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The WTO TRIPS decision on COVID-19 vaccines: What is needed to implement it?

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Research
Paper

8 November 2022

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Carlos M. Correa and
Nirmalya Syam



 **SOUTH
CENTRE**



RESEARCH PAPER

169

THE WTO TRIPS DECISION ON COVID-19 VACCINES: WHAT IS NEEDED TO IMPLEMENT IT?

Carlos M. Correa^{*} and Nirmalya Syam^{}**

SOUTH CENTRE

8 NOVEMBER 2022

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ABSTRACT

The 12th WTO Ministerial Conference adopted a Ministerial Decision on the TRIPS Agreement on 17 June 2022. This partially concluded almost two years of protracted discussions in response to a proposal by India and South Africa for a waiver from certain obligations under the TRIPS Agreement for health products and technologies for the prevention, treatment and containment of COVID-19. The adopted Decision only waives the obligation under article 31 (f) of the TRIPS Agreement. Developing country WTO members are now allowed to export any proportion of vaccines, including ingredients and processes, necessary for the COVID-19 pandemic that are manufactured under a compulsory license or government use authorization to other developing countries. It also contains some clarifications of relevant TRIPS provisions, while introducing a number of conditionalities that are not present in the TRIPS Agreement. This paper examines the object and scope of the Decision, the requirements established for its use, and the required actions to be taken by WTO members to implement it.

La 12ª Conferencia Ministerial de la OMC adoptó el 17 de junio de 2022 una Decisión Ministerial sobre el Acuerdo ADPIC. Con ello se concluyeron parcialmente casi dos años de prolongados debates en respuesta a una propuesta de la India y Sudáfrica de exención de determinadas obligaciones en virtud del Acuerdo sobre los ADPIC para los productos y tecnologías sanitarios destinados a la prevención, el tratamiento y la contención del COVID-19. La Decisión adoptada sólo exime de la obligación prevista en el artículo 31 (f) del Acuerdo sobre los ADPIC. Los países en desarrollo miembros de la OMC están ahora autorizados a exportar a otros países en desarrollo cualquier proporción de vacunas, incluidos los ingredientes y procesos, necesarios para la pandemia de COVID-19 que se fabriquen bajo licencia obligatoria o autorización de uso gubernamental. También contiene algunas aclaraciones de las disposiciones pertinentes de los ADPIC, al tiempo que introduce una serie de condiciones que no están presentes en el Acuerdo sobre los ADPIC. Este documento examina el objeto y el alcance de la Decisión, los requisitos establecidos para su uso y las medidas que deben tomar los miembros de la OMC para aplicarla.

La 12ème Conférence ministérielle de l'OMC a adopté une Décision ministérielle sur l'Accord sur les ADPIC le 17 juin 2022. Cette Décision a partiellement conclu près de deux ans de discussions prolongées en réponse à une proposition de l'Inde et de l'Afrique du Sud pour une dérogation à certaines obligations de l'Accord sur les ADPIC pour les produits et technologies médicaux pour la prévention, le traitement et le confinement du COVID-19. La Décision adoptée ne renonce qu'à l'obligation prévue par l'article 31 (f) de l'Accord sur les ADPIC. Les pays en développement membres de l'OMC sont désormais autorisés à exporter vers d'autres pays en développement toute proportion de vaccins, y compris les ingrédients et les procédés, nécessaires à la lutte contre la pandémie de COVID-19 fabriqués dans le cadre d'une licence obligatoire ou d'une utilisation par les pouvoirs publics. Il contient également certaines clarifications des dispositions pertinentes de l'Accord sur les ADPIC, tout en introduisant un certain nombre de conditionnalités qui ne figurent pas dans l'Accord sur les ADPIC. Ce document examine l'objet et le champ d'application de la Décision, les exigences établies pour son utilisation, et les actions à entreprendre par les membres de l'OMC pour sa mise en œuvre.

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1. INTRODUCTION

After nearly two years since the submission of a proposal for a “TRIPS waiver” submitted by India and South Africa, co-sponsored by other 65 WTO Member States, and supported by more than 100 countries, the 12th WTO Ministerial Conference adopted a “Ministerial Decision on the TRIPS Agreement” (hereinafter “the Decision”)² on 17 June 2022. In contrast to the original waiver proposal, this Decision provides a very limited waiver and some clarifications of existing flexibilities under the Agreement on Trade-related Aspects of Intellectual Property Rights (“the TRIPS Agreement”).

The original TRIPS waiver proposal aimed at suspending the application of sections 1, 4, 5 and 7 of part II and their related enforcement obligations under part III of the TRIPS Agreement, in relation to health products and technologies for the prevention, treatment or containment of COVID-19. The covered health products and technologies included vaccines, diagnostics, therapeutics, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture.³

As examined elsewhere,⁴ the main purpose of the waiver request was to allow for a rapid expansion of the manufacturing capacity to produce COVID-19 vaccines and other products in a context where the supply was insufficient and there was a dramatic asymmetry in the access to vaccines by developed and developing countries, as voiced by the World Health Organization, world leaders and many scholars and civil society organizations.⁵ As noted in a South Centre study, the vaccine industry at the time of the emergence of COVID-19 was dominated by a few large firms in an oligopoly market structure that erected high barriers to new entrants.⁶ Rapidly increasing the vaccines supply in view of the deadly effects of the pandemic was hence essential particularly to allow for the vaccination of the populations in developing countries, most of them dependent on foreign supplies. The African Continent,

² WTO document WT/MIN(22)/W/15/Rev.2. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:WT/MIN22/W15R2.pdf&Open=True>.

³ WTO document IP/C/W/669/Rev.1. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:IP/C/W669R1.pdf&Open=True>.

⁴ See, e.g., Carlos M. Correa, “Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South”, Policy Brief No. 92, South Centre, April 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>; Henrique Zeferino de Menezes, *The TRIPS Waiver Proposal: An Urgent Measure to Expand Access to the COVID-19 Vaccines*, Research Paper 129 (Geneva, South Centre, 2021). Available from <https://www.southcentre.int/wp-content/uploads/2021/03/RP-129.pdf>; Carlos M. Correa et al., *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements*, Research Paper 135 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP135_Implementation-of-a-TRIPS-Waiver-for-Health-Technologies-and-Products-for-COVID-19_EN-1.pdf; Olga Gurgula, “Compulsory Licensing vs. the IP Waiver: what is the best way to end the COVID-19 Pandemic?”, Policy Brief No. 104, South Centre, October 2021. Available from https://www.southcentre.int/wp-content/uploads/2021/10/PB104_Compulsory-licensing-vs.-the-IP-waiver_EN-2.pdf; Srividhya Ragavan, “Waive IP Rights & Save Lives”, SouthViews No. 231, South Centre, 29 November 2021. Available from https://www.southcentre.int/wp-content/uploads/2021/11/SV231_211129.pdf.

⁵ See for example, MSF Access Campaign, “Compromise neglects COVID-19 treatments and diagnostics and fails to address intellectual property barriers beyond patents, but there’s still time to get it right”, Press Release, 16 March 2022, Geneva. Available from <https://msfaccess.org/msf-responds-potential-compromise-trips-waiver>; Public Citizen, “Leaked WTO Text Would Undermine Global Access to Medicines”, 18 April 2022, available from <https://www.citizen.org/article/leaked-wto-proposal-is-not-the-covid-19-medicines-waiver-we-need/>; Hyo Yoon Kang et al., “Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal”, LSE Law - Policy Briefing Paper No. 46, 13 July 2021, available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3885568.

⁶ See Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper No. 131 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf.

for instance, only produced 2 per cent of the vaccines it needed to immunize its large population against known diseases.⁷

Despite characterizing immunization against COVID-19 as a “global public good”, the solemn declarations about solidarity and cooperation in United Nations (UN) resolutions,⁸ and the establishment of mechanisms such as ACT-A and COVAX, the gap in vaccines supplies and the inequity in their distribution became an urgent issue that required exceptional measures.⁹

WTO Member countries may have opted for the application of article 73(b) of the TRIPS Agreement to suspend intellectual property (IP) in their jurisdictions as called for during the early stage of the pandemic¹⁰ and confirmed by academic analyses.¹¹ But the sponsors of the TRIPS waiver looked for a coordinated action of WTO members and were confident that the dimension of the humanitarian crisis brought about by the pandemic would lead to a rapid response where global public health would be given primacy over the commercial interests of IP right holders. However, this did not happen. In contrast to the expectations of the proponents, sponsors and the broad range of supporters of the TRIPS waiver, the negotiating process was too slow and unbalanced to adequately respond to the urgent needs of the largest part of the world population. As noted in the South Centre’s Statement on the Decision:

This Decision does recognize that, as argued by developing countries and a large number of organizations and academics, intellectual property (IP) poses obstacles for the expansion of manufacturing capacity and timely access to health products and technologies to respond to COVID-19. The response to the pandemic required a rapid increase in the supply of countermeasures, while technology holders refused to share their technologies.

However, despite the efforts by the proponents and sponsors of the TRIPS waiver, WTO developed country members aligned with the narrative of the pharmaceutical industry (which benefitted from massive public investment to develop COVID-19 vaccines) and the unproven argument that a TRIPS waiver, even if temporary and limited to address the current pandemic, would irreparably jeopardize innovation.¹²

The adopted Decision, as examined below, only clarifies certain provisions and waives one obligation relating to the grant of compulsory licenses under article 31 of the TRIPS

⁷ See Carlos Correa, “A Response to COVID-19 and beyond: Expanding African Capacity in Vaccine Production”, *Contemporary Issues in African Trade and Trade Finance*, vol. 7, No. 1, December 2021. Available from <https://media.afreximbank.com/afrexim/CIAT-VOL.7-Dec.2021.pdf>.

⁸ See Nirmalya Syam, “The UN General Assembly Resolutions on COVID-19: Solemn Assurances for Access to Health Technologies without an Action Plan”, Policy Brief No. 81, South Centre, July 2020. Available from <https://www.southcentre.int/policy-brief-81-july-2020/>.

⁹ See e.g., Tedros Adhanom Ghebreyesus, “A ‘me first’ approach to vaccination won’t defeat Covid”, *The Guardian*, 5 March 2021. Available from <https://www.theguardian.com/commentisfree/2021/mar/05/vaccination-covid-vaccines-rich-nations>. Also see UN Economic and Social Council Press Release, “Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council’s Special Ministerial Meeting”, 16 April 2021. Available from <https://press.un.org/en/2021/ecosoc7039.doc.htm>.

¹⁰ See South Centre, “COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security”, Open Letter from Carlos Correa, Executive Director of the South Centre to Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, Francis Gurry, Director-General of the World Intellectual Property Organization, and Roberto Azevedo, Director-General of the World Trade Organization, 4 April 2020. Available from <https://www.southcentre.int/covid-19-open-letter/>.

¹¹ See e.g., Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116 (Geneva, South Centre, August 2020). Available from https://www.southcentre.int/wp-content/uploads/2020/08/RP-116-reduced_1.pdf.

¹² See IFPMA, “IFPMA Statement on WTO TRIPS Intellectual Property Waiver”, 5 May 2021. Available from <https://www.ifpma.org/resource-centre/ifpma-statement-on-wto-trips-intellectual-property-waiver/>.

Agreement, as well as a clarification in relation to article 39.3. It is also currently limited only to patents over vaccines for COVID-19.

Significantly, the only waived obligation in the Decision relates to paragraph (f) of article 31 of the TRIPS Agreement, which requires that compulsory licenses be limited to predominantly supply the domestic market, the same provision that required a waiver in 2003 pursuant to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.¹³ If a provision needed two waivers in twenty years to address public health issues, it can only be concluded that the restriction is misplaced, notably having in view that the **production for export** of patented products by a third party can be deemed legitimate under article 30 of the TRIPS Agreement.¹⁴

This paper¹⁵ examines the objective and subjective scope of the Decision, the waiver of article 31(f) and the clarifications provided in respect of other provisions of article 31 and article 39.3 of the TRIPS Agreement, and how to implement the notification requirements and other conditionalities relating to the use of such waiver.

¹³ See WTO Document WT/MIN(01)/DEC/2. Available from https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

¹⁴ See Carlos M. Correa and Juan I. Correa, *Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception*, Research Paper, No. 155 (Geneva, South Centre, May 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/05/RP155_Manufacturing-for-Export-A-TRIPS-Consistent-Pro-Competitive-Exception_EN.pdf.

¹⁵ The following analysis is partially based on Carlos Correa and Nirmalya Syam, "Analysis of the Outcome Text of the Informal Quadilateral Discussions on the TRIPS COVID-19 Waiver", Policy Brief No. 110, South Centre, May 2022. Available from https://www.southcentre.int/wp-content/uploads/2022/05/PB110_Analysis-of-the-Outcome-Text-of-the-Informal-Quadilateral-Discussions-on-the-TRIPS-COVID-19-Waiver_EN.pdf. For an analysis of the Decision, see also Hilty, Reto, Kim, Daria, Correa, Juan I. Batista, Pedro Henrique D. and Lamping, Matthias, *Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement adopted on 17 June 2022* (5 July 2022). Max Planck Institute for Innovation & Competition Research Paper No. 22-14, available from <https://ssrn.com/abstract=4166573> or <http://dx.doi.org/10.2139/ssrn.4166573>.

2. SCOPE OF THE DECISION

2.1 Covered Subject Matter

Paragraph 1 of the Decision makes it clear that notwithstanding the provision of patent rights under its domestic law, a member can limit the rights conferred on a patentee by virtue of article 28.1 of TRIPS by authorizing the use of a subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder, in accordance with the provisions of article 31 of TRIPS as clarified further in the Decision, to the extent necessary to address the COVID-19 pandemic.

One objective of the developed country members that negotiated the waiver proposal -with the clear intention of limiting its scope- was to ensure that the Decision would only apply in relation to vaccines needed to combat the COVID-19 pandemic. The wording “to the extent necessary to address the COVID-19 pandemic” makes it clear that the Decision could not be used to produce vaccines for other purposes. This qualification reflects the pharmaceutical industry’s concern that the waiver to be adopted could be used in other fields, notably as the mRNA technology may be applied to address other communicable as well as non-communicable diseases.¹⁶

The referred to wording “to the extent necessary to address the COVID-19 pandemic” may be read as a “necessity test” imposing on a Member the burden of eventually proving that the grant of a compulsory license was “necessary” and, for instance, not just advisable from a public health perspective. It is well known that the WTO jurisprudence has tended towards a narrow interpretation of the necessity test.¹⁷ However, in the context of this Decision and given its wording, it seems clear that the only limitation imposed by “necessary” refers to the use of the patented subject matter in relation to COVID-19 and not to other health situations. Hence, “eligible Members” should not be subject to the burden of proving that **the grant** of a compulsory license, **if made in relation to COVID-19**, was “necessary”. In other words, a “necessity test” does not apply in respect of an authorization as such but only in relation to its (limited) purpose.

On the other hand, the Decision alludes to the “pandemic”. In the absence of a legal definition of the term, a literal meaning of the word should be applied to interpret it, in accordance with the interpretative rules of the Vienna Convention on the Law of Treaties (VCLT). The literal meaning of “pandemic” is a disease or health event occurring over a wide geographical area covering multiple countries or continents and affecting a significant proportion of a population.¹⁸ Even if COVID-19 may end as a “pandemic” it could still remain an “epidemic”, that is, as a disease affecting a disproportionately large number of individuals within a population, community or region. While the reference to “COVID-19 pandemic” and not to “COVID-19” seems intentional, it remains open whether the existence of a “pandemic” can only be based on a declaration by the World Health Organization (WHO) or whether Members may have room for diverse views on its existence. Notably, no reference is made in the Decision to the WHO role in declaring a pandemic.

¹⁶ See e.g., “We’re better off with mRNA vaccines”, Harvard T.H. Chan School of Public Health. Available from <https://www.hsph.harvard.edu/news/multimedia-article/were-better-off-with-mrna-vaccines/>.

¹⁷ Gisele Kapertian, “A Critique of the WTO Jurisprudence on ‘Necessity.’” *The International and Comparative Law Quarterly*, vol. 59, No. 1, 2010, pp. 89–127. Available from <http://www.jstor.org/stable/25622271>.

¹⁸ Merriam-Webster, “Definition of pandemic.” Available from <https://www.merriam-webster.com/dictionary/pandemic#:~:text=Definition%20of%20pandemic&text=1%20%3A%20occurring%20over%20a%20wide.and%20claimed%20millions%20of%20lives.>

Interestingly, one of the hardest and longest negotiations on the Decision took place not on paragraph 1 as such, but on its footnote 1 which, as adopted, reads as follows:

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.

The long discussions and the divergencies regarding this footnote essentially reflected the concern of developed countries that the Decision may apply beyond the components that were strictly necessary to produce COVID-19 vaccines, such as equipment or vials. There was also the concern, as noted above, that the technologies eventually subject to compulsory licenses could be used for non-COVID-19 products. After considering many options, the Members negotiating on this footnote¹⁹ agreed on the wording previously proposed in the outcome text of the quadrilateral discussion introduced by the WTO Director-General (hereinafter “the draft”) through the TRIPS Council Chair.²⁰

Notably, the use of the term “including” makes it clear that the coverage of “subject matter” as indicated in the footnote is not exhaustive. While it refers to “ingredients and processes necessary for the manufacture of the COVID-19 vaccine”, it does not exclude equipment nor any products needed, for example, to stock or administer the vaccines.

In many jurisdictions patents on the **use** of a certain product to manufacture pharmaceuticals to address a disease are permitted.²¹ Given that “use” is not mentioned in the footnote, questions may arise about the scope of the Decision in this respect. It should be noted, however, that article 27 of the TRIPS Agreement only refers to “products and processes” and does not oblige WTO members to grant patents on the use of a product. Hence, a reference to “use” would have been inappropriate as there was no need to “waive” an obligation that is not provided for in the Agreement.

2.2 Subjective Scope

While all WTO members can issue a compulsory license under Article 31 of the TRIPS Agreement, the Decision is only available for use by “eligible members.” It follows in this regard the same approach applied for the 2003 waiver: to limit the WTO members that can rely on the Decision. But its subjective scope is defined differently. This was, in fact, one of the most contentious issues in the negotiations. In the referred to draft, there was an exclusion of developing countries that have exported more than 10 per cent of COVID-19 vaccine doses in 2021, with the purpose of excluding China —without explicitly naming it— from the potential use of the waiver, as it was the only developing country that reached such a threshold.²² The proposed limitation ironically penalized the country that had shown capacity to develop and produce and the willingness to export the much-needed vaccines to

¹⁹ As noted in the South Centre’s Statement, the process for the adoption of the Decision did not allow for the full and informed participation of all interested Members as “[l]ike in other negotiating areas, the methodology of arbitrarily constituted small negotiating groups, including ‘green rooms’, made a strong come back to the WTO.” See South Centre, “TRIPS Waiver: An Insufficient Multilateral Response. TRIPS-Consistent National Actions are Called for”, Statement, 21 June 2022. Available from: <https://www.southcentre.int/sc-statement-trips-waiver-21-june-2022/>.

²⁰ WTO document, IP/C/W/688, 3 May 2022, available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W688.pdf&Open=True>.

²¹ See Clara Ducimetière, *Second Medical Use Patents: Legal Treatment and Public Health Issues*, Research Paper No. 101 (Geneva, South Centre, 2019). Available from <https://www.southcentre.int/research-paper-101-december-2019/>.

²² See WTO-IMF COVID-19 Vaccine Trade Tracker. Available from https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm.

save lives and on which a large number of developing countries relied upon to fight the pandemic.

The definition of “eligible members” in footnote 1 of the Decision was the last issue to be resolved in the negotiations during the Ministerial Conference. China had reportedly objected to the proposed 10 per cent threshold. The finally adopted definition reads as follows:

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 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.

While the adopted definition does not propose a quantitative threshold for excluding certain developing countries from the scope of the Decision, the final text has included exhortations to all developing countries with existing vaccine manufacturing capacity to make binding commitments not to avail of this Decision. This is a precedent of particular concern, since developing country members with large potential to supply the world demand for therapeutics and diagnostics may be subject to pressures to make similar binding commitments not to use the Decision if an extension of its coverage is agreed upon in conformity with paragraph 8 of the Decision (see below).

The agreed upon text refers to “statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022”. It is unclear what kind of “statements” by a Member would be construed as “commitments” to opt out of the Decision. However, only those made to the General Council may be deemed as “binding”. Footnote 1 hence excludes statements made to other WTO bodies (e.g., Council for TRIPS or Trade Policy Review meetings).

The potentially legally binding character of a statement is an innovation under WTO law. Never before could they have been construed as “binding commitments”. This shows the flexibility that characterizes WTO law making. But it is in contrast with the more precise notification requirements imposed in other paragraphs of the Decision on the users of the Decision as discussed below, and also with the notifications under the waiver adopted in 2003 and incorporated in article 31*bis* of the TRIPS Agreement. For the purposes of legal certainty, it would have been reasonable to request notifications rather than mere “statements” to consider that a commitment had been made.

3. FREEDOM TO DETERMINE THE MODE OF AUTHORIZATION

Paragraph 2 of the Decision clarifies that an authorization under article 31 in relation to the subject matter of COVID-19 vaccines, ingredients and processes can be made available through any instrument under the law of an eligible Member including executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not the member has a compulsory licensing regime in place.

This clarification is not substantial since article 1.1 of the TRIPS Agreement clearly states that “Members shall be free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.” The flexibility to issue a compulsory license authorization through the instruments mentioned in the draft is clearly available in terms of the said article of the TRIPS Agreement. In the United States and Germany, for instance, compulsory licenses are granted by the courts,²³ and this has never raised an issue of non-compliance with the Agreement’s obligations. Examples of such compulsory licenses are presented in Box 1. A recent study of US Government contracts disclosed to the US Securities and Exchange Commission also found that in 166 contracts companies were permitted to use patented inventions without the authorization of the patent holder, including in 62 COVID-19 contracts.²⁴

Box 1

Compulsory Licenses Granted by Courts

Amgen v. Roche

The validity and violation of three Amgen US patents relating to Roche’s “Mircera” were established by the District Court. The District judge William Young denied a permanent injunction and ordered a compulsory license in favour of Roche on the argument that a reduced drug price would result from competition.

Amado v. Microsoft

U.S. Patent 5,293,615 held by Carlos Armando Amado from Guatemala on a “point and shoot interface for linking database records to spreadsheets” was found to be violated by Microsoft.

Microsoft requested the Federal Court of California to issue a compulsory license, which was accorded with a royalty of US\$ 0.12 per copy (Amado requested US\$ 2 per copy). The Court of Appeals for the Federal Circuit confirmed the license and requested the district court to review the royalty payment.

Shionogi v. Merck

The Japanese company Shionogi requested a preliminary injunction against Merck in 2015 for the use of its patent on raltegravir (“Isentress”). Shionogi rejected Merck’s offer for a voluntary worldwide license on the patent. Merck then requested the court, the grant of a compulsory license grounded on urgent public interest and the health risk of switching the

²³ Knowledge Ecology International, “Compulsory licensing as a limitation on availability of injunctions under eBay doctrine”, available from <https://www.keionline.org/cl/eBay/>; Jack Brodsky, “The Health of eBay: The Impact of eBay on the Future of TRIPS-Like Pharmaceutical, Compulsory Licenses in the United States”, *American Journal of Law & Medicine*, vol. 41, No. 4 (2015), pp. 656-79. Available from <https://pubmed.ncbi.nlm.nih.gov/26863852/>; Claudia Milbradt and Nicolas Hohn-Hein, “Federal Patent Court grants compulsory license for HIV drug in Germany”, 2 March 2017. Available from <https://www.deutscheranwaltspiegel.de/businesslaw/archiv/federal-patent-court-grants-compulsory-license-for-hiv-drug-in-germany/>.

²⁴ See Knowledge Ecology International, Federal Government FAR52.227-1 authorizations (for non voluntary use of patents) disclosed in 166 SEC exhibits, KEI Briefing Note No. 2, 2022. Available from <https://www.keionline.org/bn-2022-2>.

drug. The German Federal Patent Court granted the compulsory license (August 2016, confirmed in July 2017).²⁵

The key issue regarding the modality for the grant of a compulsory license or government use under the Decision is whether an administrative or judicial act issuing it would be in conformity with the national law and, hence, whether it might survive a potential challenge by the patent owner. Notably, paragraph 2 of the Decision does not empower any WTO member to ignore or break its own national law. It only clarifies that a complaint under the Dispute Settlement Understanding could not be viable if merely based on the legal nature of that act.

The last phrase in paragraph 2 (“whether or not the member has a compulsory licensing regime in place”) is quite curious from a legal point of view, as it is unclear how a WTO member could grant a compulsory license in the absence of a regime that determines the grounds and conditions under which such a license can be authorized. The negotiating parties may have wished to show their full flexibility with regard to this issue, but it does not suffice to overcome national law limitations.

Moreover, paragraph 2 does not affect obligations that a WTO member may have assumed under free trade agreements (FTAs) or other international agreements on intellectual property. It will not derogate such obligations, although there is space to interpret them in a manner consistent with a waiver in respect of TRIPS obligations on the basis of general principles of international law or specific provisions in those agreements.²⁶

²⁵ See Christoph Spennemann and Clara Warriner, “Compulsory license in Germany: Analysis of a landmark judicial decision”, Policy Brief No. 91, South Centre, April 2021. Available from <https://www.southcentre.int/policy-brief-91-april-2021/>.

²⁶ See Carlos M. Correa et. al., *Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims under Free Trade and Investment Agreements*, Research Paper No. 135 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP135_Implementation-of-a-TRIPS-Waiver-for-Health-Technologies-and-Products-for-COVID-19_EN-1.pdf.

4. NO REQUIREMENT OF PRIOR EFFORTS TO OBTAIN A VOLUNTARY LICENSE

Paragraph 3 (a) of the Decision clarifies that an eligible member need not require the proposed user of the patented subject matter to make efforts to obtain a voluntary license from the right holder in terms of article 31(b).

Quite clearly, a pandemic creates a situation of a “national emergency” and gives rise to “exceptional circumstances”, as stated in the single preambular provision of the Decision. Paragraph 3, hence, also confirms a flexibility currently available under the TRIPS Agreement, as it is explicitly stated in the article 31(b) that the prior negotiation requirement can be waived by a Member in view of a national emergency or other circumstances of extreme urgency.

In addition, a prior negotiation with the patent holder is not needed in the case of governmental use for non-commercial purposes,²⁷ a modality that is likely to be used to allow for a rapid access to and distribution of vaccines and other products to fight the emergency created by a pandemic.

5. WAIVER OF ARTICLE 31 (F) OF THE TRIPS AGREEMENT

Paragraph 3 (b) of the Decision contains the only waiver agreed upon. It waives the requirement under article 31(f) of TRIPS that an authorized use should be predominantly for domestic purposes. It also specifies that an eligible member may allow any proportion of the authorized use to be exported to eligible members and for the supply of international or regional joint initiatives that aim to ensure equitable access to COVID-19 vaccines for eligible members. This waiver would allow for exportation of even 100 per cent (“any proportion”) of the produced vaccines.

A similar waiver was adopted pursuant to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health and incorporated into article 31 *bis* of the TRIPS Agreement. A noticeable difference with this latter waiver, however, is that it refers to the supply not only to other “eligible members” but also to “international or regional joint initiatives”. While it is unclear what is meant by “joint” as a further qualification to “international or regional” the reference to their “aim” (“to ensure equitable access to COVID-19 vaccines for eligible members”) excludes those “initiatives” that may be established for the supply of vaccines to developed countries. The broad term “initiatives” leaves open the possibility of exporting to any mechanism, whether institutionalized or not, transitory or permanent, which operates in a developed or developing country, with the purpose (unique or not) of facilitating access of COVID-19 vaccines to “eligible members”.

²⁷ See Carlos M. Correa, *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents*, Research Paper No. 107 (Geneva, South Centre, 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/04/RP-107.pdf>.

As most members' national laws have included the limitation imposed by article 31(f) in their legislations, amendments would be needed —as required under the respective legal systems— to use the waiver provided for in this paragraph. The rationale for the limitation in paragraph (f) of article 31 has never been discussed in depth. It reflects the US position during the negotiation of the Agreement as it is the case for the remainder of article 31.

This is the second time since the establishment of the TRIPS Agreement that a waiver has been needed to address public health needs. It is now imperative to find alternatives to this disturbing provision. Of course, one solution would be an amendment to the Agreement, but this may face opposition from developed country members and if approved, would possibly take a long time to enter into force. One promising alternative —that does not require an amendment— is recognizing under national laws that the production for export under article 30 of the Agreement is legitimate, as patents are territorial, and the right owner would not be affected in the exploitation of its exclusive rights in the market of the exporting country. An exception of this kind has been introduced by the European Union for pharmaceuticals during the life of Complementary Protection Certificates, but the same rationale would apply during the patent lifetime.²⁸

6. RESTRICTIONS ON RE-EXPORTATION

Paragraph 3 (c) of the Decision introduces conditions limiting re-exportation that are not present in article 31 of TRIPS. While article 31 allows a compulsory licensee to export at least the non-predominant part of its production without any obligation on the importing country to prevent re-exportation, the Decision requires eligible Members to undertake “all reasonable efforts to prevent the re-exportation of COVID-19 vaccines” imported or produced under the Decision.

The wording used in this paragraph (“all reasonable efforts”) indicates that it only provides for a “**best efforts**” obligation which does not impose on the Members a commitment to effectively “prevent” exports but just to take actions to that end. This means that the circumstances of each member need to be taken into account in considering what is “reasonable” in the light of its resources and capabilities to control exports. Importantly, eligible Members are not obliged to adopt **special** measures as they can prevent re-exportation through managerial practices such as control over the stockage and distribution of vaccines.

This restriction on re-exportation mirrors a similar limitation in article 31*bis* of the TRIPS Agreement, but seems particularly unsuited in the context of COVID-19. It will limit the option of re-exportation of excess doses imported under the Decision and prevent importing developing countries to help other developing countries even if, for instance, they wish to donate such doses or to supply them to another member in need before they expire. In fact, during the initial phase of COVID-19, many developing countries re-exported vaccines they

²⁸ Carlos M. Correa and Juan I. Correa, *supra* note 14.

had obtained to assist other developing countries in need, thereby showing once again the growing importance of South-South cooperation.²⁹

Footnote 3 of the Decision provides for a narrow exception to the re-exportation limitation: only in “exceptional circumstances an eligible member may re-export COVID-19 vaccines to another eligible member for humanitarian and not-for-profit purposes”. The adopted wording may be interpreted in the sense that the existence of “humanitarian and not-for-profit purposes” in itself meets the requirement of “exceptional circumstances”, that is, the exporting country would only need to take into consideration the “purposes” of the supply and not any additional “exceptional circumstances”. Otherwise, the exception may become useless in practice.

The commented paragraph introduces another obligation of means but with a more compelling wording with regard to imports of vaccines produced under the Decision. Unlike the provision on re-exports, measures about imports need to be taken by **all** Members. It would have been logical to limit this provision to non-eligible Members, since those who are eligible Members would not have valid reasons to prevent imports and sales that are otherwise permitted under the Decision.

The only obligation in relation to the importation and sale of vaccines manufactured under the Decision is to make available means to prevent such acts. Moreover, only “the means already required to be available under the TRIPS Agreement” need to be considered. Like in the case of re-exportation, there is no need to adopt **special** measures.

Since patents and other intellectual property rights are **private** rights (as stated in the Preamble of the TRIPS Agreement), it would be the responsibility of the patent owner to make use of such measures, for instance by requesting the custom authority not to release vaccines “diverted” to the country. There will be, hence, no obligation for the Member to act *ex-officio*.

Importantly, the obligation imposed in the commented paragraph on non-eligible Members (namely developed countries) would not require the adoption of any additional measure if the enforcement provisions of the TRIPS Agreement are already in place. The same applies to eligible members.

An issue that requires interpretation is the meaning of “diverted to their markets inconsistently with its [the Decision] provisions”. The term “diverted” suggests that only cases of re-exportation would be addressed by this provision. The fact that a vaccine was sold to “eligible country A” and then re-exported to eligible “country B”, would not mean that there was a diversion “inconsistent” with the Decision to the extent that re-exportation complies with the conditions under footnote 3 of the Decision. On the contrary, any importation into a non-eligible Member would constitute such an inconsistent “diversion” and the rightsholder might act against utilizing the available procedural tools.

²⁹ See e.g., Carlos M. Correa, “Expanding the production of COVID-19 vaccines to reach developing countries: Lift the barriers to fight the pandemic in the Global South”, Policy Brief No. 92, South Centre, April 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>.

7. COMPULSORY LICENSES OR PARALLEL IMPORTATION?

Notably, the Decision **only** waives the rights in the exporting country. Another important — and less discussed issue— is therefore whether a compulsory license would need to be granted for the **importation** of the vaccines supplied under the Decision. Such importation may be deemed to infringe any relevant patent(s) granted in the importing country (if such were the case) and, hence, the right holder could sue the importer (whether a public or private entity). Under article 31bis of the TRIPS Agreement, a compulsory license has to be granted in **both** the exporting and the importing country (unless the latter is a least developed country).

An alternative to a compulsory license is to consider the importation as a “parallel import” under the doctrine of exhaustion of rights. Some national laws and jurisprudence stipulate that in order for parallel imports to be admissible, the product must have been put on the market in a foreign country by or with the **consent** of the patent owner. Therefore, the supply by a compulsory licensee would not be deemed to be a legitimate source of parallel imports. But the requirement of consent —as elaborated on by the European Court of Justice³⁰— is not provided for under article 6 nor any other provision of the TRIPS Agreement, and there is no reason why all WTO members should apply it. As the right holder has the right to receive an “adequate remuneration” under a compulsory license or government use in the exporting country (article 31, paragraph (h)) and the sales under such license are fully legitimate, the importing country can consider that exhaustion of rights has taken place.³¹ This will enormously facilitate the implementation of the Decision.

7.1 Remuneration

The option spelled out in paragraph 3 (d) of the Decision with regard to determining the level of adequate remuneration for a compulsory license is also a flexibility already allowed under article 31 (h). This is hence another clarification and not a waiver. Members can currently use —and in fact, some have done so— the WHO “Remunerations Guidelines” mentioned in footnote 4 and take into account, in determining the “economic value of the authorization” whether a compulsory license is granted to make profit or to address humanitarian needs. In the latter case, the “economic value” for the compulsory licensee is obviously different.

The drafting of this paragraph raises some interpretive issues, namely whether the referred to “vaccine distribution programs” are only regional or international, or whether national programs are included as well.³² The latter interpretation seems to be the most appropriate as the largest quantity of COVID-19 vaccines has been distributed through national vaccination programs.

In addition, at the time an authorization is given, and a remuneration determined, it may not be known which would be the destination countries or programs to be supplied and, in particular, which would be deemed to be “affordable prices for eligible members” since affordability varies depending on the level of income in the country of destination. A potential compulsory licensee may actually prefer the application of the existing article 31 of the

³⁰ Several decisions by the European Court of Justice have held that the application of the doctrine of exhaustion is conditional upon the existence of the right-holder’s consent to putting its products on the market (e.g., *Pharmon v Hoechst*, Case 19/84, 1985 ECR 2281; *Merck & Co v Primecrown Ltd*, joined cases C-267/95 and C-268/95).

³¹ See Carlos M. Correa, *Trade-Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, 2nd Edition (Oxford University Press, 2020), p. 78.

³² Regional and international mechanisms, such as COVAX, have created those programs.

TRIPS Agreement if, in exchange for a lower remuneration for the license on humanitarian grounds, he would be subject to scrutiny about the “affordability” of its prices on the basis of undefined parameters as well as to notifications not required under article 31.

Given that the only waiver provided for under the Decision relates to paragraph (f) of article 31, it seems logical that paragraph 3 (d) of the Decision only refers to the supply at affordable prices to other eligible members. A compulsory licensee may also supply the domestic market; the same considerations in determining the remuneration could be applied in relation to the sales in that market.

7.2 Test Data

Paragraph 4 of the Decision confirms that the obligation relating to the protection of test data under article 39.3 “does not prevent an eligible Member from enabling the rapid approval” of vaccines for the execution of a compulsory license.

The wording chosen in this paragraph is important, as it shows the understanding that the protection of test data as required under the TRIPS Agreement is not based on the grant of exclusive rights (“data exclusivity”). As discussed elsewhere,³³ article 39.3 only obliges to protect such data —when some conditions are met— under the discipline of unfair competition which does not generate any exclusive rights. The interpretation of this provision has been quite controversial indeed, but the reading given by the US and the European Commission suggesting a requirement of exclusivity has never been confirmed in the context of the WTO and many WTO members do not to grant exclusive rights over test data without challenge by other members.³⁴

Although the clarification in paragraph 4 of the Decision was not —strictly speaking— necessary, it is useful to confirm the interpretation of that provision.

Interestingly, some WTO members that provide for data exclusivity currently waive test data protection in case a compulsory license is granted. Such a waiver, for instance, is provided for in the European Union Regulation (EC) No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with lack or have insufficient manufacturing capacity in pharmaceuticals. It has also been admitted in the context of free trade agreements entered into by the USA.³⁵

Notably, the commented paragraph does not waive obligations relating to other undisclosed information that is not mandatory to be submitted for marketing approval, such as product specifications or manufacturing know-how that could be covered by article 39.2.

³³ See Carlos M. Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva, South Centre, 2004). Available from <https://www.southcentre.int/book-by-the-south-centre-2002/>.

³⁴ The US challenged under the WTO Dispute Settlement Understanding (DSU) the Argentine law which did not confer data exclusivity in 2000. The case was closed by a mutually agreed solution in which Argentina maintained its position (see Notification of Mutually Agreed Solution, Argentina-Certain Measures on the Protection of Patents and Test Data, WTO Document WT/DS196/4, 20 June 2002. Available from https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=53057&CurrentCatalogueIdIndex=0&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True). Thereafter, no WTO member has been challenged under the DSU for not granting data exclusivity.

³⁵ See Ellen ‘t Hoen, “Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity”, in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines* (Springer, Cham., 2022). Available from https://link.springer.com/chapter/10.1007/978-3-030-83114-1_7.

7.3 Notification Requirements

Paragraph 5 of the Decision introduces the requirement of notifying the TRIPS Council about any measure related to the implementation of the decision or grant of an authorization thereunder.

Such a requirement does not apply under article 31 of the TRIPS Agreement and represents a new condition for the use of compulsory licenses. While the notification of a measure adopted to implement the Decision may be deemed part of the general transparency obligation under the TRIPS Agreement, the notification of particular authorizations seem to rather echo article 31 *bis*.

The grant of a compulsory license (whether or not under the proposed Decision) is to be notified to the patent owner (who has the right to request a review by a higher authority). Hence, the need for and rationale for an additional notification by the member to the Council for TRIPS, as provided for in the draft, is unclear.

Footnote 5 provides for a notification when a compulsory license has been granted indicating the authorized entity, the covered “product/s” and the duration of the authorization. Nothing in this text limits the Member’s right to determine which entities may receive the authorization, what products are covered and how long it will last. Thus, such a license may be granted, for instance, for several products and/or processes until the waiver expires (in five years from its adoption).

A problematic aspect of this footnote 5 is the requirement about information regarding the “quantity(ies) for which the authorization has been granted” and on the countries “to be supplied”. These notification requirements are not imposed for compulsory licenses under article 31 of the TRIPS Agreement. Requirements of this kind have been introduced, however, in article 31 *bis* with an important difference: in the latter the notification burden is on the party exporting pharmaceuticals, while under the Decision it is on the WTO members themselves. This may oblige the governments giving an authorization to monitor the implementation of a granted compulsory license.

However, the referred to requirements would not prevent a Member from granting a compulsory license for all the term allowed under the Decision (five years), nor does it require to specify in the grant a definite quantity nor the countries to be supplied. Such a license may be granted to produce and export any quantities demanded by any eligible member.

The requested information is to be supplied *ex-post* (“as soon as possible after the information is available”). The wording “to be supplied” may give the impression that the authorizations need to specify *ex-ante* quantities (rather than those that were effectively supplied). A procedural requirement, however, cannot create a substantive obligation regarding the rights conferred under the license such as mandating that the licenses specify a given quantity, or to list the countries to be supplied. How many litres of a reagent or other compounds are to be used in manufacturing a vaccine, and what would be the destination countries is likely to be unknown when the authorization is requested and granted, as the demand for vaccines changes in accordance with needs and alternative supplies that potential destination countries may have. Hence, a compulsory license (or government use authorization) allowing for the manufacture of an unlimited quantity to supply any eligible Member would be fully consistent with the Decision.

Footnote 5 does not refer to “vaccines” but to “products” and although this may suggest a product-by-product approach that would make the use of the system burdensome.³⁶ The Decision essentially permits the export of vaccines and, therefore, it would be incoherent to request notifications for each product that may be necessary in the manufacturing process.

7.4 Duration

Paragraph 6 of the Decision states that an eligible member may apply the provisions of this Decision until 5 years from the date of the Decision (17 June 2022). It also states that the duration may be extended by the General Council taking into consideration the exceptional circumstances of the COVID-19 pandemic, and that the General Council shall annually review the operation of the Decision.

However, this does not clarify whether an authorization in force at the end of 5 years from the date of the Decision will continue to remain in force for the rest of its term. This may create significant uncertainty for potential manufacturers. A literal interpretation would suggest that after the 5 years period no new authorizations could be given while the patent holder would be able to request measures against the export/import of COVID-19 vaccines covered by a prior authorization.

7.5 Dispute Settlement

Paragraph 7 of the Decision states that members shall not challenge any measure taken in conformity with the Decision under Article XXIII.1 (b) and (c) of GATT 1994. This implies that measures taken cannot be challenged as non-violation or situation complaints in the WTO dispute settlement system. However, this should not be construed to interpret that non-violation and situation complaints would have been applicable otherwise. Non-violation complaints do not apply to the TRIPS Agreement for the time being and the TRIPS Council has agreed to recommend to the General Council the extension of the moratorium. Paragraph 7 of the Decision, therefore, should not be construed to suggest that such complaints are currently applicable to that Agreement but as a confirmation that they are inapplicable thereunder.

Paragraph 7 also implies that a measure taken under the Decision can be potentially challenged under the DSU. For instance, whether a measure taken under this Decision is “required” in terms of paragraph 1, and whether the measure is applied “to the extent necessary” to address the COVID-19 “pandemic” situation, could be the subject of a dispute under Article XXIII.1 (a) of GATT. However, nothing restrains WTO panels from applying a national deference standard to take into consideration the purpose of a measure under the Decision and raise a presumption in favour of a measure that advances public health objectives. WTO panels may be amenable to such a national deference standard in public health contexts, particularly following the landmark decision of the panel in *Australia – Tobacco Plain Packaging*.³⁷

³⁶ If in order to produce an active ingredient or formulation of a vaccine it were necessary to use a multiplicity of patented inputs, information would have to be supplied for each of them. A COVID-19 vaccine necessitates more than 90 different inputs. See Felix Lobo, *supra* note 6.

³⁷ Tamara Romero, *Public Health and Plain Packaging: An Intellectual Property Perspective*, Research Paper No. 108 (Geneva, South Centre, 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/04/RP-108-rev.pdf>.

7.6 *Extension to Therapeutics and Diagnostics*

Paragraph 8 of the Decision provides that Members shall decide no later than 6 months from the date of its adoption whether to extend it to therapeutics and diagnostics. The wording chosen for this paragraph is important as it makes it clear that Members will have to **decide** on such extension.

However, at the time of writing this paper, there is an apparent reluctance on the part of developed countries to extend the decision to therapeutics and diagnostics. In a recent meeting of the General Council, reacting to a proposal by developing countries for an extension of the Decision, the US held the view that the Decision did not include a mandate to decide but merely a deadline to conduct discussions on extension of the Decision to therapeutics and diagnostics. Other developed country members called for “evidence based” (sic) discussions on whether extension of the Decision to therapeutics and diagnostics is required.³⁸

Unlike the US suggestion, paragraph 8 does not appear to call for undertaking “further discussions” on therapeutics and diagnostics but to take a decision on the matter within the set timeframe. The need for a waiver that is sufficiently broad to cover vaccines as well as therapeutics and diagnostics has been extensively discussed in the TRIPS Council, the Ministerial Conference as well as informal discussions on the topic as part of the discussion on the waiver proposal. A broader coverage of a TRIPS waiver has been largely supported by academics, international organizations and a multiplicity of civil society organizations.³⁹ The Ministerial Conference merely agreed to an extended timeframe to conclude that discussion and take a decision. It did not mandate a new discussion to be undertaken on therapeutics and diagnostics within 6 months, much less to provide additional evidence on the need for such an extension. The impact of IP, notably on therapeutics, may be even more significant than on vaccines as many patents or patent applications may limit their manufacturing by third parties.⁴⁰ Engaging in a fresh discussion on the need for extension of the Decision to therapeutics and diagnostics would essentially ignore the agreed Decision. Given that nearly two years of discussions preceded the adoption of the Decision, any further conditions to make a decision or delay in its extension to therapeutics and diagnostics would be a wrong precedent for the WTO.

³⁸ See Priti Patnaik, “No Mandate on Extending WTO TRIPS Agreement Decision to Medicines & Tests: The U.S.”, *Geneva Health Files*, 29 July 2022, Newsletter Edition, no. 149. Available from <https://genevahealthfiles.substack.com/p/no-mandate-on-extending-wto-trips>.

³⁹ *Supra* note 4.

⁴⁰ See Srividya Ravi, *Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19*, Research Paper No. 153 (Geneva, South Centre, 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/04/RP153_Patent-Analysis-for-Medicines-and-Biotherapeutics-in-Trials-to-Treat-COVID-19_EN-1.pdf.

8. OTHER TRIPS FLEXIBILITIES AND THE DOHA DECLARATION

Paragraph 9 of the Decision clarifies that it is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including the flexibilities affirmed in the Doha Declaration on TRIPS and Public Health, and without prejudice to the rights and obligations under TRIPS, except as otherwise provided for in paragraph 3(b) of the Decision, i.e., the waiver from the condition under article 31 that a compulsory license authorization must be used predominantly for domestic purposes. Paragraph 9 further states for greater certainty that the Decision is without prejudice to the interpretation of the flexibilities, rights and obligations outside the scope of this Decision.

The language of paragraph 9 makes it clear that the Decision does not in any way impede the use of the flexibilities available under the TRIPS Agreement, as clarified under the Doha Declaration, and nothing in the Decision should be construed as limiting their scope. Even in respect of compulsory licensing, the freedom of WTO members to determine the grounds upon which compulsory licenses may be granted, and to determine what constitutes a national emergency or other circumstances of extreme urgency, are not impeded or otherwise limited by this Decision. Only paragraph 3 (b) of the Decision is specifically exempted from the existing rights and obligations of the TRIPS. Therefore, even though paragraph 1 of the Decision requires an authorization under this Decision where it is necessary to address the COVID-19 pandemic, this determination would still be the prerogative of the Member invoking a measure under this Decision, in terms of the clarification under paragraph 5 of the Doha Declaration that the determination of a national emergency or circumstance of extreme urgency (which could include a pandemic) is the right of such a Member State.

Moreover, Members may decide to use any mechanisms they have under article 31 of the Agreement and not issue an authorization with an exemption in regard to the quantity of products supplied to the domestic market or exported. In such a case, they would not be subject to the novel notification requirements nor to make the “reasonable efforts” relating to the re-exportation of vaccines. In the end, it would be the choice of a party requesting a compulsory license or the government making a non-commercial use of a patent to decide which legal framework they opt to use.

Similarly, parallel importation of a vaccine put in a relevant market under a compulsory license, including under this Decision, can be justified as discussed above

9. IMPLEMENTATION OF THE WAIVER AND OTHER OPTIONS

As noted, the waiver adopted under this Decision is not self-executing and national existing rules regarding patent rights will prevail, unless amended to make use of the new waiver. Members would need to consider the suspension of or changes to the regulations needed for that purpose. In particular, as most members' national laws have included the limitation imposed by article 31(f) in their legislations, legal action would be needed—as required under the respective legal systems—to use the waiver provided for in this Decision.

In addition, Member States could also consider the following options:

- Granting authorizations under the framework of article 31 (f)
- Aligning their legislations relating to exhaustion of rights to authorize parallel importation of products manufactured under a compulsory license.
- Member States could also apply the exception under article 30 of TRIPS to allow for the manufacture and export of patented products, based on a rigorous interpretation of article 30.⁴¹
- Member States could invoke the security exception under article 73 (b) of the TRIPS Agreement. In accordance with this exception, the obligations under the Agreement can be suspended in case of an international emergency and the COVID-19 pandemic is certainly such an emergency.⁴²

⁴¹ See Carlos M. Correa and Juan I. Correa, *supra* note 14.

⁴² See Frederick Abbott, *supra* note 11.

10. CONCLUSIONS

The Decision falls short of the expectations of the proponents of the “TRIPS waiver” and its co-sponsors. It only contains a specific waiver, once again in relation to article 31 (f) of the TRIPS Agreement. The fact that two waivers needed to be negotiated in order to address public health needs, suggests how inconvenient the limitation imposed by that article is. In fact, the rationale for such limitation is unclear and the negotiating history of the TRIPS Agreement does not shed any light on its justification since if exports under a compulsory license could be done, they could only have as destination countries in which parallel patents are not in force. What interests is article 31 (f) then protecting?

The Decision is, naturally, not self-executing and “eligible members” need to take the actions required under their national systems to implement it. This may require the suspension of rights to enforce relevant patents, and not necessarily changes in the legislation. As clarified in the Decision, any administrative or judicial act would be sufficient for that purpose. Notably, while the Decision contains provisions on re-exportation and importation and on notifications, they do not require to put in place special measures or mechanisms. In particular, the notification requirements cannot be read as creating substantive limitations with regard to the scope, duration and the countries to be supplied under an authorization that relies on the Decision.

The same observations would apply if and when a resolution is made to extend the Decision to therapeutics and diagnostics, and this is necessary to prove that the multilateral trading system is capable to effectively respond to exceptional circumstances and protect the health and life of the world population as a matter of priority.

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Patented Pharmaceuticals at the WTO

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