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TRIPS Waiver and its (Jabby) Journey: Side by side comparison of the (waiver?) drafts from 2020 – 2022

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This is a short descriptive post highlighting the vitriolic waiving of TRIPS Waiver - which began with a proposal (by India & South Africa) waiving all the Intellectual Properties (IP) limitedly but ended up with a (pre-decided?) decision giving some leeway on compulsory licensing of patents (that's it!). In sum, the journey is Intellectual Property Waiver to ~~Intellectual Property~~ Compulsory Licensing Leeway.

1. The first waiver (Oct. 2020) proposal text was sought to apply to all IPs under Sections 1, 4, 5, and 7 of Part II of the TRIPS for the "prevention, containment or treatment of COVID-19". The revised proposal text (May 2021), while kept it open for all IPs as under the abovementioned provisions, specified/limited to "health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19". The recent MC12 (Jun. 2022) decision further limited it "Article 28.1 of the TRIPS Agreement … by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines" (now it is only between Art. 28 and 31). Also, in this regard, first and revised drafts were open to all countries (developed, developing, LDCs), whereas the MC12 decision is limited to developing countries (not all!) subject to their existing capacity to manufacture COVID-19 vaccines.
    a. No payment was involved in the earlier two drafts since it was complete waiver. MC12 provides for the determination of adequate remuneration under Article 31(h) by taking into account the humanitarian and not-for-profit purpose and the existing good practices of national emergencies/pandemics/similar circumstances.
    b. The first two drafts were complete waivers therefore, no formality was needed, but the decision is limited to CL of patent hence, gave a leeway of "Rapid approval for use of a COVID-19 vaccine under Art. 39.3"

2. The original 2020 proposal draft did not specify the number of years when a waiver is applicable, mentioning [X] years from the decision of the General Council with a review by the General Council not later than one year after it is granted. The revised draft limited it to 3 years from the date of this decision with a similar review mechanism by General Council. The recent MC12 decision made it "applicable until 5 years from the date of this Decision" and provided a potential extension if the exceptional circumstances of the pandemic exist.
3. The first two proposal texts did not specify how the waiver was to be applied, whereas the MC12 decision specified this with "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".
4. The initial two proposal texts were silent on exportation or importation, the MC12 decision allows exportation (contrary to art. 31f of TRIPS) but prohibits re-exportation except under emergency circumstances for humanitarian and not-for-profit purposes with prior notice to the Council for TRIPS.

WTO MC Decision (17 Jun. 2022)	Original Waiver Text (by Ind. & SA) (2 Oct. 2020) & Revised Waiver (25 May 2021) *"{ }" is change after revision.*	EU Proposal (4 June 2021) & Annexure (18 June 2021)
1. 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, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.	The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to {health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture} prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.	The EU proposes … a global trade initiative for equitable access to COVID-19 vaccines and therapeutics … The EU proposes that WTO Members agree … the following three components: 1) trade facilitation and disciplines on export restrictions; 2) expansion of production, including through pledges by vaccine producers and developers and; 3) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory licences.
Fn 1. For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail		… EU considers … b. To support manufacturers to produce vaccines or therapeutics at affordable prices, especially for low- and middle-income countries, on … a compulsory licence, ... c. The compulsory licence could cover any exports destined to

themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.		countries that lack manufacturing capacity, including via the COVAX facility. …
2. 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.		

3. Members agree on the following clarifications and waiver for eligible Members to authorize the use of the subject matter of a patent in accordance with paragraphs 1 and 2: (a) An eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b).		For the purposes of issuing a compulsory licence pursuant to Articles 31 and 31bis of the TRIPS Agreement, a Member may waive the requirement of making efforts to obtain authorization from the right holder, provided for in Article 31(b)
3. (b) 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…		
3. (c) Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the products manufactured		

under the authorization in accordance with this Decision that have been imported into their territories under this Decision.3 Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.		
Determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members. In setting the adequate remuneration in these cases, eligible Members may take into consideration existing good practices in instances of national emergencies, pandemics, or similar circumstances.4		… Article 31(h) on the adequate remuneration to be paid to the right holder. It provides that … a compulsory licence for export purposes the adequate remuneration is to be determined taking into account the economic value of the licence to the importing member. … … a Member may provide, for the purposes of determining the remuneration to be paid to the right holder pursuant to Article 31(h) and paragraph 2 of Article 31bis of the TRIPS Agreement, that the remuneration reflects the price charged by the manufacturer of the vaccine or medicine

		produced under the compulsory licence.
4. Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.		
5. For purposes of transparency, as soon as possible after the adoption of the measure, an eligible Member shall communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization.5		… for the purposes of Article 31bis and paragraph 2.c) of the Annex to the TRIPS Agreement, the exporting Member may provide in one single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting Member directly or through indirect means, including international joint initiatives that aim to ensure equitable access to the vaccines or medicines1 covered by the compulsory licence. … The objective is to ensure that with a single notification providing the elements required under Article 31bis for transparency purposes, the export can go ahead.

6. This is applicable until 5 years from the date of this Decision; General Council may extend such a period taking into consideration the exceptional circumstances of the pandemic; General Council will review annually the operation of this Decision.	This waiver shall be in force for at least {3 years} from the date of this decision. {The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver.}	
7. Members shall not challenge any measures taken in conformity with this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994.	Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.	
8. 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.		… we affirm that the Agreement … be interpreted and implemented in a manner … to promote <u>access to vaccines and medicines</u> for all. The EU proposes … a global trade initiative <u>for equitable access to COVID-19 vaccines and therapeutics ...</u>
9. This Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities	This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the	

affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b). For greater certainty, this Decision is without prejudice to the interpretation of the above-mentioned flexibilities, rights and obligations outside the scope of this Decision.	TRIPS Agreement. 4.	

1. In all the three texts (2 proposals and MC decision), an annual review is required by the general council. However, language for extension or termination differs. The two proposal texts (original and revised) mention "provisions of paragraph 4 of Article IX of the WTO Agreement" as ground of extension/termination whereas the MC12 decision makes the extension/termination subject to “exceptional circumstances of the pandemic”.

Relevant readings - For the discussion on MC12, see Shirin Syed’s, Praharsh Gour’s, and Praharsh and Rahul’s post and Prof. Baker’s post. In general context, see James love’s posts see, and here and Praharsh post.