



DRAFT MINISTERIAL DECISION ON THE TRIPS AGREEMENT

Revision

The Ministerial Conference,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization.

Noting the exceptional circumstances of the COVID-19 pandemic;

Decides as follows:

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 the subject matter of a patent² 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.
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).
 - (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, including through international or regional joint

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 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.

² For the purpose of this Decision, it is understood that 'subject matter of a patent' includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.

initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.

- (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.
- (d) 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
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
6. An eligible Member may apply the provisions of this Decision until 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.
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.
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.
9. This Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities 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.

³ In exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes, as long as the eligible Member communicates in accordance with paragraph 5.

⁴ This includes the remuneration aspects of the WHO-WIPO-WTO Study on Promoting Access to Medical Technologies and Innovation (2020), and the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1).

⁵ 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.