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INTRODUCTORY NOTE TO MINISTERIAL DECISION ON THE TRIPS AGREEMENT (WTO)

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[June 17, 2022]

On June 17, 2022, the World Trade Organization (WTO) Ministerial Conference issued a "Draft Ministerial Decision on the TRIPS Agreement," addressing the requirements established in Articles 31 and 39.3 of the TRIPS Agreement in the context of the COVID-19 pandemic.[1] The Decision provides several clarifications regarding the process by which member countries may "authorize the use of the subject matter of a patent" without the consent of the right holder for the purposes of "production and supply of COVID-19 vaccines."[2] The decision provides guidance to countries considering the use of legal mechanisms, particularly compulsory licenses, to transfer vaccine technology with the goal of increasing the number of doses of COVID-19 vaccine available to underserved populations, especially in lower-income countries.

Background

The World Health Organization (WHO) declared COVID-19 a pandemic in March 2020.[3] As the first diagnostics, vaccines, and treatments for COVID-19 were being developed, it quickly became apparent that production levels would be insufficient to meet global demand. It also became apparent that limited supplies would be allocated predominantly to higher-income countries, even though populations in lower-income countries were disproportionately being affected by the pandemic.[4] In October 2020, India and South Africa requested that the Council for Trade-Related Aspects of Intellectual Property Rights recommend the adoption of a temporary "waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19."[5]

Informal discussions of the proposed waiver occurred throughout 2021 and early 2022.[6] Over one hundred countries expressed support for a temporary waiver covering diagnostics, vaccines, and treatments for COVID-19. By contrast, a smaller number of higher-income countries opposed the initial waiver proposal. After months of stalled negotiations, the WTO considered and adopted a Decision covering COVID-19 vaccines at the 12th Ministerial Conference that met from June 12–17, 2022. The adopted Decision was based largely on a text proposed by the European Union.

The Ministerial Decision

The decision provides clarifications on several parts of Article 31 and on Article 39.3 of the TRIPS Agreement. It also allows eligible countries to temporarily waive the restrictions imposed by the TRIPS Agreement on product exports, but only with regard to COVID-19 vaccines or components thereof. Similarly, every other provision in the Decision applies solely to COVID-19 vaccines or components thereof. This constitutes a departure from the scope of the initial proposal, which sought to cover multiple types of pharmaceutical products, including diagnostics and therapeutics, and which would have resulted in a waiver to multiple provisions of the TRIPS Agreement for the remainder of the duration of the COVID-19 pandemic.[7]

The Decision reaffirms the availability of the regime set forth in Article 31 of TRIPS, which enables member countries to allow the "use of the subject matter of a patent without the authorization of the right holder."[8] The Decision clarifies the concept of "law of a Member" in Article 31 of TRIPS as encompassing both legislative and non-legislative acts.[9] Through their laws, regulations and other legal mechanisms, members may thus authorize the use of patents covering "ingredients and processes necessary for the manufacture" of COVID-19 vaccines without the consent of the rights holder.[10] The Decision further clarifies that members do not need to require proposed users "to make efforts to obtain an authorization from the right holder as set out in Article 31(b)."[11]

The most significant changes introduced by the decision appear in the context of exports of COVID-19 vaccines. The Decision allows countries to temporarily "waive" the requirement set forth in Article 31(f) of TRIPS, which establishes that authorized uses must be "predominantly for the supply of the domestic market of the Member authorizing

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such use."[12] Eligible members may thus "allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members."[13] The Decision deems all developing countries eligible members for purposes of the application of the decision, but notes that those "with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves" of the Decision.[14] Moreover, it directs members to "undertake all reasonable efforts to prevent the re-exportation" of products manufactured pursuant to an "authorization in accordance" with the Decision.[15] Nevertheless, if "exceptional circumstances" arise, eligible members may re-export COVID-19 vaccines "for humanitarian and not-for-profit purposes"[16] with the obligation to notify the TRIPS Council "as soon as possible" of the adoption of such a measure.[17] The Decision does not, however, provide a definition of what may constitute "exceptional circumstances" within the context of the COVID-19 pandemic.

With regard to the determination of adequate remuneration of rights holders as required by Article 31(h) of TRIPS, the Decision notes that members may consider the "humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines," as well as "existing good practices in instances of national emergencies, pandemics, or similar circumstances."[18]

The Decision also addresses Article 39.3 of TRIPS, which mandates the protection against unfair commercial use of data containing undisclosed information submitted to regulators as part of an application to market a new pharmaceutical product.[19] The Decision notes that these requirements do "not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision."[20]

The provisions contained in the Decision will be in effect for a period of five years, counted from the date of the Decision, with the possibility of a future extension if the circumstances of the pandemic warrant it, and an obligation of annual review imposed on the General Council.[21] Six months after the date of the Decision, members will decide on whether to extend it to cover "production and supply of COVID-19 diagnostics and therapeutics."[22]

Significance

As adopted, the Decision is considerably narrower in scope than the original proposal. It covers only one type of pharmaceutical product, albeit a critically needed one in the response to the COVID-19 pandemic. Moreover, the Decision does not address the legal and practical issues posed by the existence of trade secrets and related hurdles to the transfer of tacit knowledge needed to scale up the manufacturing of COVID-19 vaccines (and, potentially diagnostics and therapeutics, should there be an extension).

The Decision also addressed a more limited set of legal issues than those implicated by the waiver proposal submitted by India and South Africa. As a whole, the Decision cannot be considered a waiver proper, but rather a set of clarifications to Articles 31 and 39.3 of TRIPS, with the addition of an ad hoc temporary modification (labeled a waiver) to the specific issue of product exports.

Furthermore, the Decision allows and encourages countries with existing manufacturing capacity to explicitly bind themselves to not use the framework it provides and, by extension, the underlying TRIPS Agreement provisions.

Against this backdrop, the access-to-medicines community and global health commentators largely expressed disappointment at the narrower scope of the Decision compared with the waiver as initially proposed, and further pointed out that the Decision is unlikely to have a significant impact on the manufacturing and equitable distribution of COVID-19 vaccines.

Nonetheless, the Decision can be viewed as a starting framework that can be expanded on for future interventions. It also expressly articulates the possibility of an extension to cover other types of pharmaceutical products, underscoring the need for continued reassessment of the international intellectual property framework applicable to the transfer of pharmaceutical technologies, particularly during transnational public health crises. Additionally, the temporary modification introduced by the Decision in the area of product exports is less restrictive than that presently codified in the TRIPS Agreement,[23] and may function as a blueprint for future revisions of Article 31*bis* of the Agreement.

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ENDNOTES

1 Draft Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/W/15/Rev.2 (Jun. 17, 2022) [hereinafter Decision]

2 *Id.* ¶ 1

3 *See* World Health Org., *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19, March 11, 2020*, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—11-march-2020.

4 *See, e.g.,* Duke Global Health Inst., *Will Low-Income Countries Be Left Behind When COVID-19 Vaccines Arrive?*, https://globalhealth.duke.edu/news/will-low-income-countries-be-left-behind-when-covid-19-vaccines-arrive.

5 Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, ¶ 12 [hereinafter Waiver Proposal].

6 Communication from the Chairperson, IP/C/W/688 (2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True.

7 Waiver Proposal, *supra* note 5.

8 TRIPS, art. 31.

9 Decision, ¶ 2.

10 *Id.*, note 2.

11 *Id.* ¶ 3(a). Article 31(b) of the TRIPS Agreement already gives Members the ability to waive the requirement in cases of "a national emergency or other circumstances of extreme urgency," a criterium likely met by the COVID-19 pandemic.

12 TRIPS, art. 31(f).

13 Decision, ¶ 3(b).

14 *Id.*, note 1.

15 *Id.* ¶ 3(c).

16 *Id.*, note 5.

17 *Id.* ¶ 5 and note 5. Timeliness requirements in notifying the TRIPS Council extend to the adoption any measures pursuant to the Declaration. *Ib*.

18 *Id.* ¶ 3(d).

19 TRIPS, art. 39.3.

20 Decision, ¶ 4.

21 *Id.* ¶ 6.

22 *Id.* ¶ 8.

23 *See* TRIPS, art. 31*bis* and Annex to the TRIPS Agreement, art. 1(b).

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Ministerial Conference
Twelfth Session
Geneva, 12-15 June 2022

Original: English

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 Member[1] 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 patent[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.

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:

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(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 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.

ENDNOTES

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.

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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.

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.

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