WORKING DOCUMENT

Collection of textual proposals and suggestions as of 25 May 2022
(*6 p.m.*)

1. [Notwithstanding the provision of patent rights under its domestic legislation,] [A][a]n [eligible] Member[1] may [limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter "the Agreement") by authorizing][authorize] the use of the subject matter of a patent[2] ~~whenever necessary~~ [required for][for the purpose of] 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.

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) [*deleted*]

   (b) 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).

   (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]*[COVID-19 vaccine produced under the authorization in accordance with this Decision] 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[, provided that any supply to international or regional joint initiatives is only used to supply eligible Members].

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[1] [For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with capacity to export vaccines are encouraged to opt out from this Decision.] [For the purpose of this Decision, developing country Members who exported more than 10 percent of world exports of COVID-19 vaccine doses in 2021 are not eligible Members.]

[2] For the purpose of this Decision, it is understood that 'subject matter of a patent' [includes][means patented finished COVID-19 vaccine products, patented] ingredients and [patented] processes [necessary for][in relation to] the manufacture of the COVID-19 vaccine.

* [authorized subject matter of a patent]
* [production authorized in accordance with this Decision]

New footnote suggestion

It is understood that in the case of international and regional joint initiatives, the exportation is intended to benefit eligible Members.

(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. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of COVID-19 vaccines produced under this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.

(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.

4. Nothing in Article [39][39.3] of the Agreement shall prevent an [eligible] Member from taking measures [essential][necessary] [to] [that would] enable the effectiveness of any authorization issued as per this Decision [without prejudice to the provisions of undisclosed information under Members' domestic legislation]. [[Except as otherwise provided for in Article 39.3, n][N]othing in this paragraph shall be interpreted as allowing the disclosure of undisclosed information submitted by the originator to the respective authorities of an eligible Member in a marketing approval procedure.]

5. For purposes of transparency, as soon as possible after the adoption of the measure [and before the shipment takes place], 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.[3]

6. [An [eligible] Member may apply the [waiver] provisions of this Decision [so that authorized uses continue no later than][until][3][5][10] years from the date of this Decision.[*reflect as end date as per IX:4*]] [This Decision applies for a period of [..] from the date of adoption.] ~~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 [and the waiver it contains in accordance with Article IX:4 of the Marrakesh Agreement].

[3] 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

7. [*deleted*]

8. [No later than [six][three] months from the date of this Decision, Members [will][shall] [discuss][decide] [whether to extend this decision] [on its extension] to cover the production [and exportation][and distribution] of COVID-19 diagnostics and therapeutics.]
Alternative wording
[Members will continue to discuss the extension of this decision to cover the production and distribution of COVID-19 diagnostics and therapeutics.]

New paragraph suggestion

9. [[For greater certainty] [N]nothing in this Decision shall [be [interpreted as] [used] to] limit[ing] flexibilities provided for in the TRIPS Agreement [or to interpret any right or obligation outside its scope][, including the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)].] [or as hindering other uses under the TRIPS Agreement of the clarifications provided in paragraphs 2, 3(b) and 3(e) of this Decision.]

New paragraph suggestion

9. [This Decision is without prejudice to [the rights, obligations and] flexibilities that Members have under the provision of the TRIPS Agreement, as affirmed and interpreted by the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2.] ~~other than Article [28.1, Articles]31 [(a), (b),] (f)[, and (h), and Article 39.3 including those reaffirmed by the Declaration] and their interpretation.~~]