Summary Comments on the March 15 TRIPS Waiver Leaked Text

Professor Brook Baker
Professor of Law, Northeastern University and Senior Policy Analyst, Health GAP (Global Access Project)
(based on inputs from multiple civil society experts)

March 23, 2022

1. The reported discussion outcome text (http://freepdfhosting.com/4d79fc6c70.pdf) presents some clarifications on the current TRIPS agreement particularly concerning CL on patents of vaccines; however, due to the limitations presented, it is far from being an IP "waiver" for pandemic medical tools. The proposed text still requires authorisation on a product by product basis, which was one of the shortcomings of the existing mechanism.
2. The reported outcome text does not accomplish the purpose of enabling manufacture of vaccines because it focuses on patent rights and a single Article 39.3 exception only, but **not trade secrets** more broadly. Since the beginning of the pandemic, it has been clear that alternative producers would need access to trade-secrets and confidential information, data, and know-how especially for vaccines and biologic medicines. The first three paragraphs of the proposed text focus on patents only and paragraph 4 imposes no obligation on Article 39.1 and 39.2 confidential-information/trade-secret rightholders to disclose manufacturing know how, quality assurance protocol, data, and other information and materials necessary for commercial scale production and quality assurance. Instead it principally clarifies what most experts agree to be true that data protections under Article 39.3 do not foreclose regulatory decisions concerning follow-on products that rely upon or reference originator regulatory data or the fact of a prior regulatory decision.
3. The scope of products/technologies **excludes therapeutics and diagnostics**, ignoring the present access barriers caused by IP and difficulties of using existing mechanism to facilitate collaboration and supply among countries (e.g. Latin American exclusion maps)
    - *Per para 8 of the text, WTO members will decide on the proposal's extension to therapeutics and diagnostics within six months. However, there is no guarantee that WTO will decide in 6 months. The limited scope of the TRIPS waiver will significantly impact COVID-19 treatments like baricitinib, which is not accessible in many countries due to patent barriers and geographical exclusions in licenses. Any outcome on COVID-19 should also apply to diagnostics and therapeutics as these are essential aspects of containment of COVID-19.*
4. **Arbitrary exclusion of many LMICs** that would logically be eligible to use the mechanism because they may be self-defined as "developed" countries at the WTO. China is also irrationally excluded as an eligible developing country because of it percentage in the supply of covid vaccines (over 10%). Countries that are not "eligible countries" cannot use the new mechanism to allow patent-blocked manufacturers to produce or export, even to eligible members, nor can they use the mechanism to import. The exclusion of many of

these countries with manufacturing and supplying capacities is hugely problematic both in the vaccine context, and potentially in the future with respect to tests and treatments. The failure to include reference to LDCs and non-WTO members rights as eligible countries might deprive them from the benefits of this agreement.

5. Para 3(a) introduces **TRIPS-plus requirement** of issuing compulsory licenses purely on vaccine product-by-product basis for listing all relevant patents when countries use CLs. These two requirements undermine existing flexibilities under Art 31(a) for countries to define the ground for CLs based on "individual cases" (not necessarily based on individual patents or even individual products). The duty to list patents will be burdensome and continuous given the number of component products and final vaccines that might be patent protected. The problem is compounded by the failure of the mechanism to expressly include pending patents and the problem of currently unpublished patent applications and the possibility of continued patent filings. State practice has been to the contrary to such requirements even in high-income countries. See, e.g.,
    - *Germany: In March 2020, Germany passed a new bill, the "Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance," amending the Prevention and Control of Infectious Diseases in Humans Act. Among other measures, the bill empowers the Federal Ministry of Health to instruct a government use of patented subjects concerning "medicinal products including narcotics, the active ingredients, starting materials and excipients for these, medical devices, laboratory diagnostics, aids, as well as items of personal protective equipment and products for disinfection." The measures should remain in place until an epidemic situation of national significance is revoked. This approach does not limit the action to individual patents and individual products but reflects the evolving and fluid situations of the pandemic.*
6. While waiving certain clauses such as Art31(f) is a welcomed step to easing CL for exportation, the text (footnote 4 and para 3(d)) introduces unnecessary steps and WTO reporting requirements that could undermine the effectiveness of the proposed waiver to this article. The notification requirements are imposed in compulsory licensing cases where even Article 31bis did not previously require notification, e.g. importation from a country where no CL is otherwise required.
7. WTO members should beware of the risks of the problems contained in the current text and remove problematic text and improve the scope and inclusion to realize the present barriers to access.
8. WTO members should also be aware of other existing flexibilities that might be superior to this proposal:
    a. Suspension of all national intellectual property protections on COVID-19 countermeasures under Article 73.
    b. Utilization of Article 30 to create a limited exception under Article 31(f) to allow unlimited export to other countries.
    c. Issuance of a competition-based license under Article 31(k) (for abuse of patent, excessive pricing, refusal to license, or other competition grounds) so as to allow unlimited exports to other countries.
    d. A judicial license under Article 44 of the TRIPS Agreement may not impose a export quantity limitation.
    e. Issuance of even an ordinary CL allows for export of non-predominate quantities without the new TRIPS-plus requirement in the proposed text.

Paragraph to paragraph comments

Discussion outcome text	Comments
1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member[1] may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing the use of patented subject matter[2] 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. 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. Footnote 2: For the purpose of this Decision, it is understood that 'patented subject matter' includes	**Scope of technologies:** - Limited to vaccines, ingredients and process (footnote 2) and "underlying technologies" (para 3(a)) - Not included: therapeutics, diagnostics and their ingredients and process **Patented subject matter:** • patented subject matter on its face does not include products for which there are pending patent applications, which is highly problematic as discussed further below. **Necessity test** • A necessity test is highly problematic if it is stringently construed as such clauses often are in international legal instruments. **Eligible members --- per footnote 1:** - Per footnote 1, the <10% of world exports criterion appears to exclude China as a producer, exporter or importer of finished products and/or components/materials. (https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm) - If the mechanism was to be extended to therapeutics and diagnostics in the future (per para 8), the exclusion of countries with manufacturing and supplying capacities is hugely problematic - Under WTO, categories of countries are not based on income status as those under World Bank definition. Instead, WTO uses "developing", "developed" and "LDC" categories for countries. There is no definition of "developed" and "developing" countries, both categories are largely based on self-declaration.

ingredients and processes necessary for the manufacture of the COVID-19 vaccine.	- There is however a defined scope of Least-developed Countries (LDC) following UN definition. It is unclear whether "any developing countries" stated in footnote 1 automatically includes LDC members - Knowing which countries are developing is not clear or straightforward. Brazil, Singapore, South Korea, and many other countries may have given up the status as "developing countries" in WTO and hence may be excluded from being eligible though this outcome is not certain: see, e.g., https://geneva.usmission.gov/2020/01/27/statement-by-ambassador-shea-at-davos-informal-wto-ministerial-gathering/ - The solution text does not allow supply to non-WTO members which is discriminatory and problematic. - Russia may have given up the status as a "developing country" upon WTO accession (TBC), and hence may be excluded from being eligible: https://www.sciencedirect.com/science/article/pii/S1877705816341789
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	There is no explication and limitation under TRIPS agreement on the format of instrument that can be used by the members to constitute "the law of the Member" under the current Art 31 of TRIPS agreement. The proposed text here is rather a clarification than a waiver. While it is helpful to have a clarification that a enacted compulsory license regime need not be in place, the requirements under para 3(a) and footnote 4 may impose additional complexities for implementation.

executive orders, emergency decrees, and judicial or administrative orders.	
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:	
(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.	There is no restriction of how a member implements Article 31 (a) which requires a compulsory license to be considered based on "individual merits." There is not even a requirement that CLs be issued on a product by product basis. The text proposed here is repetitive of what's already possible (e.g. single authorization to cover multiple patents); but also imposes some TRIPs-plus requirements (e.g. listing of all patents). Firstly, in reality and based on past experiences of using compulsory license by WTO members, it is already possible for member to issue a single authorization towards multiple patents associated with the concerned subject matter. It's redundant to repeat what's already possible. Secondly, requesting the authorization to list all patents covered on vaccines and underlying technologies is a TRIPS-plus requirement. It mispresents the meaning of "individual merits" under Art 31(a) of TRIPS agreement, and risks diluting the existing flexibilities enjoyed by WTO members under the current text of Art 31(a). According to literature documenting the negotiation history of TRIPS agreement (https://www.wto.org/english/res_e/booksp_e/trips_agree_e/chapter_16_e.pdf), "Individual merits" under Art 31(a) refers to the flexibilities for members to handle each case of compulsory license based on the individual situation and to freely define the

	grounds based on which a compulsory license will be granted. Handing compulsory license based on "individual merits" under Art 31(a) is never meant to request targeting individual patents. It has been documented, particularly, that during TRIPS negotiation, it was the US and India who had settled the open-ended nature and the meaning of "individual merits" under Art31(a) to affirm national discretion on individual cases. It is therefore surprising that a clear restrictive interpretation has been presented in this discussion text involving US and India negotiators. On the other hand, even with the flexibility of handing each case on its individual merits under Art 31(a), the pandemic has presented unprecedented challenges while the virus continues to evolve and mutates, alongside evolving and fluid technology landscape as candidates of therapeutics, vaccines and diagnostics continue to evolve. The product-by-product rationale under the current Art 31(a) does not provide an adequate approach to tackle pandemic challenges. In summary, Para 3(a) is redundant and even as a restrictive clarification it risks diluting the existing flexibilities under Art 31(a) concerning authorizing compulsory license based on "individual merits" at national competence and discretions and introducing TRIPS-plus requirements for listing all patents when issuing a compulsory license. **Example:** Germany: In March 2020, Germany passed a new bill, the "Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance," amending the Prevention and Control of Infectious Diseases in Humans Act. Among other measures, the bill empowers the Federal Ministry of Health to instruct a government use of patented subjects concerning "medicinal products including narcotics, the active ingredients, starting materials and excipients for these, medical devices, laboratory diagnostics, aids, as well as items of personal protective equipment and products for disinfection." The

	measures should remain in place until an epidemic situation of national significance is revoked. This approach does not limit the action to individual patents and individual products but reflects the evolving and fluid situations of the pandemic. It is deeply problematic to require that the implementing instrument list all patents, especially in an emerging pandemic when new patents are being filed by the thousands. Many of these patent applications are filed through the WIPO Patent Cooperation Treaty while others are filed, unpublished, in national patent offices. These applications are not even in the public domain yet. They are both unknown and pending. To allow bypass of listed granted patents, but not pending and unpublished and future patents on the same subject matter presents a logistical quagmire for the use of this proposed solution. These problems are compounded by the need to investigate and list patents on all patented components of a final vaccine, some of which are reported to have as many as 280 components. Needless and expensive efforts will be require to scour patent and pending patent landscape and to continually update previously filed instruments.
(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).	Article 31(b) already allow waiving the prior negotiation requirement when CL is issued for emergencies, matters of extreme urgency, and public, non-commercial use. It may help to clarify that waiving 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 comparing to the existing text of Art 31(b).
(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	This is perhaps the only "waiver" that goes beyond the existing TRIPS text. It is helpful to have Art 31(f) waiver, which eases exports without going through Art 31bis procedure. Yet, footnote 4 brings back unnecessary requirements of reporting, and may undermine the positive impact of waiving Art 31(f) in practice.

that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.	
(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.	This anti-diversion requirement is TRIPS-plus and imposes such requirements on importing countries that would not otherwise be required by either Art. 31 or Art 31 bis. This requirement is an undesirable carryover from Article 31bis to address a diversion problem that has never materialized in the past. Members are free to adopt their own exhaustion rules and if they want to prevent parallel import, they may adopt national law that accomplishes this outcome. Question on how/why "all members" shall ensure legal remedies to prevent division when only certain members are eligible to use this proposal
(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	There is nothing new in this subparagraph. Members have always had freedom to determine what is adequate remuneration. The factors listed here are certainly relevant but an even better clarification would have indicated that members were free to adopt minimal remuneration rates via guidelines or other general rules. Because this sub-paragraph does not refer to the possibility/problem of double remuneration (royalties in both the country of manufacture/export and the country of importation use), it potentially undermines the existing rule in Art. 31 bis that limits remuneration to payment based on the value of the authorization in the country of importation when there might otherwise be double-remuneration.

emergencies, pandemics, or similar circumstances.[3] 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)	
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.	This paragraph principally clarifies what most experts agree to be true – that data protections under Article 39.3 do not foreclose regulatory decisions concerning follow-on products that rely upon or reference originator regulatory data or the fact of a prior regulatory decision. Some countries may have ill-advisedly adopted data and market exclusivity rules with respect to regulatory data in which case there should be an exception to meet public health and public interest needs. However, even in those cases where an exception might be needed, the existing text is too narrow because it only addresses circumstances where steps are being taken to override patent rights, e.g., to issue a license. However, there can be cases where there is no blocking patent, but there is data/market exclusivity, in which case the current text provides no relief. Some national laws have flexibility to override Art 39.3 obligation in the event of using a CL; yet for countries who do not have such laws in place, this clarification may help. Annex 1 of the full text also states that "… In other words, the company authorised to manufacture the vaccine without the consent of the patent holder can rely on that data (which is very costly to generate) to accelerate the authorisation from the regulatory authorities." However, the text missed the recognition of other barriers caused by confidential information/trade secrets beyond test data under Art 39.3, such as those covered by Art 39 1 and 2. This is a major defect in the proposed text.

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] 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	Footnote 4 introduces unnecessary additional steps and procedures on reporting of the implementation status. There is no discernible public benefit of this requirement which is an unneeded carry-over from Art. 31bis While waiving Art 31(f) is a positive step, Footnote 4 requirements have the drawback of undermining the efficiency of implementation. Members should only be required to report the implementation status as part of the routine notification of national law and policy status, without being requested to provide the details as suggested by Footnote 4. This text imposes Article 31 *bis*-style reporting requirements even where they would not otherwise be required.
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.	Similar to the SA/India proposal text
7. Members shall not challenge any measures taken in conformity with this Decision under	Similar to the SA/India proposal text

	subparagraphs 1(b) and 1(c) of Article XXIII of the GATT 1994.	
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.	The exclusion of therapeutics and diagnostics is a hugely problematic concession. There are present access barriers and 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 6 months of delay adds more uncertainties to address access challenges.