 14(6) of the TRIPS Agreement outline exceptions to copyright in special cases, these exceptions work only if they do not conflict with the 'normal exploitation' of the rights of the patent or copyright holder. The waiver proposal, however, covers all IP. The same logic works with Article 39 of TRIPS covering undisclosed information such as trade secrets. Critical data, protected using trade secrets and regulatory exclusivities, are critical to know about and prevent adverse side-

²⁰ Andrew Karpan, "GOP Sen. Says Waiving COVID Copyrights Also 'Devastating'", *Law360*, 8 October 2021. Available from <https://www.law360.com/articles/1429671>.

effects; compulsory licenses will not cover the use of these. Such data include production and distribution information and clinical trial output, each of which is protected as trade secrets and using regulatory exclusivities in the US and the EU, especially for biologics. For example, biologics are protected using regulatory exclusivities for 12 years in the US. Different forms of data or regulatory exclusivities are often manipulated by companies. During COVID-19, in March 2020, Gilead requested an orphan drug designation which could entail a seven year market exclusivity for remdesivir. Gilead realized that remdesivir's patent expired/was expiring and therefore requested orphan drug status. Article 39(3) states that such data can be exempted for public interest purposes, but that is again subject to the rights of the owner. Some academics like Professor Doris Long, for instance, have asserted that “waiver supporters should except Article 13 from any waiver. Such an exception would provide a clear signal that fair use/fair dealing remains available to help in the critical battle against COVID-19.”²¹ Basically, her argument is that fair use should be completely allowed during COVID, so that people do not question the limits of the waiver. These are all important aspects that a waiver covers and a compulsory license will not cover.

f. Waiver & price benefit:

Without a waiver, the high price of patented products makes negotiating an affordable price immediately difficult. Even during the AIDS crisis Big Pharma refused to reduce the cost of drugs. Countries had to expend energy and time to arrive at a price that was affordable locally. The higher the cost of the drug and the more important the drug is, the harder it gets to bring down the cost.

The number of patents covering five non-COVID drugs is featured in the table below from an I-MAK study. The sample data from the study shows how hard it can be to negotiate down the prices within a compulsory licensing regime.

In the table below each drug is covered by a number of patents; it shows the percentage of price increase from 2012 to 2018. A drug has increased by 155%, and another by over 163% of the original price. Are we going to expect that pharma will reduce the price to 1% of what they're selling right now? Even that might be too high for some countries.

The benefit of the waiver is that governments will step in. For pharmaceutical companies, volume sales will offset monopoly prices. Bayer's Nexavar in India provides a great example. When the Bayer drug, Nexavar, was compulsorily licensed there was a huge hue and cry about it. But after the issuance of the license, Bayer's sales and thus, profits from Nexavar in India actually increased – despite the presence of a competitor in the form of Natco. Basically, because the price was reduced, more people could afford the Bayer medication meaning increased volume sales. The power of volume sales should not be lost on pharmaceutical companies and governments.

²¹ Doris Estelle Long, “The Overlooked Role of Copyright in Securing Vaccine Distribution Equity”, *TradeRX Report*, 6 September 2021. Available from <https://www.traderxreport.com/covid-19/the-overlooked-role-of-copyright-in-securing-vaccine-distribution-equity/>.

Name of the drug	Manufacturer/pat. Owner	No of patents	% price-hike 2012 to 2018
Humira	AbbVie	132	144%
Enbrel	Amgen	41 (primary patent expired in 2010; about 19 active patents remain)	155%
Lantus	Sanofi	49	114%
Rituxan	Biogen/Genentech	94	25%
Lyrica	Pfizer	68	163%

Source: I-MAK Study titled Overpatented, Overpriced²²

g. Reduces conflicts:

When governments step in as discussed above, the IP waiver will level the playing field. Otherwise, even if countries manage to negotiate down prices, the risk of litigation is heightened. During the AIDS epidemic, countries like South Africa and India had to fight Big Pharma in national courts to reduce price to save lives. The WTO's dispute settlement process can also be laborious and can be misused both for challenging compulsory licenses and for related questions. A waiver can prevent unnecessary litigations, international dispute settlement and third country unilateral administrative indulgence like by the USTR or the EU Commission. While price can be negotiated by compulsorily licensing, it is bound to be delayed.

Innovation Using Public Funds is not a Matter for Private Property

It is a fact that much of the vaccines have been developed using public funds. The following table highlights the extent of public funds used to develop the vaccines. Importantly, the more the public fund investment, the justification for private rights over life-saving medications becomes considerably thin.

²² I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Price*. Available from <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

S. No.	Vaccine Sponsor	Amount of public funds disbursed
1.	Johnson & Johnson	\$ 2 billion
2.	Sanofi and GSK	\$2.35 billion
3.	Merck and IAVI	\$38 million
4.	Moderna	\$5.35 billion
5.	Novavax	\$2.1 billion
6.	Pfizer (BioNTech)	\$ 5.95 billion
7.	AstraZeneca (Oxford)	\$1.6 billion

Source: Peterson Institute of International Studies²³

The table above shows a sample of how several big pharmaceutical companies have received public money in the range of billions. Considering that each of these vaccine developers have benefited from public funds, their claims for private rights remain unfounded. In fact, the claim for private rights is a disincentive when public funds are used and undermines the goals of the IP system. It is fair and appropriate for these companies to share what they have found using the public funds.

Public Health Treaty - (Re)thinking access equity

The bottom line is that intellectual property is and has been a primary barrier to access to medication before and during the pandemic. The WTO's future role as the governor of global trade is dependent on how it gives primacy to public health. Trade ultimately is to help humans improve. WTO is seemingly disconnected with this reality. Going forward, long term solutions that go beyond the narrow focus of the pandemic is required. Such a framework will necessarily require the WTO to work with WHO.

During this time, academics and non-governmental organizations have talked about the pandemic treaty. I believe what we need is a Public Health Treaty, a treaty that is much broader in scope. The goal should be beyond the IP waiver and it should be to find a sustainable basis to provide access to medications and to preserve health care access.

Fact is, when one part of the globe is affected, all of the globe is affected, hence, the need for quick, effective solutions with global outreach. Enabling global equity with the COVID-19 vaccine is but a first step to promote access; it will be the step that actually helps the trade regime by fulfilling the Articles 7 and 8 mandate of the TRIPS agreement to promote social and economic equity.

²³ Chad P. Bown and Thomas J. Bollyky, "Here's how to get billions of COVID-19 vaccines to the world", *Peterson Institute for International Economics*, 18 March 2021. Available from <https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world>.

The intellectual property ideology is rich but it is a luxury of the rich that poor people cannot afford. Let us not lose lives and global productivity for the sake of an unrealistic ideology during a pandemic.

Let us stop public health and intellectual property from becoming the greatest happiness of the smallest number.

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