



**Council for Trade Related Aspects
of Intellectual Property Rights**

COMMUNICATION FROM THE CHAIRPERSON

The following letter was received by the Chair of Council for TRIPS on 3 May 2022 and is circulated to Members at the request of the Director-General.



Ngozi OKONJO-IWEALA
Director-General

3rd May 2022

Excellency,

I am writing to inform you about progress regarding the informal TRIPS Waiver discussions. You may recall that at the Informal Heads of Delegation meeting on 3 December 2021, the Chairs of the General Council and the TRIPS Council reported on their efforts with Members regarding the WTO Response to the Pandemic and the TRIPS Waiver. What was evident was the need for additional impetus to the TRIPS Waiver discussions given the impasse in the TRIPS Council. I therefore informed Members that I would be reaching out to various Ministers for needed input. In this regard, working with DDG Gonzalez, we have tried to support an informal group of Ministers to come together around what could be a meaningful proposal, without prejudice to their respective positions, that could provide a platform to be built upon by the membership.

As I have informed Members on several occasions during TNC and General Council meetings – the most recent briefing being at the 28 March Informal General Council, I assured Members that whatever outcome emerged from this informal process would be put forward transparently to the full Membership for discussion in the TRIPS Council. Please now find attached the outcome of this process for your information. For transparency purposes, Ambassador, I request you as TRIPS Council Chair to bring the contents of this letter to the attention of the TRIPS Council.

I am grateful to all Members for their understanding and patience during this informal process.

Please accept, Ambassador, the assurance of my highest consideration.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Ngozi Okonjo-Iweala". Below the signature, the text "Dr. Ngozi Okonjo-Iweala" is printed in a smaller font.

Dr. Ngozi Okonjo-Iweala

H.E. Ambassador Lansana Gberie
Chair of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS)
Permanent Representative of Sierra Leone to the UN and the WTO
Route de Ferney 194, Grand-Saconnex
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TRIPS COVID-19

03 May 2022

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.
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.
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.]³
 - (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).
 - (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

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 'patented subject matter' includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine.

³ This paragraph is under further consideration as to whether to keep or delete.

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.

- (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.
- (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
- 4. Nothing in Article 39.3 of the Agreement shall prevent an eligible Member from taking measures necessary to enable the effectiveness of any authorization issued as per 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 [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.
- 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 distribution of COVID-19 diagnostics and therapeutics.

⁴ This includes 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
