



MSF Comments on the Reported Draft Text of the TRIPS Waiver Negotiation

Seventeen months after the proposal for a temporary waiver of certain provisions of the Agreement on Trade-related Intellectual Property Rights (TRIPS Agreement) for COVID-19 medical tools was tabled at World Trade Organization (WTO), a draft text was leaked in mid-March 2022.^{1,2} Reportedly the draft text has been discussed among the European Union (EU), United States (US), India and South Africa.

As currently articulated, the draft text does not amount to the waiver as proposed. It does not provide a meaningful solution to the challenges presented by intellectual property (IP) on access to COVID-19 medical tools during the pandemic to facilitate more independent manufacturing and supplies to address access inequities. Instead, it largely provides clarification and interpretations of some elements of the TRIPS Agreement, particularly related to compulsory licensing on patents, and it is also limited to vaccines only and does not cover therapeutics and diagnostics. The draft text largely reflects the EU and US positions in the negotiation. It is categorically different from the TRIPS waiver proposal which comprehensively addresses IP challenges, scope of products and other issues restricting production and supply of essential COVID-19 medical tools. WTO members should not adopt the current text and should instead continue to pursue a more ambitious outcome as outlined by the waiver proposal.

The current text is narrow in scope, has considerable limitations, may create more legal uncertainty due to the ambiguity of its construction, and could set a negative precedent for future global health challenges if adopted as it stands:

1. It makes the interpretations of the TRIPS Agreement time-bound, applicable only to COVID-19 vaccines, and restricted to certain WTO members only.
2. It excludes therapeutics and diagnostics from the negotiation, ignoring the access challenges caused by IP barriers for these medical tools.
3. Its problematic eligibility criteria and the complete disregard of the situation of importing countries may exclude multiple low- and middle-income countries (LMICs) from producing, supplying, exporting and importing vaccines; and legitimise division and exclusion, restricting access options for all people.
4. It may undermine and restrict existing TRIPS flexibilities, introducing burdensome, unnecessary and TRIPS-plus requirements for countries seeking to issue a compulsory license.
5. It limits existing flexibility of removing test data protection/exclusivity as a stand-alone IP challenge for production and supply, and does not cover other non-patent IP barriers such as trade secrets.

This briefing summarises the main comments from Médecins Sans Frontières (MSF) Access Campaign on the reported draft text and offers recommendations for improvement in the negotiations and its tabling before all members of the WTO.

Key issues with the current text

1. Limiting the applicability of general clarifications and interpretations on TRIPS provisions

Overall, the draft text presents a set of clarifications and interpretations of current TRIPS provisions, focusing on the mechanism of authorisation of non-voluntary use of patented subject matters, commonly known as compulsory licensing, rather than the waiver as originally proposed.

There is only one element of the current text, under Paragraph 3(c), that could be potentially considered a ‘waiver’, namely the removal of the requirement found in Article 31(f) of the TRIPS Agreement that products produced through the grant of a compulsory license be used predominantly for domestic supply. However, this narrow proposal is substantively undermined and could be rendered ineffective by other sections of the draft text that add TRIPS-plus requirements and new reporting burdens. These will be discussed below in more detail.

The issues of Article 31(f) of the TRIPS Agreement should be considered in the broader context of the evolution of issues of access to medicines and IP, and particularly in the spirit of the Doha Declaration on TRIPS Agreement and Public Health adopted by WTO members in 2001.³ As countries were required to use a compulsory license predominantly for domestic supply under Article 31(f), Paragraph 6 of the Doha Declaration mandated the TRIPS Council to find an expedited solution for countries with limited or no manufacturing capacities that could be faced with challenges of using compulsory license to facilitate production and supply of medicines.

However, the mechanism set up under the TRIPS amendment after the Doha Declaration, namely Article 31*bis*, has been heavily criticised for being overly cumbersome,⁴ not fit for purpose, and entirely inappropriate in a pandemic situation.⁵ A clear waiver from Article 31(f) should remove any strings attached to the issuance of a compulsory license for export. While Paragraph 3(c) removes the restrictions on exporting under a compulsory license, Paragraph 3(a) and Footnote 4 introduce unnecessary and detrimental conditions that immediately undermine the potential benefit of the removal of restrictions (see Annex). Hence Paragraph 3(c) cannot be considered a meaningful waiver. It should be considered as a continued effort of finding an interpretation of the TRIPS Agreement in light of the Doha Declaration.

In addition, Paragraphs 2, 3(b) and 4,^a mostly reaffirm and clarify the meaning of current provisions of the TRIPS Agreement. As such, these components should not be considered waivers, but rather as interpretations of TRIPS provisions. Yet, these paragraphs are limited only to ‘the Decision’, namely the current draft text that is time-bound, for ‘eligible members’ only, and for COVID-19 vaccines only, while they are in essence general interpretations.

These interpretations in the draft text are further mixed with paragraphs limiting eligibility to some WTO members (Paragraphs 1, 2, 3), emphasising the temporary nature of the measures (Paragraph 6) and limiting the general scope of the text to COVID-19 vaccines only. The potential danger of this approach is that it could be used to suggest that the general interpretations of TRIPS provisions could be restricted to a particular ‘Decision’, are time-bound, and applicable only to certain WTO members and certain diseases or products. This could set a negative precedent and goes against the general principle that interpretations should be made available for all situations.

It is critical that a time-bound waiver be considered distinctly from clarifications and interpretations of existing TRIPS provisions. Not doing so both exaggerates and confuses the degree to which anything is ‘waived’ and allows existing provisions to be misinterpreted and mischaracterised in ways that have troubling long-term implications.

2. Focusing only on vaccines and ignoring ongoing access challenges facing other medical tools

The focus of the draft text is limited to vaccines, including ingredients, processes and underlying technologies.^b It ignores the ongoing access barriers to affordable COVID-19 therapeutics and diagnostics that are also largely caused by IP. Denying access challenges and IP barriers on therapeutics and diagnostics in a global pandemic puts lives at risk while setting a negative precedent for future health emergencies.

The limitation of the scope of technologies covered will significantly affect access to COVID-19 treatments. For instance, baricitinib, the WHO-recommended oral treatment for severe COVID-19 patients, has been priced by the pharmaceutical corporation Eli Lilly a few hundred times higher than the estimated cost-based price in some countries.⁶ Argentina, a developing country, pays more than twice what France pays for this medicine.⁶ Eli Lilly holds patents on baricitinib in more than 50 LMICs, including most Latin American countries.⁷ While governments could use existing TRIPS flexibilities, including issuing a compulsory license, to enable generic production and supply domestically, an additional legal option will be needed to facilitate easier collaboration and exportation/importation among countries.⁸ The original proposal for the TRIPS waiver provides such an option.

Another example is nirmatrelvir/ritonavir, the most promising oral antiviral treatment so far for people with high risk of progressing to severe COVID-19, based on available data. The US pharmaceutical corporation Pfizer is the first to supply and has applied for patents across the globe. Many of these applications remain pending or unpublished at national levels. Meanwhile, most of the limited supply of the treatment has been quickly bought up by a number of high-income countries.⁷ Pfizer has also excluded the majority of Latin American countries and several other middle-income countries from the

^a Paragraph 2: possibility of using any kind of instruments to authorize the use of patents without the consent of patent holders; Paragraph 3(b): reaffirming no prior negotiation is required when issuing compulsory license for government use; Paragraph 4: test data protection/exclusivity can be removed for effective compulsory license.

^b See Paragraph 1, Footnote 2; and Paragraph 3(a) of the draft text.

territory of a voluntary license signed with the Medicines Patent Pool (MPP).⁷ Although the license will ultimately allow for generic production by companies that signed the license, it has been estimated that new generic companies may only be able to start supplying the treatment in 2023.⁹

These examples demonstrate how IP barriers limit production and supply of COVID-19 therapeutics, but they have been completely overlooked in the draft text. They also highlight the limitations that the original waiver proposal seeks to address.

Per Paragraph 8 of the draft text, WTO members will decide on the proposal's possible extension to therapeutics and diagnostics within six months after the decision on vaccines has been made. However, given the amount of time it has taken to get even to this point, it is far from assured the WTO members will reach a consensus in six months. It is therefore important to include therapeutics and diagnostics in the negotiation now.

In addition, to ensure the inclusion of therapeutics and diagnostics is meaningful, the limitations of the draft text related to eligibility criteria, conditions for export under compulsory licenses and restrictions on existing TRIPS flexibilities and provisions would need to be addressed concurrently.

3. Arbitrary criteria of eligibility that may exclude people in LMICs and major suppliers from using the proposed Article 31(f) waiver

Paragraph 1 and Footnote 1 of the draft text limit eligibility for the proposed mechanism to 'any developing country Member' that has exported less than 10% of the world export of COVID-19 vaccines in 2021. This failure to include all people in all countries in a global pandemic is concerning, as all countries have been faced or threatened with shortages of medical supplies.

This eligibility criteria with an outright exclusion of countries would also be a step backwards from the WTO response to global health challenges -- in particular the Doha Declaration and the introduction of Article 31*bis*, after dramatic and deadly inequitable access to treatment at the start of the HIV pandemic two decades ago. The TRIPS flexibilities including the heavily criticised Article 31*bis* mechanism are open to all WTO members, with no exception. Article 31*bis* also offered an opt-out approach for those who wish to do so, rather than a direct exclusion of certain countries.

The eligibility criteria, which are pinned to global vaccine exports in 2021,¹⁰ exclude only China as a developing country member. While the proposal claims to increase production and supply of vaccines to address the access inequities, excluding a major supplier of vaccines to developing countries is arbitrary and contradictory and sets a negative precedent of legitimising division and exclusion with regard to health objectives in WTO discussions, restricting people's access to medical tools. The text may further aggravate existing inequities as low-income countries have received limited supplies of COVID-19 vaccines.

The text does not specify whether ‘developing country Member’ automatically includes WTO members that are least-developed countries (LDC). Some LDCs, such as Bangladesh and Senegal, have existing capacities for vaccine manufacturing.¹¹ Given the fact that several LMICs are not WTO members,^c the text also does not specify whether they can benefit from the proposed mechanism and receive exports produced under the proposed Article 31(f) waiver in Paragraph 3(c).

In the WTO, countries are allowed to self-designate whether they are ‘developed’ or ‘developing’ countries. However, some developing countries might have reportedly chosen to give up certain benefits of special and differential treatments afforded to developing countries.¹² The current text does not specify how their eligibility as developing countries is ensured.

The text also completely omitted addressing the situation of importing countries and does not provide clarity on removing potential patent barriers that may exist in importing countries.

4. Introducing TRIPS-plus requirements that can undermine existing TRIPS flexibilities and the impact of the proposed Article 31(f) waiver

Paragraph 2 of the draft text clarifies that WTO members can use any type of instrument to authorise the non-voluntary use of patent subject matter -- a compulsory license. Paragraph 3(c) constitutes the only text in the whole draft where a waiver from a particular aspect of Article 31(f) of the TRIPS Agreement is introduced. According to paragraph 3(c), eligible WTO members can export under a compulsory license without restrictions on quantities.

However, Paragraph 3(a) and Footnote 4 introduce new obligations and onerous reporting requirements that reduce some of the existing TRIPS flexibilities and undermine the potential impact of the proposed Article 31(f) waiver. Endorsing such TRIPS-plus requirements in a pandemic is contrary to the stated efforts of strengthening public health safeguards.

Additionally, while the clarifications in Paragraph 2 should be applicable for all members and all situations of compulsory licensing by WTO members, the current wording restricts them to ‘eligible members’ only. In reality, countries may have been using a variety of instruments, according to their national discretion, to issue authorisations of compulsory licenses according to Article 31 of the TRIPS Agreement. However, the clarification in paragraph 2 that ‘the law of a Member’ goes beyond merely a legislation has been limited to ‘for the purpose of this Decision’. It therefore requires further precision, so that a general clarification as such becomes applicable for all members, across all disease areas, without time limitations, and does not reduce existing flexibilities.

^c There are 28 non-WTO member LMICs, 9 from the African continent: Algeria, Azerbaijan, Belarus, Bhutan, Bosnia and Herzegovina, Comoros, Equatorial Guinea, Eritrea, Ethiopia, Iran, Iraq, Kiribati, DPRK, Lebanon, Libya, Marshall Islands, Micronesia, Sao Tome and Principe, Serbia, Somalia, South Sudan, Sudan, Syria, Timor Leste, Turkmenistan, Tuvalu, Uzbekistan.

The wording in Paragraph 3 – ‘in accordance with paragraph 1 and 2’ – could suggest that the problematic conditions and limitations introduced under Paragraph 3 might be extended to normal situations of issuing compulsory licenses. This confusing construction could substantively undermine the existing TRIPS flexibilities.

Patent listing requirement is TRIPS-plus

Paragraph 3(a) of the draft text continues the requirement of issuing of compulsory licenses on a individual products, i.e. ‘a vaccine’, and additionally requires that members ‘shall’ list all relevant patents ‘necessary’ for production and supply when issuing a compulsory license. The obligation to list all patents when issuing a compulsory license is a TRIPS-plus requirement and could undermine the existing flexibilities under Article 31(a) of the TRIPS Agreement.

A review of the negotiation history of the TRIPS Agreement confirms that Article 31(a) was introduced by the US and India with a view to enabling WTO members to freely decide the grounds on and context in which a compulsory license can be issued.¹³ The requirement that an authorisation be made on ‘individual merits’ has never meant to refer to individual products or individual patents.¹⁴ There is no restriction as to how a WTO member may draft a compulsory license decision and the level of detail that must be included. In practice, countries have issued a single compulsory license that covers multiple products at once, without listing each individual patent.^d Paragraph 3(a) in the draft text requiring listing of all patents therefore imposes a TRIPS-plus obligation and reduces existing flexibilities.⁸

Listing all ‘necessary’ patents is practically difficult and time-consuming as corporations may continue filing new patent claims related to the same technologies or products. This is compounded by the fact that patent office databases are mostly not organised to identify all patents related to a particular product or technology.

In the case of vaccines, it is often hard to quickly identify all the patents that may be ‘necessary’ and may hinder alternative production and supply of vaccines. Research has shown that patents could be applied for and granted on nearly all aspects of technologies across the vaccine development, production and delivery process.¹⁵ Research also shows that there are complex networks of patenting and licensing underlying the mRNA vaccine technologies used to develop COVID-19 vaccines.¹⁶ While many technologies used to develop COVID-19 vaccines have already been subjected to patenting before the pandemic, research and development activities continue to generate new patent applications on improvements to technologies and newer generations of vaccines. This complex landscape of vaccine patents would make it practically impossible to list all relevant patents with the justified necessity for production and supply when a WTO member decides to issue a compulsory license.

The draft text also does not address pending and unpublished patent applications, granted patents and potential upcoming patent applications related to both the final product of the vaccine and all components. Without this clarity, alternative producers lack the legal certainty they need to produce and supply. This could potentially expose them to infringement suits in the future.

^d For instance, Malaysia issued one compulsory license covering four products at once, and Indonesia issued one compulsory license covering seven products at once. Ghana and Zambia issued the authorisation for production and importation of generic antiretroviral medicines without naming individual products. Only Indonesia mentioned indicative patent information, but for small molecule medicines. See: <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>

To be effective, the solution should not be a product-by-product approach, particularly in a health emergency such as a pandemic, but rather a single authorisation to cover a class of technologies, such as all essential COVID-19 medical tools,¹⁷ including the components, raw materials, manufacturing data, methods, process of production, delivery devices and underlying technologies; and to cover both present and emerging patents and applications, as well as other major types of IP such as undisclosed information that could hinder production and supply. The product-by-product approach and non-patent barriers have been the major shortcomings of the current compulsory licensing mechanism that the original TRIPS waiver proposal could effectively address, if adopted.⁸

The wording in Paragraph 3(a) also does not specify whether the patent listing requirement is intended for the mechanism proposed under Paragraph 3(c) only, or is a general requirement for compulsory licensing. This level of ambiguity brings even greater risk of diluting TRIPS flexibilities beyond the COVID-19 context. It is critical that this TRIPS-plus requirement for patent listing be removed in its entirety in the follow-up negotiation process.

Reporting requirement is excessive

The reporting requirements introduced in the draft text under Paragraph 5 and Footnote 4 are excessive in the context of using a compulsory license. The current text also does not specify whether this requirement is intended for implementing the mechanism under Paragraph 3(c) only, or in general situations of compulsory license. If the latter, then these excessive reporting requirements will have far-reaching impact because there is no general obligation for WTO members to report as required by Footnote 4 when issuing a compulsory license.

While ensuring transparency is an important principle, the mechanism proposed under Paragraph 5 and Footnote 4 may introduce undesirable burdens of reporting that may not help to achieve the overall objective of simplifying the procedure for compulsory licensing for export. If the text in Paragraph 5 and Footnote 4 is intended for the proposed Article 31(f) waiver under Paragraph 3(c) only, then for the purpose of transparency, members should only be required to communicate to the TRIPS Council about the general status of implementation of this special waiver, particularly in the format of reporting the instrument used nationally to incorporate the decision made at WTO. For individual authorisation decisions, in reality, countries already notify the patent holders or publish such authorisations and compulsory licenses addressing concerns regarding transparency, and those practices should suffice for the need for transparency. The requirements of reporting to the TRIPS Council about which entities are authorised, the duration of authorisation, and quantities and destinations of exportation (covered in Footnote 4) would add unnecessary procedural burdens for countries when seeking to implement the proposed mechanism.

Footnote 4 introduces provisions similar to those under Article 31*bis* of the TRIPS Agreement, which has long been criticised for its cumbersome notification requirements that hinder compulsory licensing.^{4,5}

Problematic anti-diversion requirement on compulsory licences for export

Paragraph 3(d) of the draft text requires members to take all measures to prevent re-exportation of COVID-19 vaccines imported into their territories. The requirement to prevent re-exportation is only mentioned under Article 31*bis* of the TRIPS Agreement for that special procedure. There is no general obligation for WTO members to prevent diversion of goods. Article 6 of the TRIPS Agreement clearly states that issues of exhaustion of rights, namely

placing a limitation on IP holders to claim their rights over the resale of goods, are not covered by the TRIPS Agreement.¹⁸ Members can adopt rules to allow parallel importation, namely importation of patented goods with a cheaper price from another country, as a national discretion.

This condition under Paragraph 3(d) needs to be closely examined given the fact that countries may be willing to re-export unused vaccine doses to another country to address an access gap. In addition, Paragraph 3(c) suggests that export under a compulsory license can be made to supply ‘international and regional initiatives.’ In reality, collective procurement of medical products at international or regional levels may involve re-export and dispatch of the products from the country where the collective procurement is conducted to other countries. It is unclear how the requirement of preventing re-exportation under Paragraph 3(d) may have an impact on these situations stated in Paragraph 3(c).

5. Limiting existing flexibility of removing test data protection/exclusivity and failing to consider non-patent IP

While the focus of the draft text is mainly on patents and compulsory licensing, the inclusion and exclusion of other types of IP is noteworthy.

Paragraph 4 of the draft text is a clarification of Article 39.3 of the TRIPS Agreement, which makes it possible to waive test data protection/exclusivity obligations – with one key difference. Under Article 39.3 of the TRIPS Agreement, test data protection/exclusivity can be overridden ‘where necessary to protect the public’, and not just in the context of a patent or a compulsory license. This is an important flexibility because test data protection/exclusivity can be a stand-alone barrier to access to medicines, even in the absence of patents. For instance, in 2016, pharmaceutical corporation Gilead Sciences filed a lawsuit against the Ukrainian government by invoking data exclusivity protection over sofosbuvir, a medicine to treat hepatitis C, even though Gilead did not hold a patent on the medicine in that country.^{19,20}

However, Paragraph 4 misses the point that the existing TRIPS flexibility of Article 39.3 goes beyond the granting of a compulsory license. The clarification that Paragraph 4 provides should also apply ‘where necessary to protect the public.’ It should be applicable for all WTO members and all diseases and technologies and should not be time-bound.

Information pertaining to manufacturing and technical processes is particularly important for alternative developers of vaccines and biological medicines to accelerate the development process. However, some of this information is claimed as trade secrets or confidential information by companies. The draft text does not address barriers arising from confidential information/trade secrets held by corporations. These types of protections are not just covered by Article 39.3 (which focuses on test data only), but also by Article 39.1 and 39.2 of the TRIPS Agreement.²¹ While the current text focuses on vaccine production and exportation, not waiving Article 39.1 and 39.2 together with Article 39.3 would reduce the impact of the mechanism in practical terms.

For instance, there is a challenge currently facing the mRNA Vaccine Technology Transfer Hub hosted by South Africa in collaboration with WHO. To date, major mRNA vaccine suppliers such as Moderna and Pfizer/BioNTech have declined to transfer technologies and share manufacturing information with the Hub. While South African vaccine developer Afrigen has developed the preclinical sample of an mRNA vaccine by referring to the sequence data of Moderna’s vaccines, the absence of manufacturing information and know-how could delay the process of developing production at scale. Moderna has also

chosen not to apply for regulatory approval in South Africa and continues to hold patents on the broad mRNA technology platform in the country, which could pose a legal risk when companies bring their vaccines to market.²² Overcoming patents and test data protections alone - as proposed in the current draft text - will not be sufficient to ensure access to vaccine manufacturing information.

In addition, reading Paragraph 4 together with other paragraphs of the draft text raises a general question about the implication on existing state practices concerning Article 39. For instance, if an eligible WTO member under Paragraph 1 already has a national law to allow waiving test data protection/exclusivity when issuing compulsory licensing as a general rule, the wording of Paragraph 4 may raise the question whether this is only possible under certain conditions stated in Paragraphs 1, 3 and 6 going forward. This is because while Paragraph 4 states that such a measure can be taken ‘as per this Decision,’ namely for COVID-19 vaccines only and for 3 or 5 years, but it does not specify how this is without prejudice to the existing flexibilities.

Conclusions and Recommendations

Overall, the leaked draft text is not an effective IP waiver for COVID-19 medical tools and should not be equated to the original TRIPS waiver proposal by South Africa and India. With the restriction of the scope of technologies to vaccines only, and the overall focus on patents and compulsory licensing, the leaked draft text appears to reflect the proposals made by the EU and US and not those contained in the original proposal.

The text introduces a set of clarifications and interpretations of the current TRIPS Agreement, including on Article 31(f), that intends to simplify compulsory licensing for export. However, the introduction of TRIPS-plus requirements in Paragraph 3(a), and unnecessary procedural elements in Paragraph 5 and Footnote 4, effectively undermine and remove the potential positive impact of the current text.

The ambiguity of language and structure used in the draft text may also create more legal uncertainties regarding existing TRIPS flexibilities and state practices.

Further, the scope of these clarifications and interpretations, if substantively improved, should be extended to all medical technologies across all disease areas without time limitations, and made applicable for all WTO members without TRIPS-plus provisions and other onerous requirements. To comprehensively address overall IP challenges in a pandemic situation, non-patent IP barriers such as trade secrets also need to be addressed.

The current text requires substantive revision and improvement when negotiations move forward, to avoid setting a harmful precedent for future public health challenges. **We urge WTO members not to adopt the current text and to consider the following actions while negotiating an outcome at WTO:**

- Insist that clarifications and interpretations of TRIPS provisions be applicable for all WTO members; for all diseases and technologies without time limits; and for all kinds of compulsory licenses granted beyond the scope of the draft text ‘Decision’.
- Address IP barriers to access to therapeutics and diagnostics without further delay.
- Clarify the eligibility criteria for inclusion of all countries, including all developing countries with manufacturing and supply capacities, to achieve the intended objective of facilitating increased production and supply; and clarify situations for importing countries that may need to remove possible patent barriers when importing.

- Reject TRIPS-plus requirements contained in Paragraph 3(a) that requires countries to list all patents when issuing a compulsory license; and the excessive reporting requirement in Footnote 4 which could undermine existing flexibilities and the possible impact of the proposed Article 31(f) waiver.
- Engage in a meaningful negotiation for an effective solution of removing IP challenges as suggested in the original waiver proposal.

We also call on all countries to make use of all legal and policy measures,²³ including TRIPS flexibilities such as issuing compulsory license and suspension of IP enforcement at the national level, to address current IP barriers for COVID-19 medical tools and beyond.

Annex: Paragraph-by-Paragraph Comments on Reported Draft Text

Reported Draft Text	Comments
<p>1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member¹ may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter “the Agreement”) by authorizing the use of patented subject matter² 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.</p> <p><i>Footnote 1: For the purpose of this Decision, an ‘eligible Member’ means any developing country Member that exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.</i></p> <p><i>Footnote 2: For the purpose of this Decision, it is understood that ‘patented subject matter’ includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.</i></p>	<p>Scope of technologies:</p> <ul style="list-style-type: none"> Limited to vaccines, ingredients and process (Footnote 2) and ‘underlying technologies’ (Paragraph 3(a)). Not included: therapeutics, diagnostics and their ingredients and process. <p>Patented subject matter:</p> <ul style="list-style-type: none"> Patented subject matter may not include products for which there are pending patent applications. <p>Eligible members – per Footnote 1:</p> <ul style="list-style-type: none"> Per Footnote 1, developing countries with vaccine exports in 2021 less than 10% of world exports will be eligible. This criterion appears to exclude China as a developing country producer, exporter or importer of finished products and/or components/materials, as China, the US and the EU are the only ones that have exceeded 10% of world exports of COVID-19 vaccines in 2021.¹⁰ It is unclear whether ‘any developing country Member’ stated in Footnote 1 automatically includes LDC members. The draft text does not seem to allow supply to non-WTO members, which is problematic. Failing to include all people in all countries in a pandemic is concerning.
<p>2. For greater clarity, an eligible Member may authorize the use of patented subject matter 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.</p>	<p>There is no limitation under the TRIPS Agreement on the format of instrument that can be used by members to constitute ‘the law of the Member’ under Article 31. The proposed text here is a clarification of Article 31 of the TRIPS Agreement rather than a waiver.</p> <p>Terms such as ‘an eligible member’ and ‘for the purpose of this Decision’ could limit the general clarification to certain WTO members only.</p> <p>This general clarification of the meaning of TRIPS clause should not be subject to time and eligibility limitations (set forth in Paragraphs 1, 3 and 6) and should be applicable to all areas of health and technologies, for all WTO members, and for all kinds of compulsory licenses.</p> <p>While it is helpful to have a clarification, the requirements under Paragraph 3(a) and Paragraph 5 Footnote 4 may impose additional complexities for implementation and undermine the benefits.</p>
<p>3. Members agree on the following clarifications and waivers for eligible Members to authorize the use of patented subject matter in accordance with paragraphs 1 and 2:</p>	<p>While Paragraph 2 should be treated as a general clarification of a TRIPS provision, it should not be subject to limitations set forth in Paragraphs 1, 3 and 6.</p>

<p>(a) With respect to Article 31(a), an eligible Member may issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine. The authorization shall list all patents covered. In the determination of the relevant patents, an eligible Member may be assisted by WIPO's patent landscaping work, including on underlying technologies on COVID-19 vaccines, and by other relevant sources. An eligible Member may update the authorization to include other patents.</p>	<p>The text proposed here repeats what is already possible, i.e. issuing a single authorisation to cover multiple patents and multiple products. By reiterating this existing general practice to be applicable only for 'an eligible Member' and for COVID-19 vaccines is confusing.</p> <p>Requesting the authorisation to list all patents covered on vaccines and underlying technologies is a TRIPS-plus requirement.</p> <p>It misrepresents the meaning of 'individual merits' – which is meant to affirm national discretion in deciding the grounds for compulsory licensing and assessing individual cases of compulsory licensing – under Article 31(a) of the TRIPS Agreement, and risks diluting the existing flexibilities enjoyed by WTO members under the current text of Article 31(a).</p>
<p>(b) An eligible Member need not require the proposed user of the patented subject matter to make efforts to obtain an authorization from the right holder for the purposes of Article 31(b).</p>	<p>Article 31(b) of the TRIPS Agreement already allows members to waive the prior negotiation requirement when an authorisation is issued for emergencies, matters of extreme urgency, and public, non-commercial use. It may help to clarify that waiving the prior negotiation requirement covers both public authorities/governments and private sectors (e.g. contractor of a government agency or an assigned manufacturer by the government) as the 'proposed user', but it appears to be a bit redundant compared to the existing text of Article 31(b).</p> <p>This is a general clarification of Article 31(b) and should not be limited to only 'an eligible Member' nor be time-bound according to Paragraph 6. It should be applicable for all areas of technologies, all WTO members, and all kinds of compulsory licenses.</p>
<p>(c) 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 authorized use to be exported to eligible Members and to supply international or regional joint initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.</p>	<p>This is perhaps the only 'waiver' that is proposed. It intends to waive the requirement under Article 31(f) that products under a compulsory license should be predominantly used for domestic supply, hence limiting the possibility for exportation.</p> <p>It intends to address the unsuccessful implementation of Paragraph 6 of the Doha Declaration and should be considered as an interpretation to realise the mandate of the Doha Declaration for seeking an expedited solution for compulsory licensing.</p> <p>It could be helpful to have an Article 31(f) waiver without strings attached, which could ease exports without going through Article 31bis procedure. However, Footnote 4 and Paragraph 5 bring back unnecessary requirements of reporting and may undermine the intended positive impact in practice.</p>
<p>(d) Eligible Members shall undertake all reasonable efforts to prevent the re-exportation of the COVID-19 vaccine that has been imported into their territories under this Decision. All Members shall ensure the availability of effective legal remedies to prevent the importation into their territories of COVID-19 vaccines produced under, and diverted to their markets inconsistently with, this Decision.</p>	<p>This requirement is an undesirable carryover from Article 31bis to address a diversion problem that has never materialised in the past.</p> <p>There is no general obligation of anti-diversion under the TRIPS Agreement.</p>

<p>(e) 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.³</p> <p><i>Footnote 3: This includes the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)</i></p>	<p>There is nothing new in this sub-paragraph. Members have always had freedom to determine what is adequate remuneration.</p>
<p>4. Nothing in Article 39.3 of the Agreement shall prevent a Member from taking measures necessary to enable the effectiveness of any authorization issued as per this Decision.</p>	<p>This paragraph principally clarifies and reaffirms that Article 39.3 protection should be removed when issuing an authorisation for the use of patented subject matters by WTO members. This clarification of the meaning of TRIPS clause should not be time-bound and should be applicable to all disease areas and technologies, for all WTO members, and for all kinds of compulsory licenses.</p> <p>However, the text fails to recognise other barriers caused by confidential information/trade secrets beyond test data under Article 39.3, such as those covered by Articles 39.1 and 39.2.</p> <p>It also restricts the flexibility for members to exempt test data protection/exclusivity ‘when necessary to protect the public’, and not just for compulsory licenses. It is worth noting that test data/market exclusivity can be a stand-alone barrier that needs to be removed. The current text here does not address that situation.</p>
<p>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.⁴</p> <p><i>Footnote 4: The information provided shall include the name and address of the authorized entity, the product(s) for which the authorization has been granted and the duration of the authorization. The quantity(ies) for which the authorization has been granted and the country(ies) to which the product(s) is(are) to be supplied shall be notified as soon as possible after the information is available.</i></p>	<p>The text does not specify what is ‘the measure’, and whether the requirement as such is specifically linked to the measure proposed in paragraph 3(c) or in general situations of compulsory licensing.</p> <p>Footnote 4 introduces unnecessary additional steps and procedures on reporting of the implementation status.</p> <p>Members already publish such authorisations and should only be required to report the general implementation status, without being requested to provide the details as suggested by Footnote 4.</p>

<p>6. An eligible Member may apply the provisions of this Decision until [3][5] years from the date of this Decision. The General Council may extend such a period taking into consideration the exceptional circumstances of the COVID-19 pandemic. The General Council will review annually the operation of this Decision.</p>	<p>Similar to the South Africa/India TRIPS waiver proposal text.</p>
<p>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.</p>	<p>Similar to the South Africa/India TRIPS waiver proposal text.</p>
<p>8. No later than six months from the date of this Decision, Members will decide on its extension to cover the production and distribution of COVID-19 diagnostics and therapeutics.</p>	<p>The exclusion of therapeutics and diagnostics is a hugely problematic concession. There are present access barriers and a supply shortage of priority therapeutics recommended by WHO and approved by regulatory bodies. While the decision date of the proposed waiver on vaccines remains unknown, another six months of delay adds more uncertainty.</p>

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