

## Analysis of the Outcome Text of the Informal Quadrilateral Discussions on the TRIPS COVID-19 Waiver

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### Abstract

Almost one and a half years after the proposal for a waiver of certain provisions of the TRIPS Agreement regarding health technologies for COVID-19 was proposed by India and South Africa with the support of the majority of WTO Members, the TRIPS Council has been unable to reach consensus on the proposed waiver or engage in text negotiations. In this context, the TRIPS Council agreed to suspend the discussions to allow the possibility of some solution to emerge from informal high-level consultations between the European Union, the United States of America, India and South Africa. Recently, the WTO Director-General transmitted the outcome of the informal consultations along with a draft text to the TRIPS Council. In this context, this policy brief analyzes the elements of the draft text that has been transmitted to the TRIPS Council. The proposed solution, which offers clarifications and limited waivers on some of the provisions governing compulsory licenses on patents relating to vaccines, reflects developed countries' strong opposition to the broader waiver sought by the proponents to rapidly expand manufacturing capacity and the supply of health products needed to address the pandemic.

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*Près d'un an et demi après la proposition d'une dérogation à certaines dispositions de l'Accord sur les ADPIC concernant les technologies de la santé pour la COVID-19, proposée par l'Inde et l'Afrique du Sud avec le soutien de la majorité des pays membres de l'OMC, le Conseil des ADPIC n'est pas parvenu à un consensus sur la dérogation proposée ou d'engager des négociations de texte. Dans ce contexte, le Conseil des ADPIC a convenu de suspendre les discussions pour permettre la mise en place d'une solution à partir de consultations informelles de haut niveau entre l'Union européenne, les États-Unis d'Amérique, l'Inde et l'Afrique du Sud. Récemment, le Directeur général de l'OMC a communiqué le résultat des consultations informelles ainsi qu'un projet de texte au Conseil des ADPIC. Dans ce contexte, ce rapport sur les politiques analyse les éléments du projet de texte qui a été soumis au Conseil des ADPIC. La solution proposée, qui offre des précisions et des dérogations restreintes sur certaines des dispositions régissant les licences obligatoires sur les brevets relatifs aux vaccins, reflète la forte opposition des pays développés à la dérogation plus étendue recherchée par les partisans avec le but d'accroître rapidement la capacité de fabrication et d'approvisionnement des produits de santé nécessaires pour faire face à la pandémie.*

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*Casi un año y medio después de que la India y Sudáfrica propusieran, con el apoyo de la mayoría de los miembros de la OMC, una exención de determinadas disposiciones del Acuerdo sobre los ADPIC en relación con las tecnologías sanitarias para COVID-19, el Consejo de los ADPIC ha sido incapaz de alcanzar un consenso sobre la exención propuesta o de entablar negociaciones sobre el texto. En este contexto, el Consejo de los ADPIC acordó suspender los debates para permitir la posibilidad de que surja alguna solución a partir de las consultas informales de alto nivel entre la Unión Europea, los Estados Unidos de América, India y Sudáfrica. Recientemente, la Directora General de la OMC transmitió el resultado de las consultas informales junto con un proyecto de texto al Consejo de los ADPIC. En este contexto, este informe sobre políticas analiza los elementos del proyecto de texto transmitido. La solución propuesta, que ofrece aclaraciones y exenciones limitadas sobre algunas de las disposiciones que rigen las licencias obligatorias de patentes relacionadas con las vacunas, refleja la fuerte oposición de los países desarrollados a la exención más amplia que buscan los proponentes para ampliar rápidamente la capacidad de fabricación y el suministro de productos sanitarios necesarios para hacer frente a la pandemia.*

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## Introduction

On 2 October 2020, India and South Africa circulated a communication (IP/C/W/669) proposing that certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) be waived by the World Trade Organization (WTO) membership in relation to COVID-19 products and technologies. On 25 May 2021, the proponents submitted an amended proposal (IP/C/W/669/Rev.1). The submission (hereinafter “the TRIPS waiver”), as amended, was co-sponsored by 65 countries.

The TRIPS waiver proposal aimed at waiving 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. This proposal was the subject of various analyses published by the South Centre in support of the TRIPS waiver as submitted.<sup>1</sup>

The European Union submitted an alternative proposal (IP/C/W/681) aiming at clarifying some elements in the compulsory licenses regime for patents provided for in the TRIPS Agreement, notably in article 31bis.

The “COVID-19 solution” examined below has followed the narrow approach suggested by the European Union while focusing on article 31 of the TRIPS Agreement. As noted in the critical analyses made by many organizations and scholars,<sup>2</sup> it does not incorporate the broader approach of the TRIPS waiver as submitted by the proponents and sponsored by other members.

In a statement dated 16 March 2022, the WTO Director-General, Ngozi Okonjo-Iweala, provided information on the outcomes of high-level consultations among four WTO members on the TRIPS waiver, adding that not all details have been ironed out and that domestic consultations are still ongoing. The Director-General also stressed that work must commence immediately to broaden the discussions to include all the 164 members of the WTO.<sup>3</sup>

At an informal TRIPS Council meeting on 3 May 2022, the WTO Director-General introduced a draft text (hereinafter “the draft”) through the TRIPS Council Chair.<sup>4</sup> Detailed analysis and discussion in the TRIPS Council with the participation of all WTO members are required. Consideration of the TRIPS waiver proposal in the TRIPS Council, as required under the WTO Agreement, has been kept in abeyance and the agenda item has been left open so that the TRIPS Council could resume consideration of the matter at an appropriate time. The WTO membership will now have to decide whether the proposed “COVID-19 solution”, as conceived, provides a sufficient basis to expand the manu-

facturing capacity of COVID-19 products.

The following section provides an analysis of the draft transmitted to the TRIPS Council.<sup>5</sup>

## The Draft ‘COVID-19 Solution’

The draft provides clarifications and waivers in relation to some aspects of article 31 of the TRIPS Agreement (other use without authorization of the right holder) and a clarification in relation to article 39.3 (undisclosed test or other data) in respect of patents and vaccines only. It does not waive obligations nor provide clarifications in relation to other obligations to protect or enforce other intellectual property rights as provided for in the Agreement, nor with regard to therapeutics, diagnostics and other technologies. Thus, the subject matter of the proposed waivers and clarifications address COVID-19 vaccines, their active ingredients and manufacturing processes. Members will decide later on the extension of the decision to cover the production and distribution of COVID-19 diagnostics and therapeutics. The proposed “TRIPS COVID-19 solution” would only be available to “eligible developing countries”.

*1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member<sup>1</sup> may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter “the Agreement”) by authorizing the use of patented subject matter<sup>2</sup> 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.*

*Footnote 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 of 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.]*

*Footnote 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.*

Paragraph 1 of the draft makes it clear that it contains both **clarifications** and **waivers** in relation to some provisions of article 31 of the TRIPS Agreement. As noted below, it also adds some conditionalities not provided for in the Agreement. In this regard, it is important to note that if the draft were approved, this would not undermine the Members’ right to use the compulsory licensing system, including for COVID 19 products and technologies, as provided for in their legislations, in conformity with article 31 of the TRIPS Agreement without such conditionalities. They can also use the system under article 31bis which, as examined elsewhere, imposes burdensome conditions on potential users.<sup>6</sup>

The introductory phrase of paragraph 1 “Notwithstanding the provision of patent rights under its domestic legislation” suggests that the waiver is not self-executing and that national existing rules regarding patent rights will prevail unless amended to make use of the new waivers. If this draft were approved, Members would need to consider changes in the regulations needed for that purpose.<sup>7</sup>

The reference to “the production and supply” of COVID-19 vaccines may be deemed to also cover the use of a vaccine, since use claims are admitted in many “eligible” developing countries (although there is no obligation to grant use claims under the TRIPS Agreement).<sup>8</sup>

The commented paragraph confirms that granting compulsory licenses in relation to COVID-19 vaccines is legitimate. There is no legal doubt in this respect since the TRIPS Agreement does not determine the grounds for the grant of such licenses, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, nor the covered subject matter. The wording “to the extent necessary to address the COVID-19 pandemic”, however raises two issues.

On the one hand, it introduces a “necessity test” that the WTO jurisprudence has interpreted narrowly, which may limit the capacity to grant compulsory licenses based on the waiver: it will impose on a Member the burden of eventually proving that such a grant was “necessary”<sup>9</sup> and, for instance, not just advisable from a public health perspective to increase the availability of vaccines in the light of an uncertain evolution of the disease.

On the other hand, the text alludes to the “pandemic” and, in the absence of a legal definition of the term, a literal meaning of the word would be applied to interpret it (in accordance with the interpretative rules of the Vienna Convention on the Law of the Treaties). 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.<sup>10</sup> But COVID-19 may end as a pandemic but still remain an “epidemic”, that is, as a disease affecting a disproportionately large number of individuals within a population, community or region at the same time. Thus, the “COVID-19 solution” would not be available if the global extent of COVID-19 diminishes to such an extent that it is no longer a pandemic, even if an epidemic presence of the disease remains in any country.

All WTO members can issue compulsory licenses under article 31 of the TRIPS Agreement. The “COVID-19 solution”, nevertheless would be limited to “eligible developing country Members”. In accordance with the WTO Secretariat, “there are no WTO definitions of ‘developed’ and ‘developing’ countries. Members announce for themselves whether they are ‘developed’ or ‘developing’ countries”.<sup>11</sup> The developing country sta-

tus cannot be deemed to be lost even if a country communicates a decision not to claim special & differential treatment under WTO rules.

Footnote 1 of the draft has two parts in separate square brackets. The first part makes all developing country Members eligible but encourages such Members that have capacity to export vaccines to opt out of the decision. The other formulation in the third sentence of footnote 1, in square brackets, excludes developing countries that have exported more than 10 percent of COVID-19 vaccine doses in 2021.<sup>12</sup>

Least developed countries (LDCs) have been exempted from complying with the TRIPS Agreement obligations by virtue of an extension of the transition period established in article 66.1 of the Agreement<sup>13</sup> and, hence, the use of any COVID-19 related technology without observing the TRIPS Agreement rules is permissible in their territories. LDCs that may have committed not to use the transition period, could use the “COVID-19 solution” as LDCs may be deemed a sub-category of “developing countries”. It would be incongruous to interpret that they are excluded from the waivers. If this would have been the intention of the drafters, this should have been mentioned in footnote 1 of the draft that defines an eligible member. Nevertheless, a specific reference to LDCs as ‘eligible’ members would provide legal certainty on this aspect.

The rationale for the standard applied to exclude from the potential use of the “COVID-19 solution” a developing country member that has accounted for more than 10 per cent of world exports of COVID-19 vaccine doses in 2021 is unclear. Ironically such a member would have demonstrated both the capacity and the willingness to provide other countries with the much-needed vaccines to save lives. This restriction creates a precedent of particular concern if the same criteria were to be applied to diagnostics and therapeutics in the future (in accordance with para. 8 of the draft) since developing country members with large potential to supply the world demand for those products would become automatically excluded as well.

Based on information from the WTO-IMF Vaccine Tracker<sup>14</sup> (cumulative data until January 2022 but mostly relating to the year 2021), it appears that China would be the only developing country member to be excluded from the COVID-19 solution insofar as vaccines are concerned.

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.

The draft clarifies in paragraph 2 (“For greater clarity...”) that an authorization under article 31 in relation to the subject matter of COVID-19 vaccines, components 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 already and clearly available in terms of said article of the TRIPS Agreement. In the United States and Germany, for instance, compulsory licenses are granted by the courts,<sup>15</sup> and this has never raised an issue of non-compliance with the Agreement’s obligations.

*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.]<sup>3</sup>*

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

Paragraph 3(a) of the draft allows the issuance of a single authorization applicable to multiple patents necessary for the production or supply of a COVID-19 vaccine. This does not introduce a novel element. WTO members can currently issue a single authorization applicable to multiple patents relating to a class of products. In fact, the wording ‘individual merits’ in article 31(a) allows WTO members a broad policy space for the determination of the object of compulsory licences (and non-commercial government uses), including certain categories of products that are required to address a specific need (such as a disease).<sup>16</sup> For example, in 2003 Malaysia issued a single authorization covering patented inventions covering three separate patented antiretroviral drugs – didanosine, zidovudine, and lamivudine+zidovudine combination.<sup>17</sup> In 2004, Indonesia issued a single authorization covering 2 antiretroviral drugs – nevirapine and lamivudine.<sup>18</sup> In 2012, Indonesia issued another authorization covering 7 products.<sup>19</sup>

As noted in relation to paragraph 1 above, the text in this paragraph omits a necessary reference to the “use” of COVID-19 vaccines since, as mentioned, often claims are made on such a use separately or in patent applications relating to products and/or manufacturing processes.

The proposed language in paragraph 3(a) of the draft seems to subject the grant of authorizations to a “necessity test”, which is absent in article 31(a). Any patent relating to COVID-19 may be subject to a compulsory license under the current regime in article 31(a). Whether it is “necessary” or not for the production, supply or use of vaccines may be determined in the process of developing the active ingredient or the formulation and may not be possible to be anticipated at the time of initiating it. For instance, the compulsory licensee may find a new formulation which ultimately does not infringe on a granted patent. Further, this provision suggests adoption of a product-by-product approach as it says that all patents necessary for “a COVID-19 vaccine” can be covered by a single authorization.

Paragraph 3(a) also requires eligible members using the system to list all patents covered – a requirement that is not in the TRIPS Agreement. Implementation of this requirement will be onerous and incongruous to the need for a rapid solution given the difficulty in mapping the patent landscape for such listing; it may in fact be impossible to comply with.

It will be extremely difficult, in effect, to obtain the patent landscape and list the patents for all the inputs (90 or more) needed to produce a vaccine<sup>20</sup> or for second generation of COVID-19 vaccines which may be required in the near term. While the commented paragraph refers to WIPO as a possible source of information in this regard, the WIPO Patent Landscape Report on COVID-19 related vaccines and therapeutics states that in the context of a short patenting period since the outbreak of the COVID-19 pandemic its patent analysis cannot highlight systematically the top patent applicants as the patent data is not fully available.<sup>21</sup>

Moreover, given that patent applications are typically not published before 18 months, listing of most of the recently filed COVID-19 vaccine patents will be impossible, making the mechanism under this paragraph impossible to implement. This difficulty may arguably be addressed by an “update” of the “authorization to include other patents” contemplated in the commented paragraph, a possibility that is not barred by article 31 of the TRIPS Agreement (although it has not typically been provided for in national laws). In any case, if a not listed patent were infringed by a compulsory licensee, the right owner would retain the right to claim an infringement or a compensation for its use, while the compulsory licensee could request the relevant granting authority to include it in the respective authorization.

Interestingly, compulsory licenses have been granted in the USA in the past without the required listing, in relation to **present and future** patents.<sup>22</sup> The difficulty in iden-

tifying all patents relating to a pharmaceutical product has been more recently addressed under the US law in the Biologics Price Competition and Innovation Act of 2009 that entails an elaborate “patent dance” in which the biologic originator and prospective biosimilar market entrant exchange lists of patents that may or may not be infringed by market entry of a biosimilar.<sup>23</sup>

Footnote 3 of the draft states that this paragraph is still under discussion with regard to whether to retain or delete it from the text.<sup>24</sup>

*(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).*

Paragraph 3 (b) of the draft clarifies that an eligible member need not require the proposed user of the patented subject matter (i.e., the entity producing or supplying the product under a compulsory license authorization) to make efforts to obtain a voluntary license from the right holder in terms of article 31(b). This provision confirms a flexibility currently available under the TRIPS Agreement, as it is explicitly stated in the said article that the prior negotiation requirement can be waived by a member in view of a national emergency or other circumstances of extreme urgency. It does not apply either in the case of government use for non-commercial purposes, whether in a situation of emergency or not.

*(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 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.*

Paragraph 3 (c) 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% (“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 31bis of the TRIPS Agreement. A noticeable difference with this latter waiver, however, is that the draft refers to the supply not only to other “eligible members” but also to “international or regional joint initiatives”.

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.

*(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.*

The limitation on re-exportation provided for in paragraph 3(d) of the draft is a new condition not present in article 31, as a compulsory licensee can export (at least a non-predominant part of its production) without any obligation imposed on the importing countries regarding re-exportation.

Paragraph 3(d) requires eligible members to undertake “all reasonable efforts to prevent the re-exportation of COVID-19 vaccines” imported under this decision. This restriction on re-exportation mirrors a similar limitation in article 31bis of the TRIPS Agreement, but seems particularly unsuited in the context of the “COVID-19 solution”. It will limit the option of re-exportation of excess doses imported under the system 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.

South-South Cooperation played an important role during the pandemic. Not only developing countries that developed and produced vaccines donated them to other developing countries (like in the case of China, India and Cuba), but also non-producer countries donated doses to assist other developing countries (as Chile, for instance, did with donations to Paraguay and Ecuador).

Moreover, the context of article 31bis and of the “COVID-19 solution” are different as the latter does not apply -as proposed so far- to therapeutics. Generic equivalents of therapeutics can be produced that would compete with the “originator” products, and this is why article 31bis presumably provides for information and product differentiation obligations. In the case of COVID-19 vaccines, the use of relevant patented inventions does not necessarily mean that a “generic” vaccine will be developed and produced,<sup>25</sup> but a compulsory licensee will have to develop its own vaccine even if using technology developed by the patent owner. It’s unclear how the patent owner would be affected by the re-exportation of a vaccine which would need its own trials and to comply with the necessary approval procedures. In addition, the patent holder will in all cases receive a remuneration for the use of its patents in the exporting country, whether the products supplied under the license are re-exported or not.

Furthermore, the requirement to provide remedies against the importation of reexported products is problematic, as eligible developing countries may not have the capacity nor the will to do so if vaccines are urgently needed

to protect the population (what should be seen as the main objective to achieve with the proposed Decision). Consider, for instance, a situation where one African country has imported vaccines and it is willing to share part of them (through donation or resale) with another African or other developing country in need. Should it be prevented from doing so? Patent owners could exercise their rights if re-exportation were done to non-eligible members or to eligible members who have not made use of the waiver, as their rights would be unaffected there.

While parallel imports may be allowed in accordance with article 6 of the TRIPS Agreement in respect of products manufactured under a compulsory license, most countries limit such imports to those originating from the patent owner or a party authorized by him under a narrow “consent doctrine”.<sup>26</sup> Thus, products manufactured under a compulsory license could be prevented from being imported, or otherwise infringement could be claimed, unless eligible members abandon such doctrine. Potential importing countries would need to align their legislation to parallel import such products and prevent possible right holders’ legal actions.

The “COVID-19 solution” does not directly address this issue but would seem to implicitly (and correctly) presume that parallel imports of products made under the proposed Decision are to be deemed legitimate under article 6 of the TRIPS Agreement.

The commented paragraph would ultimately shift the burden of enforcement to the governments of eligible developing countries while the enforcement of patents—as private rights—<sup>27</sup> is to be carried out by the patent owners as and when they deem it appropriate and at their cost.

*(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.<sup>4</sup>*

*Footnote 4: This includes the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)*

The option spelled out in paragraph 3 (e) of the draft is a flexibility already allowed under article 31 (h). Members can currently use—and in fact, some have done so—the “Remunerations Guidelines” mentioned in footnote 3 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. The latter interpretation seems to be the most appropriate as the largest quantity of COVID-19 vaccines has been distributed through national vaccination programs and not by regional or international mechanisms, including COVAX (which failed to achieve the expected delivery of vaccine doses).

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 compulsory licensee may prefer the application of the existing article 31 of the 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.

Finally, this paragraph refers to the supply at affordable prices to other eligible members as if it would only apply to exports. The same rule should apply to domestic supplies.

*4. Nothing in Article 39.3 of the Agreement shall prevent a Member from taking measures necessary to enable the effectiveness of any authorization issued as per this Decision.*

Paragraph 4 confirms that obligations relating to the protection of test data under article 39.3 may not be applied to enable the execution of a compulsory license. Some WTO members 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 public health problems*. It has also been admitted in the context of free trade agreements entered into by the USA.<sup>28</sup>

This paragraph introduces another “necessity test” that may lead to a narrow interpretation of the text in accordance with WTO jurisprudence.

Notably, this 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.

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.<sup>5</sup>

Footnote 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.

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

This “transparency” requirement does not apply under article 31 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 31bis.

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.

A problematic aspect of this paragraph is found in footnote 4 as it requires information regarding the “duration of the authorization” and the “quantity(ies) for which the authorization has been granted”. These are limitations that are not imposed for the grant of a compulsory license under article 31 of the TRIPS Agreement.

Although the requested information is to be supplied *ex-post* (“as soon as possible after the information is available”), the text suggests that the authorizations need to specify *ex-ante* quantities and destination countries “to be supplied” (rather than those that were effectively supplied) as well as the duration of the authorization. Notably, the draft does not refer to “vaccines” but to “products” and suggests a product-by-product approach that can make the use of the system burdensome or fully ineffective. Thus, if in order to produce an active ingredient or formulation of a vaccine it were necessary to use a multiplicity of patented inputs, information should be supplied for each of them. Notably, paragraph 3(a) of the draft refers to “underlying technologies on COVID-19 vaccines” thereby making it clear that the authorizations may need to include many different products (e.g., nanoparticled lipid, stabilized protein) or processes.

Moreover, the authorization would presumably need

to spell out how many litres of a reagent or other compounds are to be used in manufacturing a vaccine, which may be impossible to know before production starts. Similarly, it would have to indicate the destination countries, something that 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.

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.

Paragraph 6 does not clarify if an authorization in force at the time of end of the 3 or 5 years will continue to remain in force for the rest of its remaining term. This creates significant uncertainty for potential manufacturers.

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.

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 would seem, however, to suggest that such complaints are currently applicable to that Agreement, an implication that should be avoided.

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.

Paragraph 8 refers to a decision to be taken but it does not refer to solving the issue nor does it oblige the members to actually engage in negotiations. For reference of alternative wording, paragraph 6 of the Doha Declaration instructing the General Council to arrive at an “expeditious solution” can be considered, as well as the obligation to negotiate established in article 24.1 of the TRIPS Agreement (“Members agree to enter into negotiations...”).

## Conclusion

As shown by the analysis above, the limited scope and reach of the ‘COVID-19 solution’ amounts, in practical terms, to the rejection by developed countries of the request of a TRIPS waiver as formulated by its proponents. The proposed text clarifies and waives certain provisions relating to the grant of compulsory licenses regarding patents over vaccines only. While this clearly reflects the position that the European Union took since the debates on such a waiver started, it suggests that -despite the stridently announced readiness to engage in text-based negotiations- the US has followed the same negative approach. If it finally prevails, the capacity of the WTO, to rapidly<sup>29</sup> and effectively respond, as a multilateral organization, to a global emergency like the one created by COVID-19 will

be seriously put in question. And there will be no doubt that the most powerful countries are to be deemed responsible for that.

#### Endnotes:

<sup>1</sup> 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](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](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](https://www.southcentre.int/wp-content/uploads/2021/11/SV231_211129.pdf).

<sup>2</sup> 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](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3885568).

<sup>3</sup> World Trade Organization, "Director-General Okonjo-Iweala hails breakthrough on TRIPS COVID-19 solution", WTO News, 16 March 2022. Available from [https://www.wto.org/english/news\\_e/news22\\_e/dgno\\_16\\_mar22\\_e.htm](https://www.wto.org/english/news_e/news22_e/dgno_16_mar22_e.htm).

<sup>4</sup> WTO document, IP/C/W/688, 3 May 2022.

<sup>5</sup> The outcome text and the proposed legal form (a Decision) raise questions -which are not dealt with in this document- about its enforceability and its relationship with other provisions in the TRIPS Agreement, especially in case of conflict.

<sup>6</sup> See, e.g., Carlos M. Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief No. 57, South Centre, January 2019. Available from [https://www.southcentre.int/wp-content/uploads/2019/01/PB57\\_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf).

<sup>7</sup> See in this regard, 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](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); Henning Grosse Ruse-Khan and Federica Paddeu, *A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements*, Research Paper 144 (Geneva, South Centre, 2022). Available from <https://www.southcentre.int/wp-content/uploads/2022/01/RP-144.pdf>.

<sup>8</sup> See e.g., Clara Ducimetière, *Second Medical Use Patents – Legal Treatment and Public Health Issues*, Research Paper 101 (Geneva, South Centre, 2019). Available from [https://www.southcentre.int/wp-content/uploads/2019/12/RP101\\_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf).

<sup>9</sup> On the 'necessity' test under WTO law, see e.g. Gisele Kapterian, "A Critique of the WTO Jurisprudence on 'Necessity'", *The International and Comparative Law Quarterly*, Vol. 59, No. 1 (Jan., 2010), pp. 89-127; Clive Vinti, "The 'Necessity Test' as Expressed by the Enigmatic Article XX(j) of the General Agreement on Tariffs and Trade (1994): Appellate Body Report, *India - Certain Measures Relating to Solar Cells and Solar Modules*", *PER/PELJ* (2019). Available from <http://www.saflii.org/za/journals/PER/2019/74.html>.

<sup>10</sup> See e.g. Heath Kelly, "The classical definition of a pandemic is not elusive", *Bulletin of the World Health Organization*, No. 89 (2011), pp. 539-540. Available from [https://www.scielosp.org/article/issm/content/raw/?resource\\_ssm\\_path=/media/assets/bwho/v89n7/a17v89n7.pdf](https://www.scielosp.org/article/issm/content/raw/?resource_ssm_path=/media/assets/bwho/v89n7/a17v89n7.pdf).

<sup>11</sup> See World Trade Organization, "Who are the developing countries in the WTO?" Available from [https://www.wto.org/english/tratop\\_e/devel\\_e/d1who\\_e.htm](https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm).

<sup>12</sup> The first formulation would be certainly preferable as it will allow developing countries with vaccine export capacity to choose whether or not to implement the proposed waivers.

<sup>13</sup> Nirmalya Syam, "Need for Extension of the LDC Transition Period Under Article 66.1 of the TRIPS Agreement Until Graduation and Beyond", Policy Brief No. 88, South Centre, March 2021. Available from <https://www.southcentre.int/wp-content/uploads/2021/03/PB-88.pdf>; South Centre, Statement on the extension of the transition period for LDCs under the TRIPS Agreement. Available from <https://www.southcentre.int/wp-content/uploads/2021/07/SC-LDC-Extension-Statement-FINAL.pdf>.

<sup>14</sup> See [https://www.wto.org/english/tratop\\_e/covid19\\_e/vaccine\\_tracker\\_e.htm](https://www.wto.org/english/tratop_e/covid19_e/vaccine_tracker_e.htm).

<sup>15</sup> 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", *Am J Law Med*, 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/>.

<sup>16</sup> See, e.g., Carlos Maria Correa, *Trade Related Aspects of Intellectual Property Rights* (Oxford University Press, Second Edition, 2020), p. 305.

<sup>17</sup> Padmashree Gehl Sampath, "Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing", in *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, Carlos Correa, ed. (South Centre, 2013). Available from [https://www.southcentre.int/wp-content/uploads/2016/05/Bk\\_2013\\_Pharmaceutical-innovation\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2013_Pharmaceutical-innovation_EN.pdf).

<sup>18</sup> Lutfiyah Hanim and Hira Jhamtani, "Indonesia: Manufacturing generic AIDS medicines under the 'government use' approach". Available from [https://www.citizen.org/wp-content/uploads/cl\\_in\\_indonesia\\_2004.pdf](https://www.citizen.org/wp-content/uploads/cl_in_indonesia_2004.pdf).

<sup>19</sup> German Velasquez, "Indonesia Government Granted 7 Compulsory Licenses to Promote Access to HIV Related Medicines", *Vitae*, vol.19 (no.3), 2012. Available from [http://www.scielo.org.co/scielo.php?pid=S0121-40042012000300002&script=sci\\_arttext&tlng=en](http://www.scielo.org.co/scielo.php?pid=S0121-40042012000300002&script=sci_arttext&tlng=en).

<sup>20</sup> See Felix Lobo, *Restructuring the Global Vaccine Industry*, Research Paper No. 134 (South Centre, Geneva, 2021). Available from [https://www.southcentre.int/wp-content/uploads/2021/09/RP134\\_Restructuring-the-Global-Vaccine-Industry\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf).

<sup>21</sup> World Intellectual Property Organization (WIPO), *COVID-19-related vaccines and therapeutics: preliminary insights on related patenting activity during the pandemic* (WIPO, Geneva, 2022). Available from [https://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_ip\\_covid\\_ge\\_22/publication\\_1075\\_e.pdf](https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_covid_ge_22/publication_1075_e.pdf).

<sup>22</sup> See, e.g. Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, Working Paper No. 5 (South Centre, Geneva, October 1999). Available from [https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual\\_Property\\_Rights\\_and\\_the\\_Use\\_of\\_Co.pdf](https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual_Property_Rights_and_the_Use_of_Co.pdf).

<sup>23</sup> See, e.g., *Sandoz v. Amgen*, 582 US \_\_ (2017), 137 S. Ct. 1664 (2017).

<sup>24</sup> In view of the above analysis demonstrating that the proposed paragraph does not introduce more flexibilities but conditionalities not present in article 31(a), deletion of this paragraph would be the preferred option.

<sup>25</sup> See Felix Lobo, *supra* note 20.

<sup>26</sup> See, e.g. Carlos Maria Correa, *Trade Related Aspects of Intellectual Property Rights* (Oxford University Press, Second Edition, 2020), p. 71.

<sup>27</sup> See Preamble of the TRIPS Agreement.

<sup>28</sup> See, e.g., Carlos Correa, *Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements*, Research Paper No. 74 (South Centre, Geneva, February 2017), p. 12. Available from [https://www.southcentre.int/wp-content/uploads/2017/02/RP74\\_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf).


<sup>29</sup> The 'solution' does not have a provision for automatic application to future pandemics.



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